CADRENAL THERAPEUTICS

2025 ANNUAL REPORT

NASDAQ: CVKD

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 001-41596

CADRENAL THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**88-0860746**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
822 A1A North, Suite 306 Ponte Vedra, Florida	**32082**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(904) 300-0701**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CVKD	The Nasdaq Stock Market, LLC (The Nasdaq Capital 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 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 error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of $12.05 per share of the registrant's common stock on June 30, 2025, as reported by the Nasdaq Capital Market on such date, was approximately $24,868,103.

As of March 27, 2026, there were 2,506,817 shares of Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None

PART I

Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of 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 involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report in some cases you can identify forward-looking statements by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected or implied in or by the forward-looking statements.

You should refer to Part I, Item 1A. "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake any obligation to update any forward-looking statements. Unless the context requires otherwise, references to "we," "us," "our," and "Cadrenal," refer to Cadrenal Therapeutics, Inc.

This Annual Report also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may harm on our business, results of operations, financial condition and the market price of our common stock, par value $0.001 per share (the "Common Stock").

Summary Risk Factors

Our business faces significant risks and uncertainties of which investors should be aware before making a decision to invest in our Common Stock. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. The following is a summary of the more significant risks relating to the Company. A more detailed description of our risk factors is set forth below under the caption "Risk Factors" in Item 1A in Part I of this Annual Report.

Risks Related to Our Financial Position and Need for Capital

- Our financial statements have been prepared assuming that we will continue as a going concern.
- Any shutdown of the U.S. federal government may adversely affect our business.
- We are a clinical development biopharmaceutical company with a limited operating history.
- We have a limited operating history upon which to evaluate our ability to commercialize our product candidate.
- We have a limited operating history, a history of losses and expect to continue to incur losses.
- We may never become profitable or, if achieved, be able to sustain profitability.
- Our cash and the proceeds from our financings will only fund our operations for a limited time.
- We will need to raise additional capital.
- Our need for future financing may result in the issuance of additional securities, which will cause investors to experience dilution.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

- Our future success depends heavily on review of our Phase 3 trial protocol by the U.S. Food and Drug Administration (the "FDA") and commencement of our Phase 3 clinical trial.
- The 12-LOX platform of assets is subject to significant clinical risks that could impede our ability to advance CAD-1005 or our second-generation oral candidates.
- Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' staffing and operations could negatively impact our business.
- Our business is dependent upon the success of our product candidates, each of which require additional clinical testing.
- Our business is substantially dependent on a license agreement, and the termination, non-renewal or failure to maintain that agreement could materially and adversely affect our business, financial condition and prospects.
- All of our current data for our product candidates are the results of clinical trials conducted by third parties.
- Our development efforts may not generate data sufficient to support regulatory approval and the FDA and/or the European Medicines Agency (the "EMA") may require additional clinical testing.
- Even if we complete our clinical trials, we may not receive regulatory approval for any of our product candidates.
- Orphan drug designation does not translate to approval and, even if we obtain FDA approval, we may not enjoy marketing exclusivity or other expected benefits.
- Fast Track designation and Orphan Drug Designation does not assure FDA or any other regulatory approval.
- Even if we obtain regulatory approval, we may not enjoy marketing exclusivity and we may face other difficulties.
- Clinical trials are very expensive, time-consuming and difficult to design and implement.
- We may experience delays in the enrollment of patients in any or all of our clinical trials.
- If any of our product candidates are approved, our success depends on our commercialization efforts and market acceptance.
- Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.
- We have never submitted a New Drug Application to the FDA or comparable applications to other regulatory authorities.

- Any product candidate if approved for commercialization will remain subject to regulatory obligations and other restrictions.
- After approval, our products could be subject to labeling and other restrictions and we may be required to withdraw from the market or be subject to penalties if we fail to comply with regulatory requirements.
- We are subject to federal and state obligations and regulations applicable to our marketing practices.
- We rely, or will rely, on third-party manufacturers to produce our product candidates.
- If the manufacturer fails to comply with stringent regulations, we may face delays.
- We face substantial competition.
- Serious adverse effects may be identified with respect to our products candidates, which may harm our business.
- Recently enacted and future legislation may affect marketing approval and commercialization of our product candidates.
- We may be subject to penalties if we violate healthcare fraud and abuse laws or price reporting laws.
- Our ability to generate product revenues will be diminished if our products sell for inadequate prices.
- The impact of recent healthcare reform legislation in healthcare spending could adversely effect our business.
- We will rely on third parties to conduct all of our clinical trials.
- We currently do not have any distribution, marketing, support or sales capabilities.
- Our employees, contractors, consultants, commercial partners and vendors may engage in misconduct.
- If we are not successful in establishing a sales force, our ability to generate sales and profits will be limited.
- We plan to rely on third parties to develop, commercialize, market and promote our products.
- Our future growth depends, in part, on our ability to penetrate foreign markets.
- Global health crises may adversely affect our planned operations.
- Compliance with regulations regarding the treatment of animals could increase our costs.

General Company-Related Risks

- Our business depends upon our ability to attract and keep senior management and key scientific personnel.
- We will need to increase the size of our organization, and we may experience difficulties managing this.
- If product liability lawsuits are brought against us, we may incur substantial liabilities.
- Computer system failures could be costly and expose us to litigation and government enforcement actions.
- We are increasingly dependent on information technology and our systems face certain risks.
- Any failure to maintain the security of information relating to our patients, customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could disrupt our operations and harm our reputation.
- Our use of artificial intelligence presents risks that could adversely affect our business.
- Acquisitions of other businesses could harm our operating results.
- Declining general economic or business conditions may have a negative impact on our business.

Risks Related to Our Intellectual Property

- We may be unable to obtain and maintain market exclusivity or patent protection for our product candidates.
- We may become involved in intellectual property lawsuits, which could be costly and time consuming.
- If we are sued for infringing the intellectual property rights of third parties, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our product candidates.
- Patent law changes in the United States and other jurisdictions could diminish the value of patents.
- Patent protection depends on compliance with requirements imposed by governmental patent agencies.
- We may not be able to enforce our intellectual property rights throughout the world.
- Our U.S. patents and foreign patents for tecarfarin have expired.
- We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Risks Related to Ownership of Our Common Stock

- An active public trading market for our Common Stock may not be maintained.
- We cannot be assured that we will be able to maintain our listing on the Nasdaq Capital Market.
- Our stock price has been extremely volatile.
- Even if our product candidates receive FDA approval, the trading price of our Common Stock may not increase, and may decline.
- If favorable research or reports about us are not published our stock price could decline.
- Our Chief Executive Officer can exercise significant control over our Company.
- Sales of Common Stock could result in dilution and depress the market price of our Common Stock.
- Our charter documents have anti-takeover provisions.
- Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware or the federal district court for the District of Delaware is the exclusive forum for certain disputes between us and our stockholders.
- Claims for indemnification by our directors and officers may reduce our available funds.
- We do not intend to pay dividends in the foreseeable future.
- Certain members of our management team have limited experience managing a public company.
- We have incurred significant increased costs as a result of operating as a public company and expect to incur additional costs when we commence clinical trials.
- We are an emerging growth company and may avail ourselves of reduced disclosure requirements or extended transition periods for complying with new or revised accounting standards.
- There is no public market for our outstanding warrants.
- Holders of our outstanding warrants will have no rights as common stockholders with respect to the shares of our Common Stock underlying the warrants until such holders exercise their warrants and acquire our Common Stock, except as otherwise provided in the warrants.

Item 1. Business.

The Company

We are a late-stage biopharmaceutical company advancing novel therapies for life-threatening immune and thrombotic conditions. As a result of our acquisition of a 12-lipoxygenase ("12-LOX") platform of assets in December 2025 (as described in more detail below), we transitioned our primary strategic focus to the development of CAD-1005 for the treatment of immune-mediated and thrombotic disorders. Our lead product candidate, CAD-1005, is a first-in-class selective 12-LOX inhibitor being developed to treat heparin-induced thrombocytopenia ("HIT"), a deadly immune-mediated thrombotic disorder. CAD-1005 has been evaluated in a blinded, placebo-controlled study Phase 2 clinical trial of 24 patients as well as Phase 1 clinical trials in more than 100 patients. On March 26, 2026, we completed our End-of-Phase 2 ("EOP2") meeting with the FDA and clarified a potential registrational path for our planned Phase 3 pivotal trial of CAD-1005 in patients with HIT. Our Phase 3 trial protocol will still be subject to additional information which may be set forth in the final meeting minutes from the FDA and any further comments we may receive from the FDA upon their review of the protocol. CAD-1005 has an orphan drug designation ("ODD") from the FDA for the prophylaxis of thrombosis in patients with HIT, as well as an FDA Fast Track designation for the treatment and prevention of HIT, and an orphan designation from the EMA for the treatment of platelet-activating factor 4 disorders.

Our broader pipeline includes two additional clinical-stage assets—tecarfarin and frunexian. Tecarfarin is an oral vitamin K antagonist ("VKA") (a warfarin replacement for patients with complex needs) designed to prevent heart attacks, strokes, and deaths due to blood clots in patients requiring chronic anticoagulation. Specifically, our focus for tecarfarin is for chronic use in patients with kidney dysfunction or left ventricular assist devices ("LVADs"). Tecarfarin has been specifically designed to overcome metabolic factors that can make warfarin less reliable. Frunexian is a first-in-class, Phase 2-ready intravenous ("IV") Factor XIa inhibitor designed for acute care settings where contact activation of coagulation by medical devices or artificial surfaces is significant. Frunexian is the only IV FXIa inhibitor in clinical development that targets the acute/critical care hospital setting exclusively.

Recent Developments

Veralox Asset Purchase

On December 10, 2025, we entered into an Asset Purchase Agreement (the "Veralox Purchase Agreement") with Veralox Therapeutics Inc., a Delaware corporation ("Veralox"), pursuant to which Veralox sold to us all, or substantially all, of its right title and interest in assets owned or otherwise used or held for use by Veralox in connection with the compound known as CAD-1005 (formerly "VLX-1005"), and all back-up and follow-on compounds, including the CAD-2000 (formerly "VLX-2000") series (the "Compounds"), including, without limitation, all intellectual property related to the Compounds, all inventory related to the Compounds, certain contracts including a license agreement, all Permits and other Governmental Authorizations and Books and Records (as such terms are defined in the Veralox Purchase Agreement), free and clear of any liens (the "Veralox Assets"). The transactions contemplated by the Veralox Purchase Agreement were consummated on December 10, 2025.

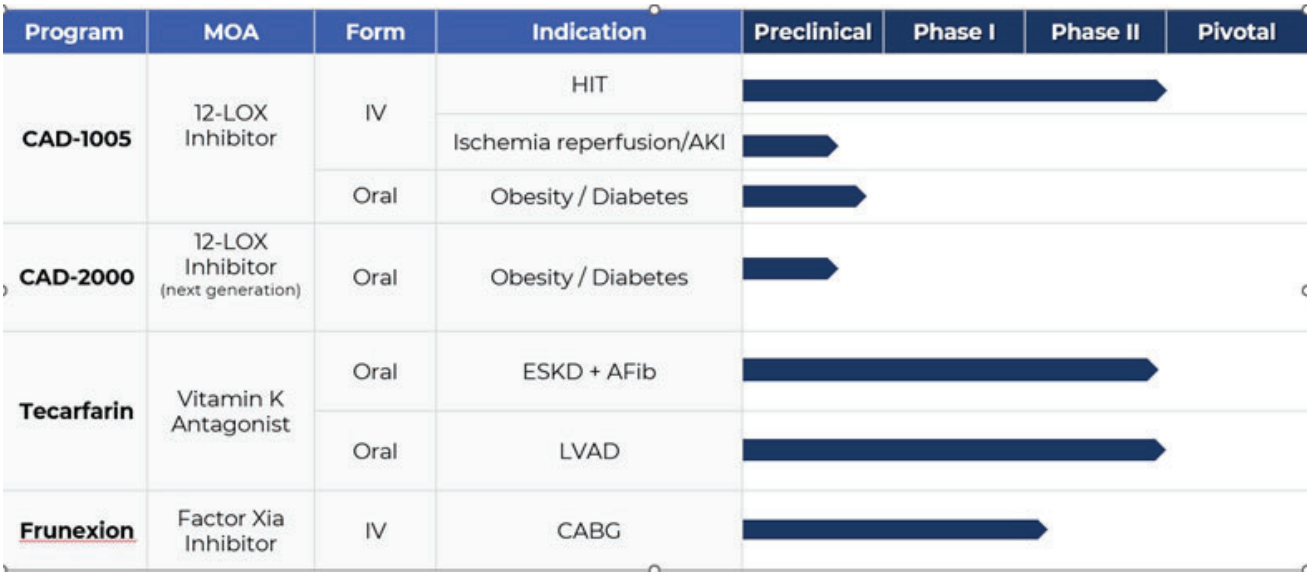
The Veralox Assets also include the assignment of an Amended and Restated Exclusive License Agreement by and between Veralox and Old Dominion University, as successor in interest to Eastern Virginia Medical School ("Licensor"), dated as of May 1, 2020, as amended on December 9, 2025 pursuant to a First Amendment to Amended and Restated Exclusive License Agreement (the "Amendment to License Agreement") by and between Old Dominion University, as successor in interest to Eastern Virginia Medical School, and Veralox (as amended, collectively, the "Old Dominion License Agreement"), pursuant to which Licensor granted Veralox an exclusive worldwide license under the EVMS Patent Rights (as such term is defined in the Old Dominion License Agreement) related to the development and commercialization of 4-((2-Hydroxy-3-MethoxyBenzyl)Amino) Benzenesulfonamide Derivatives as 12-Lipoxygenase Inhibitors.

See "Veralox Purchase Agreement" and "Old Dominion License Agreement" below for more detailed descriptions of the Veralox Purchase Agreement and the Old Dominion License Agreement.

Our Strategy

Our overarching goal at Cadrenal is to advance novel therapies for life-threatening immune and thrombotic conditions. Our current primary focus is advancing a transformative therapeutic approach for the treatment of HIT. On March 26, 2026, we completed our EOP2 meeting with the FDA and clarified a potential registrational path for our planned Phase 3 pivotal trial of CAD-1005 in patients with HIT. Our Phase 3 trial protocol will still be subject to additional information which may be set forth in the final meeting minutes from the FDA and any further comments we may receive from the FDA upon their review of the protocol. Commencement of a pivotal Phase 3 clinical trial in patients with HIT will also be subject to obtaining sufficient financing.

If we are successful in obtaining FDA approval of CAD-1005 for our first indication, we intend to seek to expand the label for CAD-1005 through additional filings, to explore the full spectrum of applications where we believe CAD-1005 can improve on existing standard treatment; including diabetes, atherosclerosis and chronic vascular inflammation and hyper-inflammatory responses, as seen in severe respiratory infections.



CAD-1005

Our lead product candidate, CAD-1005, is a first-in-class selective 12-LOX inhibitor being developed for the treatment of HIT, a deadly immune-mediated thrombotic disorder. CAD-1005 is designed to selectively inhibit 12-LOX, a pathway integral to the primary immune mechanisms driving HIT. Unlike existing therapies for HIT, which are only directed at preventing thrombotic complications, this approach addresses the primary underlying pathophysiology of HIT. CAD-1005 has an ODD from the FDA for prophylaxis of thrombosis in patients with HIT, as well as an FDA Fast Track designation for the treatment and prevention of HIT, and an orphan designation from the EMA for the treatment of platelet-activating factor 4 disorders.

Heparin-Induced Thrombocytopenia (HIT)

Heparin is the most widely used parenteral anticoagulant in modern-day practice. HIT is a serious, life-threatening prothrombotic complication of heparin administration, with high morbidity and mortality. HIT arises as a consequence of an immune reaction to endogenous platelet factor 4 (PF4) bound to exogenous heparin. Binding of HIT antibodies to platelet FcγRIIa (the platelet IgG receptor) and the FcγRI receptor (CD64) on monocytes results in the generation of thrombin, tissue factor, platelet-fibrin thrombi, procoagulant microparticles, and further PF4 release, creating a vicious cycle of additional platelet activation and resulting in a high likelihood of adverse thrombotic events. Argatroban and bivalirudin, both non-heparin-directed thrombin inhibitors, were approved in the United States for the treatment of HIT in the early 2000s, but, as parenteral anticoagulants, they only limit the progression of thrombus and do not address the underlying immune-mediated, platelet-centric pathophysiology of the disease. Since their approval, no additional treatments have been approved to prevent or treat HIT. Moreover, despite the use of such parenteral non-heparin anticoagulants, severe thrombotic complications of HIT occur frequently. Recent findings reported by Shatzel et al. and Ramadan et al. highlight the high incidence and clinical burden of thrombotic complications in contemporary HIT patients, highlighting the limitations of existing therapies. Therefore, we are developing a new drug candidate designed to directly address the pathophysiology of HIT by targeting platelet 12-LOX and thereby interrupting a vicious cycle of immune-mediated platelet activation.

12-LOX Inhibition and CAD-1005

12-LOX is highly expressed in human platelets and catalyzes the formation of 12-hydroxyeicosatetraenoic acid (12-HETE), which is a key intermediary signaling molecule in FcγRIIa-mediated platelet activation. Growing scientific evidence has identified 12-LOX as a key mediator of platelet activation and immune thrombotic responses. Foundational work by McKenzie et al. (2022) significantly advanced the understanding of 12-LOX signaling in platelet-driven immune thrombosis, including in HIT, supporting the 12-LOX pathway as a compelling therapeutic target. Pharmacologic inhibition of 12-LOX has been shown to suppress platelet activation, while having minimal impact on normal hemostasis and without increasing bleeding risk, a common limitation of current antiplatelet therapies. Historically, however, industry-wide drug development efforts targeting 12-LOX have been hindered by a lack of selectivity, raising concerns about off-target effects and safety. This challenge has limited the development of earlier 12-LOX inhibitors by other developers, none of which advanced to clinical stage development.

CAD-1005 is a potent and selective inhibitor of 12-LOX and is the only such inhibitor currently in clinical-stage development. It represents a novel approach to reduce the risk of severe thrombotic events in patients with HIT by specifically targeting a key platelet inflammatory signaling pathway that is believed to play a major role in HIT. In animal models of HIT, CAD-1005 has been shown to prevent or treat HIT and halt the development of both thrombocytopenia and abnormal blood clots, and has not been associated with increased bleeding in either animals or healthy human volunteers. The 12-LOX portfolio obtained from Veralox includes both parenteral (injectable) and oral second-generation candidates, addressing a range of acute and chronic conditions.

Pre-Clinical Data

In vivo inhibition of 12-HETE synthesis and the efficacy of CAD-1005 have been demonstrated in animal models of thrombosis and in immune-mediated thrombocytopenia and thrombosis. Importantly, this impact on thrombosis was not accompanied by increases in bleeding. In mice expressing the human immune receptor on their platelets, Veralox showed that administration of CAD-1005 following HIT induction resulted in blunted thrombocytopenia and reduced platelet activation and thrombus formation. Veralox further demonstrated that coagulation (assessed by thromboelastography) was not impacted by CAD-1005, while the direct thrombin inhibitor argatroban significantly delayed the onset of coagulation and clot formation. Moreover, bleeding times in these mice were not altered by CAD-1005, whereas argatroban-treated mice required cauterization to stop bleeding. Finally, human whole blood, as measured by whole-blood aggregometry and high-shear arterial flow chamber experiments, was protected from platelet activation and clot formation in the presence of CAD-1005. Thus, preclinical studies demonstrate the potential effectiveness of CAD-1005 in blocking platelet activation, clot formation, and thrombosis in both mouse models and human blood.

Phase 1 Data

Veralox conducted two Phase 1 clinical studies of CAD-1005 in healthy volunteers; these demonstrated that CAD-1005 was well tolerated, with no deaths, no serious adverse events, and no trend in adverse event reporting with increasing doses. The first was a 2-part, placebo-controlled, study of the safety, tolerability, and pharmacokinetics (“PK”) of single and multiple ascending doses of IV CAD-1005 in 96 healthy subjects. In this study CAD-1005 was found to be well tolerated with no reports of serious adverse events (“SAEs”), dose-limiting toxicities (“DLTs”) or discontinuations; adverse events (AEs) were infrequent and mild. There were dose-linear increases in key PK metrics, approaching dose proportionality, with no upper limit on tolerability to the maximum dose tested. The second study was a Phase 1b drug-drug interaction (“DDI”) study of CAD-1005 in conjunction with argatroban. The study showed that co-administration of CAD-1005 with argatroban was well tolerated with no SAEs; AEs were infrequent and mild. Analyses of PK and PD (as measured by activated partial thromboplastin time (“aPTT”) data revealed no evidence of a pharmacokinetic or pharmacodynamic interaction

Phase 2 Data

Veralox also recently completed a Phase 2 randomized, double-blind pilot study of CAD-1005 versus placebo in participants with suspected HIT already treated with the standard of care ("SoC") (argatroban or bivalirudin). After confirming a 4Ts score ≥ 4 and a positive PF4 immunoassay, participants were consented and enrolled; a confirmatory serotonin release assay (SRA) test was also performed, but participants were randomized and treated once the test was drawn; they did not await the test results. Participants were randomized 1:1 to either CAD-1005 plus SoC or placebo plus SoC. The study had hoped to validate a potential new surrogate endpoint for clinical efficacy, with platelet count recovery rate selected as the primary endpoint, and the composite of new or worsening thromboembolic events as the key secondary endpoint against which the surrogate was to be validated. Notably, this was the first blinded, placebo-controlled trial in HIT ever undertaken. The study was initiated in 2024; it originally intended to enroll 60 patients and was concluded in December 2025 following the transfer of program ownership from Veralox to Cadrenal. At the time the study was terminated a total of 22 participants had received study medication (12 received CAD-1005 and 10 received placebo – all on a background of either argatroban or bivalirudin). CAD-1005 failed to meet its primary endpoint since it did not significantly affect the primary endpoint of platelet count recovery rate, but a high rate of thrombotic events (>75%) was observed in the placebo group, with fewer thrombotic events in the CAD-1005 group (50%), although the study was not powered to detect statistical significance.

Planned Pivotal Phase 3 Trial

On March 26, 2026, we completed our EOP2 meeting with the FDA and clarified a potential registrational path for our planned Phase 3 pivotal trial of CAD-1005 in patients with HIT. Our Phase 3 trial protocol will still be subject to additional information which may be set forth in the final meeting minutes from the FDA and any further comments we may receive from the FDA upon their review of the protocol.

Potential Additional Applications for 12-LOX Inhibitors

Beyond HIT, selective 12-LOX inhibition has potential applications in several high-impact disease areas with multi-billion-dollar market opportunities:

- Acute Indications: Potential opportunities in ischemia-reperfusion injury, acute kidney injury, microvascular thrombosis, and other immune thrombocytopenias.
- Chronic Indications: Potential opportunities in diabetes (Type 1 and Type 2), obesity, atherosclerosis, vascular inflammation, and heart failure
- Other Indications: Potential opportunities in stored platelet preservation

Tecarfarin

Tecarfarin is a novel late-stage, reversible VKA (a warfarin replacement for patients with complex needs) designed to prevent heart attacks, strokes, and deaths due to blood clots in patients requiring chronic anticoagulation. Tecarfarin is specifically designed to overcome metabolic factors that can make warfarin less reliable. Cadrenal's approach with respect to tecararin has been a pipeline-in-a-product approach. Tecarfarin has ODD and Fast Track designation from the FDA for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with end stage kidney disease ("ESKD") and atrial fibrillation ("AFib"). Tecarfarin also has ODD from the FDA for the prevention of thrombosis and thromboembolism in patients with an implanted mechanical circulatory support device, which includes LVADs, a mechanical heart pump.

Tecarfarin has been evaluated in eleven (11) human clinical trials in over 1,000 individuals (269 patients were treated for at least six months, and 129 patients were treated for one year or more). In Phase 1, Phase 2, and Phase 2/3 clinical trials, tecarfarin has generally been well-tolerated in both healthy adult subjects and patients with chronic kidney disease ("CKD"). In the Phase 2/3 trial, EMBRACE-AC, the largest tecarfarin trial with 607 patients, including those with mechanical heart valves, only 1.6% of the blinded tecarfarin subjects suffered from major bleeding, and there were no thrombotic events.

Over the course of the last twelve months, the development strategy for tecarfarin has continued to evolve. We have recently completed the manufacturing of tecarfarin drug product in accordance with current good manufacturing practices ("cGMP") and are evaluating opportunities for additional Phase 2/3 trials for ESKD patients with atrial fibrillation and/or stable LVAD patients currently treated with warfarin.

Background

There are multiple medical conditions or clinical circumstances that require anticoagulation to prevent the development of blood clots. Despite the availability of a number of parenteral (acute) and oral (chronic) agents, there is no single perfect anticoagulant for all clinical situations, and significant treatment gaps exist in the safety, predictability, and efficacy of anticoagulant therapy in a number of high-risk circumstances. The prevailing treatment for patients requiring chronic anticoagulation includes two types of oral anticoagulants: VKAs and direct acting oral anticoagulants ("DOACs").

Warfarin is currently the predominant VKA treatment option in the U.S. and has been in use since the early 1950s, including in patients with non-valvular AFib and in patients with valvular heart diseases with AFib. Warfarin is metabolized via the cytochrome p450 (CYP450) pathway primarily by the CYP2C9 enzyme; approximately 15% of clinically used drugs are metabolized by the same enzyme, including certain anticoagulants, antiplatelets, and non-steroidal anti-inflammatory drugs. Patients taking warfarin and on CYP2C9 interacting drugs may experience either warfarin being eliminated by the body too quickly, thereby decreasing its anticoagulation effect and increasing the risk of thrombotic complications, or warfarin being eliminated by the body too slowly, resulting in excessive risk for bleeding. Other commonly appreciated drawbacks of warfarin include a relatively narrow therapeutic range, requirements for monitoring and adjustment, slow onset (with initial paradoxical prothrombotic effects due to its early inhibition of proteins C and S), and a relatively slow offset of action (making it difficult to manage with invasive procedures), and multiple drug and food interactions.

DOACs are a form of treatment that inhibits certain blood-clotting factors. While VKAs block the synthesis of vitamin K-dependent blood clotting factors (II, VII, IX, X, protein C and protein S), DOACs block the activity of specific clotting factors. DOACs are generally more rapid in onset and offset of action than VKAs, have few strong drug-to-drug interactions and do not require INR monitoring. DOACs have been approved in the U.S. for the treatment of specific oral anticoagulation indications; however, there are a number of clinical scenarios for which DOACs are contraindicated or not recommended for use, including for anticoagulation treatment in patients with LVADs, patients with ESKD and AFib, patients with ESKD and mechanical heart valves, and patients with thrombotic APS. DOACs do not have the same broad label indication as warfarin, and there are a number of indications where VKAs continue to be the standard of care, despite their limitations.

Tecarfarin is a next-generation Vitamin K antagonist that is metabolized via the human carboxylesterase 2 ("CES2") pathway, a different metabolic pathway than warfarin, thereby avoiding CYP450 metabolism in the liver. This CES2 pathway is abundantly distributed throughout the body, unlike CYP450, which is confined to the liver. Although it exhibits genetic variability, the variants have not been shown to significantly alter drug clearance. In contrast, patients taking multiple medications that interact with CYP2C9, or CYP3A4, or those with impaired kidney function, can experience an overload in the pathway, creating a bottleneck that often leads to insufficient clearance, which results in the unstable levels of anticoagulation, an issue well documented with warfarin use. Tecarfarin has been shown in clinical studies to result in more reliable levels of anticoagulation in certain patient subgroups.

For chronic applications, two specific patient groups for which we had focused our studying were tecarfarin are patients with ESKD and AFib and patients with LVADs. Both of these clinical circumstances are particularly challenging and provide meaningful opportunities to improve care. Additionally, DOACs like Eliquis and Xarelto have either not shown clinical benefit, or their efficacy and safety remain uncertain for both indications.

ESKD + Atrial Fibrillation

AFib is the most frequently encountered human arrhythmia, with its incidence and prevalence increasing over the last 20 years. AFib is associated with an approximate five-fold increased risk of stroke. The risk of developing AFib increases in patients with CKD. According to 2023 estimates by the Centers for Disease Control and Prevention (CDC), approximately 14% of the U.S. adult population, or 35.5 million people, have CKD. An estimated 0.33% of people in the U.S. suffer from Stage 4 CKD, and 0.14% of people in the U.S. have ESKD.

There are more than 808,000 Americans with ESKD, with approximately 68% on dialysis, according to the United States Renal Data System 2023 Annual Report. Approximately 145,000 ESKD patients also have AFib. AFib nearly doubles the anticipated mortality and increases the stroke risk by approximately fivefold in these patients. There is evidence that AFib is an independent risk factor for developing ESKD in CKD patients. Both diseases share common risk factors, including hypertension, diabetes, vascular disease, and advancing age. Cardiovascular disease contributes to more than half of all deaths among patients with ESKD. According to the 2025 Annual Data Report published by the United States Renal Data System, total Medicare spending for patients with ESKD reached $55.3 billion in 2023, accounting for approximately 4.7% of the Medicare-paid claims costs.

Patients with ESKD and AFib have very high rates of stroke and death; however, there is no standard of care for these patients since there has never been a study demonstrating the benefit of any anticoagulant. The presence of either CKD or AFib increases the risk of serious thromboembolic adverse clinical outcomes, such as stroke and death. Antithrombotic therapy is typically recommended to decrease this risk in AFib patients. Still, there are no approved treatment options for patients with ESKD and AFib, and there is no standard of care for these patients. At present, there is no evidence to support the use of any drug for the prevention of thromboembolic events in patients with ESKD and AFib.

LVAD

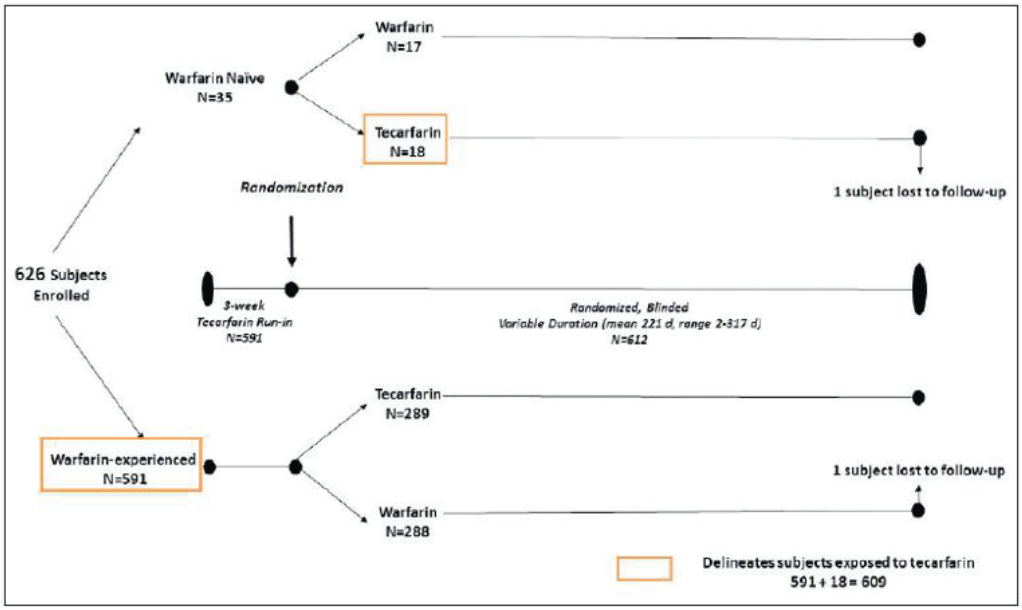
Anticoagulation management in patients with LVADs remains a challenge. Recent randomized controlled trials in LVAD patients have shown that currently available VKAs (warfarin) result in relatively poor-quality anticoagulation (as reflected by the TTR), despite efforts to manage anticoagulation tightly in clinical trials. The ARIES-HM3 study was designed to evaluate the need for chronic aspirin treatment in patients with the newest LVAD, the HeartMate3. The use of aspirin in LVAD patients was standard but had never been proven to be beneficial. The ARIES study randomized LVAD patients to continue aspirin, along with warfarin, versus warfarin alone. The main finding of the study revealed that aspirin is not helpful in LVAD patients; however, since all patients were receiving warfarin and had careful monitoring of the quality of anticoagulation, the study also provided the opportunity to determine if the quality of anticoagulation provided by warfarin had an impact on patient outcomes. The analysis of this carefully controlled and monitored study showed that the average TTR was only 56% with warfarin, far below the benchmark for well-controlled anticoagulation of 70%, and that, despite the superior design of the HM3 device, poor quality anticoagulation was associated with excess thrombotic and bleeding events.

In March of 2025, we announced the signing of a Collaboration Agreement with Abbott Global Enterprises Limited ("Abbott") to support the development of tecarfarin in patients with an implanted HeartMate 3 LVAD. Under the terms of the Collaboration Agreement Abbott will support us on the planning and execution of the TECarfarin Anticoagulation and Hemocompatibility with Left Ventricular Assist Devices (TECH-LVAD) trial to evaluate the efficacy and safety of tecarfarin in patients with LVADs. Under the Collaboration Agreement, Abbott will share insights from recent HeartMate trials and will support us with: trial design, site identification, trial awareness, and HeartMate expertise.

Tecarfarin Clinical Trial Summary

Tecarfarin has been evaluated in eleven (11) human clinical trials in over 1,000 individuals (269 patients were treated for at least six months and 129 patients were treated for one year or more). In Phase 1, Phase 2 and Phase 2/3 clinical trials conducted by third-parties, tecarfarin has generally been well-tolerated in both healthy adult subjects and in patients with CKD.

The Phase 2/3 EMBRACE-AC study, which was conducted by the company that owned the rights to tecarfarin at the time of the trial, was a Phase 2/3 trial multi-center, randomized, double-blind, parallel group, active control trial that compared tecarfarin to warfarin in 607 patients with indications for chronic anticoagulation, with a primary endpoint of TTR, which quantifies the percentage of INR values that are in the appropriate target range for an individual patient.



Study flow diagram for EMBRACE AC (Whitlock RP *et al. Thromb Haemost* 2016; 116(02): 241-250)

Dosing of study drugs was managed by a centralized dose control center. As a result of this aggressive management, the TTRs in this study were higher than in general practice. A stable dose of tecarfarin, defined as 10 % variation in weekly dose for three consecutive weeks while the INR stays within the therapeutic range, was attained in 94.5 % (290/307) of the tecarfarin patients during the study. There were no differences in the frequency of significant deviations either below (tecarfarin 2.9 % vs warfarin 3.5 %, p = 0.19) or above (tecarfarin 2.0 % vs warfarin 2.3 %, p = 0.39) the targeted therapeutic range seen between treatment groups.

The trial did not meet its primary endpoint; the mean TTR with tecarfarin (the primary endpoint) was numerically higher but not significantly superior to warfarin in terms of the primary endpoint (72.3% with tecarfarin vs 71.5% with warfarin; p=0.51), but numerically virtually all subgroups favored tecarfarin, which was especially noteworthy given the aggressiveness of INR management in the warfarin group. As part of its original analysis plan, EMBRACE-AC also included analyses of INR measurements while patients were temporarily off their trial drug due to other medical reasons. In a subsequent post-hoc analysis excluding these INR values while off therapy, the number of INR values in the therapeutic range was significantly higher on tecarfarin (68.8%) than on warfarin (66.4%) ($p<0.04$).

% TTR and % INR Values in therapeutic Range in EMBRACE AC

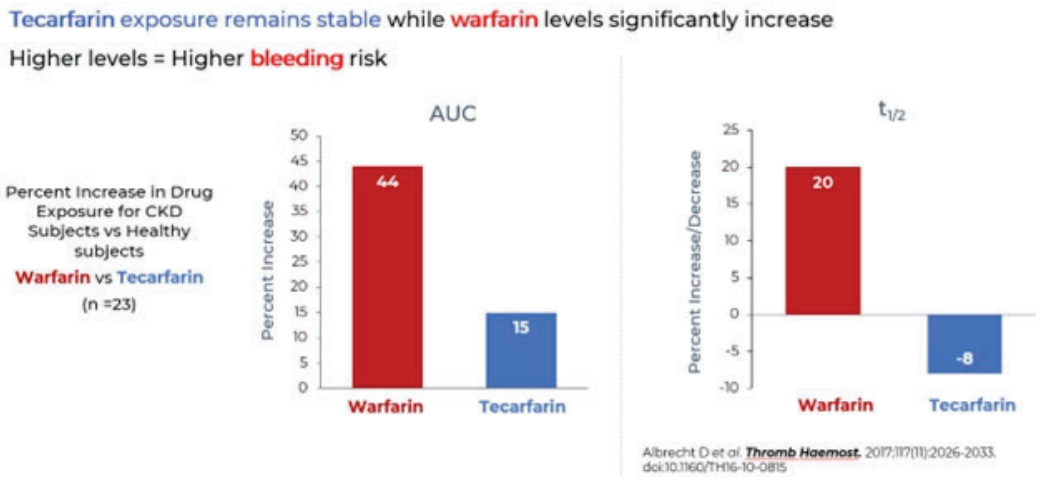
Population		% Time in Therapeutic Range		% INR Values in Therapeutic Range	
		Warfarin	Tecarfarin	Warfarin	Tecarfarin
ITT Population		71.5%	72.3%	65.4%	67.3%
On Rx (excluding interruptions)		72.5%	73.3%	66.4% p = 0.04	68.8%
Mechanical Valve	No	75.1%	75.5%	68.9%	70.9%
	Yes	66.3%	68.4%	60.5%	61.9%
CYP29 Interacting Rx	No	70.4%	70.2%	64.4%	65.7%
	Yes	69.0%	72.2%	64.1%	67.6%
CYP2C9 Variant Allele + CYP2C9 interacting Rx	No	70.0%	70.4%	63.9%	65.7%
	Yes	60.5%	76.5%	65.9%	71.3%

Tecarfarin was well tolerated - only 1.6% of the tecarfarin subjects had major bleeding and there were no thrombotic events. When thrombotic and major bleeding events were combined, there was a numerical imbalance (but not statistical significance) favoring tecarfarin over warfarin was seen (warfarin 11 subjects, 3.6%; tecarfarin subjects, 1.6%).

In EMBRACE-AC there were comparable rates of treatment emergent adverse events ("TEAEs") (all adverse events observed, regardless of relationship to study drug) between the two treatment groups. TEAEs were reported for 93.2% of patients who received tecarfarin and 90.5% of patients who received warfarin. TEAEs reported by ≥10% of patients in either treatment group were nasopharyngitis (18.6% and 19.3%, blinded tecarfarin and warfarin, respectively), contusion (15.6% and 14.8%, respectively), epistaxis (8.1% and 11.1%, respectively), upper respiratory tract infection (10.7% and 10.8%, respectively), diarrhea (10.1% and 9.2%, respectively) and headache (10.7% and 8.9%, respectively). Most TEAEs were mild (32.2%, tecarfarin and 30.2%, warfarin) or moderate (45.0% and 46.6%, respectively) in severity.

Five patients died during the trial, with four deaths occurring during the double-blind period: one patient (tecarfarin; off drug) died due to mantle cell lymphoma, pneumonia and sepsis; one patient (tecarfarin; on drug) died due to cardiorespiratory arrest and myocardial infarction; one patient (warfarin; off drug) died due to metastatic colon cancer; one patient (warfarin; off drug) died due to lung cancer; and one patient (not randomized) died due to intracerebral hemorrhage. The patient who died due to intracerebral hemorrhage was considered to be possibly related to the study drug, but the remaining four deaths were not attributed to the drug. During the blinded period of the trial, five patients on tecarfarin and six patients on warfarin experienced major bleeding events. The occurrence of major bleeding events for both tecarfarin and warfarin was lower when compared to prior anticoagulation trials. Among warfarin-treated patients, there were five thrombotic events (two ischemic strokes, two deep vein thromboses and one pulmonary embolism), while there were no such events among tecarfarin-treated patients.

In a subsequent Phase 1 single-dose study comparing 13 patients with Stage 4 CKD and 10 healthy volunteers, the metabolism of warfarin was shown to be significantly inhibited, whereas tecarfarin metabolism was not altered, in the setting of significant renal insufficiency.



Frunexian

Background

Epidemiological data and studies in established animal models suggest that Factor XIa could have a substantially more significant effect on thrombosis than in hemostasis (preventing bleeding in response to an injury). Patients with plasma Factor XI levels in the top 10% of the normal range are more than twice as likely to develop deep venous thrombosis as everyone else in the study population, with a dose-response relationship between Factor XI levels and the potential for venous thrombosis. There is also an association between high plasma Factor XI levels with increased incidences of myocardial infarction and stroke. In contrast, Factor XI-deficient individuals exhibit no significant reduction in the rate of acute myocardial infarctions as compared to those with normal Factor XI levels, but have a greater than eight-fold reduction in ischemic stroke and a statistically significant reduced incidence of venous thromboembolism. Importantly, unlike hemophilia A or B, Factor XI deficiency (Hemophilia C) rarely presents as spontaneous bleeding, though in some patients, greater-than-expected blood loss is noted after trauma, surgery, or other challenges to hemostasis.

Small molecule inhibitors bind reversibly to the active site of Factor XIa and block its activity. Small-molecule Factor XI inhibitors are synthetic compounds characterized by a relatively low molecular weight, predictable potency, metabolic stability, membrane permeability, and oral bioavailability. Frunexian is unique in being the only small molecule that is administered by continuous IV infusion and being developed for acute clinical settings.

Frunexian is a highly potent, rapid-onset, selective small molecule inhibitor of Factor XIa, that inhibits factor XIa activity in a dose-proportional fashion, with a close correlation between plasma concentration of frunexian and changes in aPTT over time, and no appreciable changes in prothrombin time ("PT"). The PK and PD characteristics of frunexian — with a rapid onset of action, stable, predictable effect on coagulation, short pharmacodynamic half-life, and apparent lack of dependence on renal clearance mechanisms—appear well-suited for use in a critical care environment. Overall, frunexian administered as a single intravenous bolus or with continuous infusions over five consecutive days in healthy subjects has been generally well tolerated, and the adverse event profile did not suggest any increased risk of bleeding events.

Frunexian is the only IV small molecule Factor XIa antagonist in active development for acute indications at this time. *In vivo* animal studies have been conducted with frunexian to demonstrate the ability of the molecule to inhibit thrombosis, as measured by clot size and an increase in aPTT, while minimizing the risk of unwanted bleeding, as shown by the observation of no significant change in PT.

Phase 1 Studies

There are two completed Phase 1 studies with frunexian.

The first study was a placebo-controlled, randomized, double-blind, SAD/MAD study in healthy male and female subjects evaluating the safety, tolerability, PK and PD of frunexian following IV administration of single doses, via bolus injection, and multiple doses, via continuous infusion. There was a marked dose-proportional increase in the aPTT for both single dose and continuous multiple doses. In Part A frunexian was generally well tolerated when administered as single bolus IV doses of 0.01, 0.03, 0.1, 0.3, and 1.0 mg/kg. In Part B frunexian was also generally well tolerated when administered as a 24-hour continuous IV infusion over five consecutive days at doses of 0.01, 0.03, 0.1, 0.3, and 0.6 mg/kg/h. There were no SAEs. No bleeding or fluid loss was reported at the injection site. The score for bruising and bleeding at the blood sampling site was also zero at the majority of time points.

The second study evaluated higher doses of frunexian in a single-center, randomized, partially blinded, placebo-controlled, and comparator-controlled study of the safety, tolerability, PK, and PD of frunexian administered intravenously over a 5-day period in 54 healthy subjects. The main objective of the study was to extend the findings of the original Phase 1 study to evaluate the higher doses of frunexian which might be used for procedural anticoagulation. The study was blinded for frunexian dose and placebo and was open-label for subjects receiving the heparin comparator infusion. When frunexian was administered for five days, there was a strong linear relationship between exposure and dose of frunexian. After infusion, the blood concentration of frunexian decreased rapidly. PD biomarkers (aPTT, PT and activated clotting time) and their ratios/changes from baseline showed that aPTT was significantly prolonged with increasing doses of frunexian after five consecutive days of IV infusion.

A total of 54 subjects were entered into the safety data set. Excluding the TEAEs of prolonged aPTT (expected with frunexian), the incidence of TEAE during the study period was 52.5% in the frunexian group, 100% in the heparin comparator group, and 30.0% in the placebo group. TEAEs related to study drugs occurred in 10.0% of the frunexian group, 100% of the heparin group, and 10.0% of the placebo group. The TEAE associated with frunexian treatment was primarily abnormal liver function (10.0%). In the frunexian group, there was one case (2.5%) with a grade 2 infusion site reaction (1.5mg/kg/h group).

Veralox Purchase Agreement

On December 10, 2025, we entered into the Veralox Purchase Agreement pursuant to which Veralox sold to us all, or substantially all, of its right title and interest in the Veralox Assets. The Veralox Assets also included the assignment of the Old Dominion License Agreement. See, "License Agreement with Old Dominion" below for a more detailed description of the Old Dominion License Agreement. The purchase price for the Veralox Assets consisted of (i) a cash payment of $200,000, (ii) the assumption of certain assumed liabilities by us; (iii) contingent milestone payments in an amount not to exceed $15 million, and (iv) royalty payments. The transactions contemplated by the Veralox Purchase Agreement were consummated on December 10, 2025.

The contingent milestone payments, which are payable in cash, common stock, or in any combination thereof in our sole discretion, are payable upon the achievement of the following clinical and regulatory milestone events:

(i) $2,000,000 upon the occurrence of the dosing of the first patient enrolled in the first clinical trial initiated after the closing of the transaction for CAD-1005;

(ii) $8,000,000 upon approval of the first regulatory filing seeking approval to market a pharmaceutical product for human use containing a Compound that is covered by a patent owned or licensed by Veralox (the "Product") in the United States;

(iii) $2,000,000 upon approval of the first regulatory filing seeking approval to market a Product outside the United States;

(iv) $2,000,000 upon approval of a regulatory filing seeking approval to market a Product for a subsequent indication in the United States; and

(v) $1,000,000 upon approval of a regulatory filing seeking approval to market a Product for a subsequent indication outside the United States.

We will pay Veralox royalties of 5% on the Annual Net Sales (as such term is defined in the Veralox Purchase Agreement) of each Product containing any of the Compounds that are the subject of the Veralox Purchase Agreement which are covered by a Valid Patent Claim (as such term is defined in the Veralox Purchase Agreement) in any country, such royalty to be payable from the first commercial sale of the Product in each country until the expiration of the last-to-expire Valid Patent Claim that would be infringed by the commercialization of such Product in that country, provided however that, on a Product-by-Product and country-by-country basis, in the event that, with respect to a Product in a country, Generic Competition (as such term is defined in the Veralox Purchase Agreement) exists with respect to such Product in such country in a calendar year, then the royalty rates in such country for such Product will thereafter be reduced by fifty percent (50%). The Veralox Purchase Agreement also provides that in the event that Veralox or its affiliates licenses or otherwise acquires rights from one or more third-parties in order to make, use, sell, import or otherwise exploit a Product in a country, then 50% of any amounts payable to the third-party in such country shall be deductible from the royalty amounts payable to Veralox.

The Veralox Purchase Agreement contains customary representations, warranties and agreements by us and Veralox, customary conditions to closing, and other obligations of the parties. Subject to certain customary limitations, Veralox agreed to indemnify us, our affiliates and each of our respective successors, assigns, officers, directors, shareholders, partners, employees and agents against certain losses related to, among other things, breaches of Veralox's representations, warranties and covenants contained in the Veralox Purchase Agreement, as well as any retained liabilities or excluded assets described therein. Subject to certain customary limitations, we also agreed to indemnify Veralox, its affiliates and each of their respective successors, assigns, officers, directors, shareholders, partners, employees and agents against certain losses related to, among other things, breaches of our representations, warranties and covenants as well as any assumed liabilities.

License Agreement with Old Dominion University

Pursuant to the Old Dominion License Agreement, the Licensor granted Veralox an exclusive worldwide license under the EVMS Patent Rights (as such term is defined in the Old Dominion License Agreement) related to the development and commercialization of 12-LOX. Veralox agreed to pay Licensor certain royalties and certain milestone payments related to the first Licensed Product or Licensed Service developed, some of which were assumed by us pursuant to the terms of the Veralox Purchase Agreement. The term "Licensed Product" is defined in the Old Dominion License Agreement as any process or method, material, composition, drug or other product, the manufacture, use or sale of which by Veralox, its affiliates or sublicensees would constitute, but for the license granted to Seller pursuant to the Old Dominion License Agreement, an infringement of any Valid Claim (as such term is defined in the Old Dominion License Agreement) of any of the EVMS Patent Rights. The term "Licensed Service" is defined in the Old Dominion License Agreement as the performance on behalf of a third-party by Veralox, its affiliates or sublicensees of any method or the manufacture of any product or the use of any product or composition which would constitute, but for the license granted to Veralox pursuant to the Old Dominion License Agreement, an infringement of a Valid Claim of the EVMS Patent Rights.

Pursuant to the Old Dominion License Agreement, we will pay Licensor milestone payments in the aggregate amount of $300,000 upon regulatory approval to market a Licensed Product in: (i) Japan or the European Union; and (ii) the United States, provided however that irrespective of whether such milestones are met, such milestone payments will be due in 2031 and 2032, respectively. Additionally, we will pay to Licensor royalties of 2% on worldwide net sales of a Licensed Product or Licensed Service less than or equal to $200,000,000 and royalties of 3% on worldwide sales greater than $200,000,000. Regardless of the commercialization status of any Licensed Product or Licensed Service, the Old Dominion License Agreement requires a minimum annual royalty payment to be paid to Licensor within (30) days of May 1st of each year beginning May 1, 2025, ranging between $10,000 and $50,000 per year. Such annual royalty payments have been waived by Licensor for fiscal years 2026, 2027 and 2028, with the first payment to be made by us due May 1, 2029.

The Old Dominion License Agreement may be terminated: (i) upon the failure of a party to perform any material obligation required of it to be performed under the Old Dominion License Agreement and thereafter such failure to perform is not timely cured, by the non-defaulting party upon written notice; (ii) by either party upon the bankruptcy or insolvency of the other party upon written notice: (iii) by us with or without Cause (as such term is defined in the Old Dominion License Agreement) upon 90 days' written notice to Licensor; and (iv) by Licensor: (a) in the event we fail to meet any of the Milestone Deadlines (as such term is defined in the Old Dominion License Agreement) upon 90 days' written notice; or (b) immediately in the event we or any of our affiliates brings, or assists others in bringing, a Patent Challenge (as such term is defined in the Old Dominion License Agreement) against Licensor or any co-owner of the EVMS Patent Rights.

The foregoing descriptions of the Veralox Purchase Agreement and Old Dominion License Agreement do not purport to be complete and are qualified in their entirety by reference to the Veralox Purchase Agreement and Old Dominion License Agreement, copies of which are filed as exhibits to this Annual Report and are incorporated by reference herein.

eXIthera Purchase Agreement

On September 12, 2025, we entered into an asset purchase agreement (the "eXIthera Purchase Agreement") with eXIthera Pharmaceuticals, Inc. ("eXIthera"), to acquire its assets, including its proprietary portfolio of investigational IV and oral Factor XIa inhibitors, including the compounds known as frunexian (EP-7041) and EP-7327 and certain other compounds, as well as all intellectual property, regulatory filings (including two inactive Investigational New Drug Applications filed with the FDA), clinical and non-clinical data, Chemistry, Manufacturing, and Controls materials, drug substance inventory, books and records, and the exclusive license agreement (the "Haisco License Agreement") with Sichuan Haisco Pharmaceutical Co., Ltd. ("Haisco"), which relates to development of eXIthera's lead asset, frunexian, in the Chinese market (the "eXIthera Assets"). The purchase price for the eXIthera Assets consisted of (i) $50,000 of transaction closing costs, (ii) the assumption of specific assumed liabilities related to post-closing obligations arising from the Haisco License Agreement, (iii) certain milestone payments, and (iv) royalty payments. The transactions contemplated by the eXIthera Purchase Agreement were consummated on September 12, 2025.

We have agreed to pay milestone payments to eXIthera in the aggregate amount of up to $15 million, payable in cash or in shares of our Common Stock in our sole discretion, upon the achievement of certain clinical and regulatory milestone events. The contingent milestone payments are payable upon the achievement of the following clinical and regulatory milestone events:

(i) $500,000 upon the occurrence of the first patient dosed in first Phase 2 study initiated after the closing of the transaction with respect to frunexian or an Other IV Compound (as such term is defined in the eXIthera Purchase Agreement);

(ii) $500,000 upon the occurrence of the first patient dosed in first Phase 1 study initiated after the closing of the transaction with respect to EP-7327 or an Other Oral Compound (as such term is defined in the eXIthera Purchase Agreement);

(iii) $1,000,000 upon the occurrence of the first patient dosed in first Phase 3 study initiated after the closing of the transaction with respect to frunexian or an Other IV Compound;

(iv) $1,000,000 upon the occurrence of the first patient dosed in first Phase 3 study initiated after the closing of the transaction with respect to EP-7327 or an Other Oral Compound);

(v) $6,000,000 on the date the FDA grants approval of a New Drug Application ("NDA") for frunexian or an Other IV Compound;

(vi) $6,000,000 on the date the FDA grants approval of an NDA for EP-7327 or an Other Oral Compound.

We are obligated to pay eXIthera and its assignees, a royalty equal to 2% of the Annual Net Sales (as such term is defined in the eXIthera Purchase Agreement) of pharmaceutical products containing any of the Compounds that are the subject of the eXIthera Purchase Agreement which are covered by a valid patent in any country except China, such royalty to be payable from the first commercial sale of a product in each country until the later of: (a) expiration of the last-to-expire Valid Patent Claim (as such term is defined in the eXIthera Purchase Agreement) that would be infringed by the commercialization in that country, (b) expiration of regulatory exclusivity in that country (including when generic competition occurs), or (c) ten years from the first commercial sale of the product in that country.

Additionally, we are obligated to pay eXIthera 50% of all royalties actually received by us from Haisco under the existing Haisco License Agreement, without any limitations on the total amount paid or the time period within which such payments will be made. We also agreed to assume only post-closing obligations arising from the Haisco License Agreement, but only to the extent that such obligations do not arise from any breach or default by eXIthera under the Haisco License Agreement on or before the closing of the transaction.

Manufacturing

We do not have a manufacturing infrastructure and do not intend to develop one. With respect to tecarfarin, we have recently completed the manufacturing of tecarfarin drug product in accordance with cGMP. We have executed contracts with third-party pharmaceutical contract development and manufacturing organizations ("CDMOs") for the development of validated processes and the supply of active pharmaceutical ingredients and clinical trial material for tecarfarin in accordance with cGMP. Such CDMOs have the capability to scale-up for commercial production of tecarfarin. However, we have not entered into any long-term supply agreements or commercialization partnerships with these vendors. Certain material suppliers and manufacturing sites for tecarfarin are in locations outside of the U.S.

With respect to the drug candidates we acquired from eXIthera and Veralox, we intend to execute contracts with third-party CDMOs for the supply of drug substance and drug product in accordance with cGMP, but do not yet have such contracts in place.

While the materials and substances used in our product candidates are manufactured by more than one supplier, the number of suppliers is limited. In the event it is necessary or advisable to acquire drug materials, substances, and products from alternative suppliers, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to transfer or redesign our manufacturing processes to work with another company. If approved by the FDA, we anticipate that we will be able to enter into agreements with third parties to manufacture and distribute our product candidates on commercially reasonable terms.

Sales and Marketing

If the FDA or other regulatory authorities approve any of our product candidates, we may commercialize our products by hiring and training a small and dedicated salesforce to commercialize our products in the U.S., and possibly other major markets. In addition, we anticipate entering into a variety of distribution agreements and commercial partnerships in those territories where we do not establish an internal sales force, including if we expand outside of the U.S. We expect that our specialized commercial cardiovascular team would be comprised of experienced marketing and sales management professionals.

Competition and Market Opportunity

The development and commercialization of new drugs is highly competitive. We face competition with respect to developing our current product candidates, and we will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

CAD-1005

We are not aware of any other 12-LOX inhibitors currently in clinical development. CAD-1005 would be an addition to existing treatment standards, which include non-heparin anticoagulants such as direct thrombin antagonists (bivalirudin and argatroban), fondaparinux (a direct Xa antagonist), and DOACS (direct oral anticoagulants).

Tecarfarin

We are seeking to develop tecarfarin for use in circumstances where warfarin may still be regarded as the standard of care, but with persistent unmet medical needs that are inadequately addressed by current alternative anticoagulants. If we succeed in developing tecarfarin, we will face substantial competition, primarily from warfarin as the most widely used VKA, although warfarin is not specifically approved for use in our intended patient populations – ESKD and AFib and LVADs. Additional oral anticoagulants intended for chronic use include DOACs such as Pradaxa (dabigatran), Xarelto (rivaroxaban), Eliquis (apixaban) and Savaysa (edoxaban) for specific indications. Warfarin is a generic and is manufactured by multiple generic pharmaceutical companies.

Frunexian

Frunexian is the only parenteral XIa antagonist currently being evaluated for acute care applications. The most widely used inpatient parenteral anticoagulant is unfractionated heparin; other alternatives include LMW heparin, direct thrombin antagonists (bivalirudin and argatroban), and direct Xa inhibitors (fondaparinux).

Many of these named competitive products are marketed by some of the largest and most successful pharmaceutical companies worldwide, including generic pharmaceutical companies. The companies that market these products have substantially more resources than we do and substantially more experience developing and marketing pharmaceuticals. We may not be able to successfully compete with these existing products. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of competing drugs and potentially competing drugs. Our competitors are developing or may be attempting to develop therapeutics for our target indications.

Based upon management's analysis of market research and external data, and assuming that we receive FDA approval of CAD-1005, we estimate that the peak annual market revenue potential for CAD-1005 in patients with HIT will be approximately $825 million.

Based upon management's analysis of market research and external data, and assuming that we receive FDA approval of tecarfarin and frunexian, we estimate that the combined peak annual U.S. market revenue potential for these product candidates in patients with orphan and high-risk cardiovascular conditions is approximately $2 billion.

Intellectual Property

Our success will significantly depend upon our ability to obtain and maintain patent and other intellectual property and proprietary protection for our drug candidates, including market and data exclusivity granted by regulatory agencies and composition of matter, dosage, method of use, and formulation patents, as well as patent and other intellectual property and proprietary protection for our novel discoveries and other important inventions and know-how. In addition to patents, we rely upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed, or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see "Risk Factors — Risks Related to Our Intellectual Property."

We have acquired intellectual property from Veralox that contains U.S. and foreign patents and applications directed to 12-Lox inhibitors, including particular compounds formulated for intravenous and oral administration, and know-how regarding the design of the compounds. There are three U.S. patents and four foreign patents for compositions of matter, including intravenous formulations, and methods of treatment. Additional patent applications are pending in various jurisdictions and are directed to additional disease indications for treatment, aqueous formulations of CAD1005, dosing protocols using CAD1005, oral formulations of CAD1005, and additional/secondary compounds and methods of treatment using the same. The intravenous formulation patents will expire in 2034, and the oral formulation applications are expected to expire in 2043.

We have filed an international patent application for the use of tecarfarin in patients having undergone implantation of a cardiac device. In addition, we have filed U.S. provisional patent applications covering additional uses for tecarfarin and continue to monitor further patent filing opportunities. The two issued tecarfarin U. S. patents, for both composition of matter and method of treatment, expired on April 8, 2024. Foreign patents directed to tecarfarin, for composition of matter and use, expired in April 2025. In the absence of (i) future ODD marketing exclusivity if granted by the FDA, (ii) future market and data exclusivity if granted by regulatory agencies and (iii) additional patent filings covering new inventions, we would not be able to adequately protect our tecarfarin intellectual property, and competitors would be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We have acquired intellectual property from eXIthera that contains U.S. and foreign patents and applications directed to Factor XIa inhibitors, including particular compounds formulated for intravenous and oral delivery, and know-how regarding the design of the compounds. There are five U.S. patents and twelve foreign patents for the intravenous formulation covering compositions of matter and methods of treatment; additional patent applications are pending in various jurisdictions directed to methods of manufacturing, solid dosage forms, and pharmaceutical formulations. There are two U.S. patents and three foreign patents for the oral formulation covering compositions of matter and methods of treatment, as well as two pending foreign applications. The intravenous formulation patents will expire in 2035, and the oral formulation patents will expire in 2039.

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent but cannot extend the remaining term of a patent beyond a total of fourteen years from the date of product approval. Only one patent among those eligible for an extension may be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted. Provisions are available in certain other jurisdictions to extend the term of a patent that covers an approved drug or to provide data exclusivity. For example, data exclusivity in the European Union may be available for ten years from approval and in Japan for eight years from approval. It is possible that issued U.S. patents covering tecarfarin may be entitled to patent term extensions. If our product candidate receives FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available; however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

Data Exclusivity

If our product candidates are approved by the FDA, we expect to receive five years of data exclusivity, often referred to as new chemical entity exclusivity, for our NDA, so long as the FDA has not approved a drug containing the same active moiety as such product candidate. It is possible that the FDA may disagree with our position and not approve our product candidate or grant new chemical exclusivity to our NDA for our product candidate. Assuming the FDA approves our product candidate and new chemical entity exclusivity is granted, during the five-year period, no generic applicant can file an abbreviated new drug application ("ANDA") referencing our NDA for our product candidate, unless the generic applicant challenges a patent listed in the FDA Orange Book for the referenced NDA, in which case the generic applicant can file after four years. If the patent is asserted against the generic applicant within 45 days of receipt of a required notice letter by the generic applicant, the generic ANDA cannot be approved by FDA for up to thirty months.

Government Regulation

The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning or untitled letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties.

Product development and marketing activities are subject to extensive regulation by various government authorities, including the FDA, other federal, state and local agencies and comparable regulatory authorities in other countries, which regulate the design, research, clinical and non-clinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products and devices. Generally, before a new drug can be sold, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. The data are often generated in two distinct development states: pre-clinical and clinical.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Development of Drugs in the United States

Pharmaceutical products must be approved by the FDA before they may be legally marketed in the United States. Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves pre-clinical laboratory and animal tests, the submission to the FDA of an IND application, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

The pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism trials that support subsequent clinical testing. These pre-clinical laboratory and animal tests must comply with federal regulations and requirements, including the FDA's good laboratory practices regulations. A drug's sponsor must submit the result of the pre-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature and a proposed clinical protocol to the FDA as part of an IND application. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted (i) in compliance with federal regulations, including good clinical practices ("GCP"), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; and (ii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

Clinical trials to support NDAs for marketing approval can generally be divided into three sequential phases that may overlap, Phase 1, Phase 2 and Phase 3 clinical trials. In Phase 1, generally, small numbers of healthy volunteers are initially exposed to single escalating doses and then multiple escalating doses of the product candidate. The primary purpose of these trials is to assess the metabolism, pharmacologic action and general safety of the drug. Phase 2 trials typically involve trials in disease-affected patients to determine the dose required to produce the desired benefits, common short-term side effects and risks. Phase 2 trials are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred patients. Phase 3 trials are intended to gather the additional information about effectiveness and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 trials usually include from several hundred to several thousand patients and are closely controlled and monitored. In many cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in some instances. In addition to these Phase 1-3 trials, other trials may be conducted to gather additional safety, pharmacokinetic and pharmacodynamic information. Pharmaceutical products with active ingredients that are the same as or similar to those already approved by the FDA may have more streamlined development programs than new chemical entities.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Trials must be conducted in accordance with GCP and reporting of study progress and any adverse experiences is required. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, responsible for overseeing trials at particular sites and protecting human research trial patients. An independent institutional review board may also suspend or terminate a trial once initiated, for failure to comply with the IRB's requirements, or may impose other conditions. Accordingly, we cannot be sure that submission of an IND, will result in the FDA allowing clinical trials to begin, or that once begun, issues will not arise that could cause the trial to be suspended or terminated.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. Sometimes, these trials are used to gain additional experience from the treatment of patients in the intended therapeutic condition. In certain instances, the FDA may mandate the performance of Phase 4 trials. In other situations, post-approval trials aim to gain additional indications for a medication.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Review and Approval in the United States

Following Phase 3 trial completion, data are analyzed to determine safety and efficacy, with any final such determination to be made by the FDA. Data are then submitted to the FDA in an NDA, along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. The cost of preparing and submitting an NDA is substantial. Manufacturers may be assessed up to five program fees for a fiscal year for prescription drug products identified in a single approved NDA. These fees are typically increased annually. In the United States, FDA approval of an NDA must be obtained before marketing a new drug.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for standard review drug products are reviewed within 10 to 12 months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of advisory committees, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured.

The FDA may conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA") NDAs or supplements to NDAs must contain data 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 drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, ("BPCA"), provides NDA holders a six-month extension of any exclusivity — patent or non-patent — for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA's written request for pediatric studies, and the applicant's agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. It also does not suggest FDA approval or exclusivity. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $500,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

Orphan drug exclusivity means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There has been recent litigation concerning FDA's interpretation of the orphan drug exclusivity provisions.

Accelerated Approval

There are a variety of pathways under which applicants may seek expedited approval from FDA, including Fast Track, breakthrough therapy, priority review and accelerated approval. Fast Track is a process designed to facilitate the development and expedite the review of investigational drugs to treat serious conditions and fill an unmet medical need. Drugs that receive Fast Track designation may be eligible for more frequent communications and meetings with the FDA to discuss the drug's development plan, including the design of the proposed clinical trials, use of biomarkers and the extent of data needed to support approval. Drugs with Fast Track designation may also qualify for accelerated approval and priority review of NDAs if relevant criteria are met. However, Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The FDA accelerated approval program provides for early approval of drugs based on a drug on a clinical trial(s) showing that the drug meets a surrogate or an intermediate clinical endpoint rather than a clinical benefit endpoint. Accelerated approval is possible for drugs for serious conditions that fill an unmet medical need. Under priority review, the FDA reviews an application in six months rather than ten months after it is accepted for filing.

A surrogate endpoint used for accelerated approval is a marker, such as a laboratory measurement, that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Likewise, an intermediate clinical endpoint is a measure of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity and mortality. Because it sometimes can take many years for a drug trial to show a clinical benefit, the use of a surrogate endpoint or an intermediate clinical endpoint can significantly shorten the time required to complete clinical trials and obtain FDA approval.

If a drug receives accelerated approval, the company that sponsored the application must conduct a post-approval trial to confirm the anticipated clinical benefit. These trials are known as Phase 4 or post-approval confirmatory trials. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA and other regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations not described in the drug's approved labeling (known as "off-label use"), and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. The FDA regulations require the products be manufactured in specific approved facilities and in accordance with cGMP, and NDA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms. These firms are subject to inspections by the FDA at any time, and the discovery of violative conditions could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them.

Drug Development in Europe

In the European Union, our future products may also be subject to extensive regulatory requirements. Similar to the United States, the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

Review and Approval in the European Union

In the European Union, approval of new medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure and the decentralized procedure. We intend to determine which process we will follow, if any, in the future.

Mutual Recognition Procedure*:* An applicant submits an application in one European Union member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussion among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state.

Centralized Procedure*:* This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other "innovative medicinal products with novel characteristics." Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

Decentralized Procedure*:* The most recently introduced of the three processes for obtaining approval of new medicinal processes in the European Union, the decentralized procedure is similar to the mutual recognition procedure described above, but with differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of, among other things, "clock stops" during the procedure.

Orphan Designation in the European Union

In the European Union, companies are encouraged to research and develop medicines for rare diseases that otherwise would not be developed. A medicine may be orphan-designated by the European Commission, based on a recommendation from the EMA's Committee for Orphan Medicinal Products, provided that certain criteria are met, as set forth in the article entitled "Orphan medicines in the EU," published by the Publications Office of the European Union, 2025 (the "EU Orphan-designated Medicines Article"). Such criteria include that the medicine is intended to treat, prevent or diagnose a disease which is life-threatening or chronically debilitating, or it is unlikely that the medicine will generate sufficient returns to justify the investment needed for its development, and the disease must not affect more than five in 10,000 people in the European Union. To qualify for orphan designation, the sponsor must also demonstrate that no satisfactory method of diagnosis, prevention, or treatment of the condition exists, or that the medicine provides a significant benefit to patients affected by the condition. Between the years 2014 and 2024, an average of 163 medicines received an orphan designation by the European Commission.

Orphan designation in the European Union provides several regulatory and commercial incentives, including scientific advice on study protocols from the EMA, access to European Union research funding, reduced regulatory fees, and, upon regulatory approval, ten years of market exclusivity for the designated indication, provided that it can be demonstrated that the criteria for their designation still apply, as described in the EU Orphan-designated Medicines Article. The designation does not guarantee that a product will reach the marketing authorization application stage, nor does it affect the strict safety or efficacy standards that apply to all medicines evaluated by the EMA's Committee for Medicine Products for Human Use.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. These laws and regulations include:

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

- Federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent. The government may assert that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback law or related to off-label promotion constitutes a false or fraudulent claim for purposes of the federal false claims laws;

- The Federal Physician Payments Sunshine Act within the Patient Protection and Affordable Care Act of 2010, as amended (the "ACA"), and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report on an annual basis information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members, with the information made publicly available on a searchable website; and

- The Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates" — independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- Applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.

- The Lanham Act and federal antitrust laws.

- State law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual physicians in these states. Other states prohibit various other marketing-related activities, and still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Massachusetts and Nevada require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, traceability, and storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Third-Party Payer Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our drug candidates that ultimately may obtain regulatory approval. In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payer has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payers often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our products can be subject to challenge, reduction or denial by the government and other payers.

The pharmaceutical industry has been and continues to be affected by federal and state legislation that alters the pricing, coverage, and reimbursement landscape. The United States Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products and product candidates profitably. For example, in the first quarter of 2018, President Trump signed a law requiring pharmaceutical companies to pay for a substantially larger percentage of the coverage gap, or the so-called “donut hole,” between regular and catastrophic Medicare Part D prescription drug coverage, a change that is estimated to have a multi-billion-dollar effect on brand-name drug companies. Additional changes could be made in the future to governmental healthcare programs and many other laws that could significantly impact the success of our products.

Additionally, in August 2022, President Biden signed into law the Inflation Reduction Act (“IRA”), which includes provisions that effectively authorize the government to establish prices for certain high-spend single-source drugs and biologics reimbursed by the Medicare program, starting in 2026 for Medicare Part D drugs and 2028 for Medicare Part B drugs. It is not yet certain which products the federal government will select and subject to government-established prices, or how the federal government will establish prices for selected products, as the IRA specifies a ceiling price but not a minimum price. One or more of our product candidates, if approved, could be selected and subject to the government-established price.

The IRA also contains provisions that impose rebates if certain prices increase at a rate that outpaces the rate of inflation, beginning October 1, 2022, for Medicare Part D drugs and January 1, 2023, for Medicare Part B drugs. Separate IRA provisions redesign the Medicare Part D benefit in various ways, including by shifting a greater portion of costs to manufacturers within certain coverage phases and replacing the Part D coverage gap discount program with a new manufacturer discounting program. Failure to comply with IRA provisions may subject manufacturers to various penalties, including civil monetary penalties. The impact of the IRA on our business and the broader pharmaceutical industry remains uncertain, as the federal government has yet to make various IRA implementation decisions.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payers also require pre-approval of coverage for new or innovative devices or drugs before they will reimburse healthcare providers that use such drugs. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our products and product candidates and operate profitably.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Trade Laws

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Human Capital Employees

As of March 27, 2025, we had five employees, all of which are full-time, and engage approximately thirty-five consultants and contractors. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated as a Delaware corporation in January 2022. Our principal executive offices are located at 822 A1A North, Suite 306, Ponte Vedra, Florida 32082, and our telephone number is (904) 300-0701. Our website address is *www.cadrenal.com*. The information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider any information contained on, or that can be accessed through, our website as part of this Annual Report or in deciding whether to purchase our Common Stock.

Facilities

Our corporate headquarters are located at 822 A1A North, Suite 306, Ponte Vedra, Florida 32082, which are leased pursuant to a Lease Agreement, originally dated October 15, 2022 with Veranda III Partners, Ltd. (the "Lease Agreement"), as subsequently amended. The Lease Agreement, as most recently amended by an addendum dated October 14, 2025, has a term of 12 months commencing on November 1, 2025. The monthly rent is $2,346. We believe that these headquarters are adequate for our current operations and needs.

Legal Proceedings

We are not currently a party to any material legal proceedings. We may, however, in the ordinary course of business face various claims brought by third parties, and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation. If this were to happen, the payment of any such awards could have a material adverse effect on our business, financial condition and results of operations. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Available Information

Our website address is *www.cadrenal.com*. We will file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other materials with the U.S. Securities and Exchange Commission (the "SEC"). We are subject to the informational requirements of the Exchange Act and will file or furnish reports, proxy statements and other information with the SEC. Such reports and other information filed by the Company with the SEC are available free of charge on our website at http://cadrenal.com/investors/SEC filings. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider information on our website to be part of this Annual Report.

The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we remain an emerging growth company, we may take advantage of specified reduced reporting requirements and other burdens that are otherwise applicable generally to other public companies. These provisions include, but are not limited to:

- Reduced obligations with respect to financial data, including presenting only two years of audited financial statements and selected financial data, and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in our initial registration statement;

- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended ("SOX");

- reduced disclosure about executive compensation arrangements in our periodic reports, registration statements and proxy statements; and

- exemptions from the requirements to seek non-binding advisory votes on executive compensation or stockholder approval of any golden parachute arrangements.

We may take advantage of some or all of these provisions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day the fiscal year following the fifth anniversary of the completion of our initial public offering, (ii) the last day of the first fiscal year in which our annual gross revenues exceed $1.235 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, or the SEC. We may choose to take advantage of some but not all of these reduced burdens. For example, we have taken advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report, and have taken advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period. As a result of this election, our timeline to comply with new or revised accounting standards will in many cases be delayed as compared to other public companies that are not eligible to take advantage of this election or have not made this election. Therefore, our financial statements may not be comparable to those of companies that comply with the public company effective dates for these accounting standards.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a "smaller reporting company" as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an "emerging growth company" may continue to be available to us as a "smaller reporting company," including exemption from compliance with the auditor attestation requirements pursuant to SOX and reduced disclosure about our executive compensation arrangements. We will continue to be a "smaller reporting company" until we have $250 million or more in public float (based on our Common Stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our Common Stock) or a public float (based on our Common Stock) that is less than $700 million, annual revenues of $100 million or more during the most recently completed fiscal year.

Item 1A. Risk Factors.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this Annual Report or elsewhere. The following information should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes beginning on F-1 of this Annual Report.

You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report, including our consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and stock price. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past or their likelihood of occurring in the future.

Because of the following factors, as well as other factors affecting our financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Investors should carefully consider the risks described below before deciding whether to invest in our securities. If any of the following risks actually occur, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our Common Stock could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements made throughout this Annual Report a result of different factors, including the risks we face described below.

Risks Related to Our Financial Position and Need for Capital

Our financial statements have been prepared assuming that we will continue as a going concern.

We had an accumulated deficit of approximately $39.0 million as of December 31, 2025 and a net loss of approximately $13.2 million for the fiscal year ended December 31, 2025. We expect to incur significant expenses and continued losses from operations for the foreseeable future. We believe that our existing cash and cash equivalents will not be sufficient to meet our anticipated cash requirements for the next twelve months. We will require additional financing as we continue to execute our business strategy, including the need for additional funds for the commencement of our planned clinical trials. Our audited financial statements for the fiscal year ended December 31, 2025, were prepared under the assumption that we will continue as a going concern; however, we have incurred significant losses from operations to date and we expect our expenses to increase in connection with the commencement of our planned clinical trials. These factors raise substantial doubt about our ability to continue as a going concern for one year after the financial statements are issued. Our auditor's report on our audited financial statements for the fiscal year ended December 31, 2025 contains an explanatory paragraph with respect to this uncertainty. Our liquidity may be negatively impacted as a result of research and development cost increases in addition to general economic and industry factors. In order to meet our expected obligations, we intend to raise additional funds through partnering and equity and debt financings or a combination of these potential sources of liquidity. There can be no assurance that funding will be available on acceptable terms, on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. If we raise funds through partnering, such as collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or grant licenses on terms that are not favorable to us. If we do not succeed in raising additional funds on acceptable terms or at all, we may be unable to complete the planned clinical trials. As such, we cannot conclude that such plans will be effectively implemented within one year after the date that the financial statements included in this Annual Report are filed with the SEC and there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

Any shutdown of the U.S. federal government may adversely affect our business.

A shutdown of the U.S. federal government may adversely affect our business operations and regulatory compliance. During such shutdowns, while the SEC's EDGAR system remains operational, the unavailability of SEC staff to review filings, issue comments, or declare registration statements effective may delay our ability to complete public offerings, respond to comment letters, or obtain timely regulatory approvals. These delays could impact our access to capital markets, hinder strategic transactions, and create uncertainty around our disclosure obligations. Additionally, the lack of interpretive guidance or exemptive relief during a shutdown may increase legal and compliance risks. We continue to monitor developments and adjust our regulatory strategies accordingly, but there can be no assurance that future shutdowns will not materially affect our operations or financial condition.

We are a clinical development biopharmaceutical company with a limited operating history.

We were formed in January 2022 and have had limited operations to date. We have not yet performed any clinical trials. We have to manufacture product, complete clinical trials and receive regulatory approval of NDAs before commercial sales of our product candidates can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with building and expanding clinical development pharmaceutical businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the later stage of development, especially clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to:

- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of our product candidates, including our Phase 3 trial for CAD-1005 in patients with HIT;
- secure acceptance of our product candidate in the medical community and with third-party payors and consumers;
- if approved for commercial sale, launch commercial sales of our product candidate, whether alone or in collaboration with others;
- successfully build an internal sales force meeting our requirements for the marketing and sale of our product candidates;
- successfully manufacture our clinical product and establish commercial drug supply;
- secure market exclusivity and/or adequate intellectual property protection for our product candidate;
- attract and retain an experienced management, board and scientific advisory team;
- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound; and
- raise sufficient funds in the capital markets to effectuate our business plan.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

We have a limited operating history upon which to evaluate our ability to commercialize our product candidate.

We are a development-stage company and our success is dependent upon our ability to obtain regulatory approval for and commercialize our product candidates and we have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidate. We have yet to demonstrate our ability to overcome the risks frequently encountered in our industry and are still subject to many of the risks common to such enterprises, including our ability to implement our business plan, market acceptance of our proposed business and lead product, under-capitalization, cash shortages, limitations with respect to personnel, financing and other resources, competition from better funded and experienced companies, and uncertainty of our ability to generate revenues. In fact, though individual team members have experience running clinical trials, we have yet to prove that we can successfully run a clinical trial and our lead product candidate. There is no assurance that our activities will be successful or will result in any revenues or profit, and the likelihood of our success must be considered in light of the stage of our development. In addition, no assurance can be given that we will be able to consummate our business strategy and plans, or that financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early-stage company. Our revenue and income potential are unproven and our business model is continually evolving. In fact, we have recently changed our focus from the development of tecarfarin to the development of CAD-1005. We are subject to the risks inherent to the operation of a new business enterprise, and cannot assure you that we will be able to successfully address these risks.

We have a history of operating losses and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

To date, we have not generated any revenue from operations and we expect to continue to incur significant operating losses in connection with the development and sale of our product candidates. We may continue to incur operating losses until such time, if ever, as we are able to achieve sufficient levels of revenue from operations. Our ability to achieve profitability will depend on regulatory approval of our product candidates and, if approved, the market acceptance of our product offering and our capacity to develop, introduce and sell our product to our targeted markets. In fact, if the FDA determines that we require larger patients numbers in our planned clinical trial of CAD-1005 in patients with HIT or additional clinical trials our financing needs will increase and our ability to commercialize our product candidate will be delayed beyond our currently planned timeline. There can be no assurance that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

Even if we succeed in developing and commercializing one or more product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to plan for and commence the clinical trials for our product candidates;
- seek regulatory approvals for our product candidate;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

We may not be able to generate revenue or achieve profitability in the future. Our failure to achieve or maintain profitability would likely negatively impact the value of our securities and could prevent us from continuing as a going concern.

Even if we can secure such arrangements, we may continue to have obligations and expenses that exceed the revenue generated by these marketed products. In addition, we could incur significant development and other expenses if we were to make alterations to the manufacturing process for any product candidate including CAD-1005, for preparation and submission of a supplemental NDA for such alterations, if required by the FDA, and in connection with the launch of such product, if approved. Further, as we pursue FDA approval for CAD-1005, we expect that our research and development expenses will continue to increase significantly as we advance our product candidates and conduct planned clinical trials.

Our cash and the proceeds from our completed financings will only fund our operations for a limited time, and we will need to raise additional capital to fund our planned clinical trials and to support our development and commercialization efforts for our product candidates.

If we do not succeed in raising additional funds on acceptable terms, we will be unable to commence our planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities If the FDA determines that we require larger patients numbers in our clinical trial or additional clinical trials our financing needs will increase and our ability to commercialize our product candidate will be delayed beyond our currently planned timeline. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities.

We will also need to raise additional capital to expand our business to meet our long-term business objectives.

We believe that our existing cash and cash equivalents will not be sufficient in the aggregate to meet our anticipated cash requirements for at least the next twelve months. We will require additional financing prior to commencing any clinical trial and as we continue to execute our business strategy, including that we will require additional funds for the initiation of enrollment of patients and completion of the planned clinical trials. Our liquidity may be negatively impacted as a result of research and development cost increases in addition to general economic and industry factors. We anticipate that, to the extent that we require additional liquidity, it will be funded through the incurrence of other indebtedness, additional equity financings, or a combination of these potential sources of liquidity. In addition, we may raise additional funds to finance future cash needs through grant funding and/or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities or convertible debt, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our products, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. The covenants under future credit facilities may limit our ability to obtain additional debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any failure to raise capital in the future could have a negative impact on our financial condition and our ability to pursue our business strategies.

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

- the outcome, timing, and cost of our planned clinical trials;
- the final minutes from our EOP2 meeting with the FDA and any comments we may receive from the FDA after submission of our Phase 3 trial protocol for CAD-1005 in patients with HIT;
- obtaining regulatory approval of our product candidates in the United States and Europe;
- the costs of manufacturing our clinical products and establishing commercial drug supply;
- the degree and rate of market adoption of our products, if approved;
- the emergence of new, competing technologies and products;
- the costs of R&D activities we undertake to develop new products and indications;
- the costs of commercialization activities, including sales, marketing and manufacturing;
- the costs of building an internal sales force meeting our requirements for the marketing and sale of our product candidates, if approved;
- our ability to collaborate with third parties on the development and commercialization of our product candidates and products;
- the level of working capital required to support our growth; and
- our need for additional personnel, information technology or other operating infrastructure to support our growth and operations as a public company.

Other than our at-the-market facility with H.C. Wainwright & Co., LLC ("H.C.W.") we do not currently have any arrangements or credit facilities in place as a source of funds, and there can be no assurance that we will be able to use such facility or even if we can use such facility there can be no assurance that we will raise sufficient additional capital on acceptable terms, or at all. Availability of funding from the at-the-market facility is limited due to certain restrictions. We anticipate that the additional funding we require will be funded through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including issuing shares of our Common Stock or other securities and incurring additional debt, and could increase our expenses and require that our assets secure such debt. Equity financing, if obtained, could result in dilution to our then existing stockholders and/or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. In addition, if we are unable to secure sufficient capital to fund our operations, we might have to enter into strategic collaborations that could require us to share commercial rights to our products or product candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. If we choose to pursue additional indications and/or geographies for any of our products or product candidates or otherwise expand more rapidly than we presently anticipate, we may also need to raise additional capital sooner than expected.

Our need for future financing may result in the issuance of additional securities, which will cause investors to experience dilution.

Our cash requirements may vary from those now planned, depending upon numerous factors, including the results of future research and development activities. We expect our expenses to increase if and when we initiate and conduct clinical trials, and seek marketing approval for our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. There are no other commitments by any person for future financing. Our securities may be offered to other investors at a price lower than the price per share offered to current stockholders, or upon terms which may be deemed more favorable than those offered to current stockholders. In addition, the issuance of securities in any future financing may dilute an investor's equity ownership and have the effect of depressing the market price for our securities. Moreover, we may issue derivative securities, including options and/or warrants, from time to time, to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders.

Risks Related to Product Development, Regulatory Approval, Manufacturing, and Commercialization

Our future success depends heavily on FDA review of our Phase 3 trial protocol and commencement of our Phase 3 clinical trial.

We completed our EOP2 meeting with FDA on March 26, 2026. Although we clarified a potential registrational path for our planned Phase 3 pivotal trial of CAD-1005 in patients with HIT, we have not yet received the meeting minutes from the FDA, which may contain additional information not discussed in the meeting. Our Phase 3 trial protocol will still be subject to any further comments we may receive from the FDA upon their review of the protocol. The FDA may also require us to conduct additional studies.

The 12-LOX platform of assets is subject to significant clinical risks that could impede our ability to advance CAD-1005 or our second-generation oral candidates.

Our second-generation oral 12-LOX inhibitors for Type 1 Diabetes and vascular health are in early development; any safety or efficacy failures in these programs could negatively impact the perceived value of the 12-LOX platform of assets as a whole. Since the Phase 2 study of CAD-1005 for patients with HIT was not powered for statistical significance, the observed benefit in thrombotic events could be due to chance rather than the product candidate's efficacy. In addition, the Phase 2 trial did not complete enrollment, only 24 patients out of a planned 60 were treated in the trial before it was terminated. There can be no assurance that future trials will not have recruitment difficulties given the acute and complex nature of the disease.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' staffing and operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Our business depends on timely interactions with the FDA, including the review of regulatory submissions, scheduling of formal meetings, and oversight of clinical trials. In fact, we recently attended an EOP2 meeting with the FDA to discuss a registration pathway for our Phase 3 trial. Disruptions at the FDA and other federal agencies, including substantial leadership departures, personnel cuts, policy changes and those related to the federal government shutdown, may result in reduced staffing or suspension of non-essential FDA operations, which could delay or cancel meetings with the FDA, hinder regulatory guidance, delay the implementation or enforcement of regulatory requirements in a timely fashion or at all, and postpone the review of IND applications, New Drug Applications (NDAs), and Biologics License Applications (BLAs). Any delay in our interactions with the FDA or future meetings will result in delay in us commencing future clinical trials of our lead product candidate CAD-1005 in patients with HIT. These disruptions may also affect the initiation, conduct, and monitoring of other clinical trials, particularly those requiring FDA authorization or ongoing regulatory engagement. Interruptions in FDA activities could materially delay our development timelines, increase operational costs, and adversely impact our ability to complete our planned clinical trials and to advance product candidates toward approval and commercialization. Any such delays or uncertainties may have a significant negative effect on our business, financial condition, and results of operations.

In addition, the current U.S. administration is focused on reducing costs of the federal government generally, including significantly reducing the number of government employees. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. 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, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

If the U.S. federal government should experience another shutdown or if the FDA, National Institutes of Health ("NIH"), SEC or the United States Patent and Trademark Office ("USPTO") experiences significant decreases in funding or personnel, it could significantly impact the ability of the FDA to issue licenses needed for conduct of our clinical trials, the NIH to conduct research or provide grants, and the abilities of the FDA and the USPTO to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

There is substantial uncertainty as to whether and how the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. Additionally, the new administration could also issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates. Complying with any new legislation and regulatory requirements could be time-intensive and expensive.

Our business is dependent upon the success of our lead investigational product candidate, CAD-1005, which require additional clinical testing before we can seek regulatory approval and potentially launch commercial sales.

Our business and future success depends upon our ability to obtain regulatory approval of and then successfully commercialize our product candidates. Our main focus and the investment of a significant portion of our efforts and financial resources is expected to be in the development of CAD-1005, for which we are currently planning a pivotal Phase 3 clinical trial for the treatment of HIT with a primary endpoint of reduction in thrombotic events. Even if the FDA agrees with our planned registration pathway, there are many uncertainties known and unknown that may affect the outcome of the trial. These include adequate patient enrollment, adequate supply of our product candidate, potential changes in the regulatory landscape, the results of the trial being successful, and FDA acceptance of the data to support approval. We will also rely on third parties to conduct the appropriate clinical trials, and their failure to perform in accordance with applicable law would have a negative effect on our regulatory submission.

Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval, and commercialize our product candidates, which may never occur. We currently generate no revenues from our product candidates, and we may never be able to develop or commercialize a marketable drug.

Our business is dependent on the Old Dominion License Agreement, and the termination, non-renewal or failure to maintain that agreement could materially and adversely affect our business, financial condition and prospects.

We do not own the intellectual property rights to our lead product candidate, CAD-1005, and instead license them and rely on the Old Dominion License Agreement for the development, manufacture and commercialization of CAD-1005. As a result, our ability to advance our CAD-1005 clinical program, obtain regulatory approval, and commercialize CAD-1005, if approved, is dependent on our continued rights under such agreement. The Old Dominion License Agreement may be terminated by the Licensor upon the occurrence of certain events, including our failure to meet development or regulatory milestones, to use commercially reasonable efforts, to make required payments (including upfront, milestone or royalty payments), or to comply with other material obligations. In addition, the Licensor may have the right to terminate the agreement for insolvency-related events or, in some circumstances, for convenience. Any termination would result in the loss of our rights to the licensed intellectual property, which would likely force us to discontinue development and commercialization of the CAD-1005. The Old Dominion License Agreement also requires us to make significant payments to the Licensor, including upfront fees, development and regulatory milestone payments, and royalties on future sales. These obligations increase our operating expenses and may reduce our profitability, if achieved, and could require us to raise additional capital.

If we were to lose our rights under the Old Dominion License Agreement, or if the agreement were otherwise terminated or materially modified in a manner adverse to us, we may be unable to continue development or commercialization of CAD-1005 on commercially reasonable terms, if at all. In such event, our business, financial condition, results of operations and prospects would be materially and adversely affected.

All of our current data for our product candidates are the results of clinical trials conducted by third parties and do not necessarily provide sufficient evidence that our products are viable as potential pharmaceutical products or that we can successfully conduct clinical trials.

We possess toxicology, pharmacokinetic, and other preclinical data and clinical data on our product candidates from studies and trials conducted by third parties, some of which were several years ago. There is no guarantee that Phase 1 or Phase 2 results, as applicable, from the clinical trials for our product candidates that were conducted by third-parties can or will be replicated by our planned clinical trials for such product candidates. Further, as the clinical trials were conducted by third parties and were completed prior to our ownership of the technology and data, we cannot be assured that such trials were conducted in compliance with applicable statutes, rules, regulations, and guidelines applicable to such trials.

Previous clinical trials may have had different trial designs, doses, parameters and endpoints than the planned clinical trials. With respect to our planned Phase 3 clinical trial that is expected to serve as a basis for approval of CAD-1005, we intend to design the Phase 3 protocol based on input from our EOP2 meeting with the FDA. Our Phase 3 trial protocol will still be subject to any further comments we may receive from the FDA upon their review of the protocol. However, it is possible that the results seen in the Veralox Phase 2 trial may not be demonstrated sufficiently in our clinical testing.

As all of the clinical trials for our product candidates to date were conducted by third parties, we cannot be assured that such clinical trials were in compliance with applicable laws, rules and regulations.

Since we did not acquire CAD-1005, tecarfarin and frunexian until December 2025, April 2022 and September 2025, respectively, we do not have first-hand knowledge of how the Phase 1 and Phase 2 clinical trials for such product candidates, as applicable, were completed to date. As such, we cannot be assured that such clinical trials were conducted in full compliance with applicable laws, rules and regulations. Additionally, we cannot be assured historical data for such trials are accurate and sufficient for acceptance by the FDA. While we are not aware of any issues in relation to such trials and the performance thereof, we cannot be assured that we may learn in the future that there was a failure to abide by such laws, rules and regulations, which could potentially expose us to issues with regards to our planned clinical trials or otherwise create risks unknown to us with regards to our technology.

Our efforts to develop our product candidate may not generate data sufficient to support an application for regulatory approval.

Despite the global burden of cardiovascular disease, investment in cardiovascular drug development has stagnated over the past two decades, with relative underinvestment compared with other therapeutic areas. The reasons for this trend are multifactorial, but of primary concern is the high cost of conducting cardiovascular outcome trials in the current regulatory environment that demands a direct assessment of risks and benefits, using clinically meaningful cardiovascular endpoints. In addition, clinical trials are difficult to design and implement, can take many years to complete and are uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. There is no guarantee that our clinical trials will reach statistical significance on their endpoints, or that any product candidate including CAD-1005 will demonstrate superiority to current standard of care or any other therapy. A failure of one or more of clinical trials can occur at any stage of testing. Our product candidate may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications. In addition, we may experience other numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to continue development. Development stage risks include the following:

- the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the actual design or implementation of our clinical trial and refuse to let them proceed;

- we may not be able to provide acceptable evidence of the safety and efficacy of our product candidates or an acceptable benefit/risk profile for our product candidate especially in light of the fact that Veralox's Phase 2 trial for CAD-1005 for treatment of patients with HIT did not meet its primary endpoint;

- we may not be able to successfully manufacture drug supplies for our clinical trial;

- the results of our planned clinical trial may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, the EMA, or other comparable foreign regulatory authorities to demonstrate effectiveness;

- we may not be able to determine the optimal dosing of our product candidates; and

- patients in our clinical trial may suffer adverse effects that are deemed related to our product candidates, leading us or regulatory authorities to stop clinical trial temporarily or permanently.

If unacceptable safety concerns or other adverse events arise in the development of a product candidate, our clinical trials could be suspended or terminated or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of such product candidate for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Inadequate training in recognizing or managing the potential side effects of a product candidate could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

Even if we successfully complete our clinical trials, we may not receive regulatory approval for our product candidates, and we may not be able to commercialize our product candidates and our ability to generate revenue will be limited.

The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA and, in non-U.S. markets, until we receive the requisite approval from comparable regulatory agencies in such countries. Of the large number of drugs in development, only a small number are submitted for approval to the FDA through an NDA and even fewer are eventually approved for commercialization. We may not succeed at gaining regulatory approval, which would materially harm our business.

Receipt of necessary regulatory approval is subject to a number of risks, including the following:

- the data collected from pre-clinical and clinical trials may not be accurate or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the relevant laws, approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We cannot guarantee that regulators will agree with our assessment of the results of our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidates. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional clinical trials, or pre-clinical or other trials. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Failure to obtain regulatory marketing approval for our product candidates in any indication will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory review for a submitted product application may cause delays in approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek or gain approval in a different jurisdiction. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our current product candidates or any future product candidates will be harmed.

Orphan drug designation does not translate to approval and, even if we obtain FDA approval, we may not enjoy marketing exclusivity or other expected benefits.

CAD-1005 has ODD from the FDA for prophylaxis of thrombosis in patients with heparin-induced thrombocytopenia (HIT) as well as FDA Fast Track designation for the treatment and prevention of HIT and orphan designation from the EMA for the treatment of platelet-activating factor 4 disorders. Tecarfarin has ODD from the FDA for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with ESKD and AFib, as well as for the prevention of thrombosis and thromboembolism in patients with an implanted mechanical circulatory support device, which includes LVADs, a mechanical heart pump. However, these orphan designations do not guarantee that the FDA or the EMA will approve the NDAs (or equivalent in the European Union) for such product candidates. Even if we obtain FDA or EMA approval, we may not be able to obtain or maintain orphan drug exclusivity for such product candidates. We may not be the first to obtain marketing approval of CAD-1005 and/or tecarfarin for their respective orphan-designated indications due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition, or the competitive product is otherwise outside the scope of exclusivity. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same product candidate for indications other than those in which orphan designation have been granted.

Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidate.

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA Fast Track designation. However, a Fast Track designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while CAS-1005 has received Fast Track designation for the treatment and prevention of HIT and tecarfarin for the prevention of systemic thromboembolism of cardiac origin in patients with ESKD and AFib an, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures and does not assure ultimate approval by the FDA.

Even if we obtain regulatory approval, we will still face ongoing regulatory requirements and our product candidates may face future development and regulatory difficulties.

Even if we receive regulatory approval of our current product candidates or any future product candidates, we will be subject to ongoing regulatory obligations, such as post market surveillance and cGMP requirements, and continued regulatory review, which may result in significant additional expense. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with product candidates. In addition, third parties on whom we rely must comply with regulatory requirements, and any non-compliance on their part may negatively impact our business, assuming we obtain regulatory authorization at all.

Any regulatory approvals that we receive for product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy ("REMS") program in order to approve product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA could also require a boxed warning, sometimes referred to as a Black Box Warning on the product label to identify a particular safety risk, which could affect commercial efforts to promote and sell the product. In addition, if the FDA or a comparable foreign regulatory authority approves product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and current GCP for any clinical trials that we conduct post-approval. We are also subject to certain user fees imposed by the regulatory agencies. Later discovery of previously unknown problems with product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- import alerts or automatic detentions;
- restrictions on the marketing or manufacturing of product candidates, withdrawal of the product from the market, or product recalls;
- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- labeling changes;
- product seizure or detention, or refusal to permit the import or export of product candidates;
- injunctions or the imposition of civil or criminal penalties; and
- inability to obtain government contracts.

The policies of the FDA and other regulatory authorities may change, such as those required by the 21st Century Cures Act, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current product candidates or any future product candidates. In addition, it is unclear what changes, if any, the new presidential administration may bring. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities. As we advance CAD-1005 or any future product candidates we expect that our expenses will increase. The number and design of the clinical trials that will be required varies depending upon product candidate, the condition being evaluated, current medical strategies and the trial results themselves. Therefore, it is difficult to accurately estimate the cost of the clinical trials. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of each of our product candidates, will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or prevented by several factors, including:

- unforeseen safety issues;
- failure to determine appropriate dosing;
- greater than anticipated cost of our clinical trials;
- failure to demonstrate effectiveness during clinical trials;
- slower than expected rates of subject recruitment or difficulty obtaining investigators, particularly during COVID-19;
- subject drop-out or discontinuation;
- import delays of clinical trial materials;
- inability to monitor subjects adequately during or after treatment;
- third party contractors, including, without limitation, CROs and manufacturers, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- reaching agreements with prospective CROs, and trial sites, both of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- insufficient or inadequate supply or quality of product candidates or other necessary materials to conduct our trials;

- potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies;

- problems engaging Institutional Review Boards ("IRBs"), to oversee trials or in obtaining and maintaining IRB approval of studies;

- imposition of clinical hold or suspension of our clinical trials by regulatory authorities; and

- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend or terminate our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot predict with any certainty when, if ever, future clinical trials will commence or be completed.

Delays or difficulty in the enrollment of patients in any or all of our clinical trials could increase our development costs and delay completion of our clinical trials and associated regulatory submissions.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. The Phase 2 trial of CAD-1005 in patients with HIT enrolled only 24 patients out of a planned 60 and was terminated early. It is unclear whether the trial would have been fully enrolled if it were not terminated early. A pandemic or epidemic would likely make this even more challenging. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase, and the completion of our trials may be delayed or our trials could become too expensive to complete.

Even if approved, our product candidates may not have labeling that allows us to successfully commercialize it.

The commercial success of our product candidates will depend in significant measure upon our ability to obtain approval from the FDA and other regulatory authorities of labeling describing a product candidate's expected features or benefits. Regulatory authorities may approve a product candidate for fewer or more limited indications than we request or may approve a product candidate with labeling that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Failure to achieve approval from the FDA or other regulatory authorities of product labeling containing certain types of information on features or benefits of our products will prevent or substantially limit our advertising and promotion of such features in order to differentiate our product candidates or any future product candidates from those products already existing in the market. This may make it difficult or impossible to achieve commercial success.

If any of our product candidates is approved, our success depends on our commercialization efforts, which may not be achieved. If we are unable to commercialize our product candidate, or experience significant delays in doing so, our business could be materially harmed.

We will invest a significant portion of our efforts and financial resources into the development and commercialization of our product candidates. Product revenues from our product candidates which will not be realized until after regulatory approval, if ever, will depend on the successful development, regulatory approval and eventual commercialization of these product candidates. The success of our product candidate will depend on several factors, including the following:

- receipt of marketing approvals for our product candidate from the FDA and similar regulatory authorities outside the United States;

- obtaining product indications, other labeling information and product attributes that are acceptable and attractive to the medical community, third-party payors and patients;

- our ability to manufacture product commercially at acceptable costs;

- establishing and maintaining commercial manufacturing arrangements with third parties;

- successfully commercializing our product candidate, if approved, whether alone or in collaboration with others;

- a continued acceptable safety profile of the product candidate following approval; and

- obtaining, maintaining, enforcing and defending intellectual property rights and claims and available product exclusivities.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidate, which would materially harm our business. In addition, even if we obtain regulatory approvals for any of our product candidates, the timing or scope of any approval may prohibit or reduce our ability to commercialize such product candidate successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Also, any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render such product candidate not commercially viable. For example, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or, outside the U.S., they may not accept or approve the price we intend to charge for a product candidate. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals, such as risk management plans and Risk Evaluation and Mitigation Strategies ("REMS"), to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of such product candidate. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates for which we may obtain marketing approval from the FDA or other regulatory authorities, will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost-effective and safe. The degree of market acceptance of any drug depends on a number of factors, such as:

- effectively competing with other therapies;
- the prevalence and severity of any side effects;
- success of patients in well-controlled clinical trials compared to real-world success of patients post FDA approval;
- our ability to educate and increase physician awareness of the benefits of our products relative to competing drugs;
- the willingness of physicians and healthcare organizations to change their current treatment practices, especially with respect to warfarin, a drug that is dominant in the market and with which physicians and healthcare organizations have 60 years of familiarity;
- the willingness of hospitals and hospital systems to include our product candidates as treatment options;
- efficacy and potential advantages compared to alternative treatments;
- the price we charge for our product candidates;
- interpretations of the results of our clinical trials;
- the status of our products on the formularies of third-party payers;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the target patient population to pay for our products, including co-pays under their health coverage plans;
- the strength of marketing and distribution support; and
- the availability of third-party coverage and adequate reimbursement.

The failure to attain market acceptance among the medical community, patients and third-party payors may have an adverse impact on our operations and profitability.

We have never submitted an NDA to the FDA or comparable applications to other regulatory authorities and we may not be successful in achieving approval of our product candidates.

We have never submitted an NDA to the FDA or comparable applications to other regulatory authorities and expect to rely on consultants and third-party contract research organizations ("CROs"), with expertise in this area to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Regulatory authorities in other jurisdictions impose similar requirements. If we are unable to successfully complete the approval process with the FDA or comparable applications of other regulatory authorities, our business will not be successful.

After approval of a product candidate, it will remain subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional risk and expense.

Drug products remain subject to the jurisdiction of the FDA and non-U.S. regulatory authorities after they have been approved. Even if we obtain regulatory approval of our product candidates, the FDA and other regulatory authorities may impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval trials, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our product candidates, if approved, as well as our marketed products, are subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, sampling, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA and continued compliance with cGMP and current GCP requirements for any clinical trials that we conduct post-approval.

After approval, our products could be subject to labeling and other restrictions and we may be required to withdraw from the market or be subject to penalties if we fail to comply with regulatory requirements.

The product labeling, advertising and promotion of our products and our product candidates, if approved, are subject to regulatory requirements and continuing regulatory review. Government authorities, including the FDA and the Office of the Inspector General of the Department of Health and Human Services ("OIG"), strictly regulate the promotional claims and activities that may be made about prescription products. A drug product may not be promoted for uses that are inconsistent with the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved labeling. However, if we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The federal government has extracted very large settlements and levied very large civil and criminal fines against companies for alleged improper promotion, has enjoined companies from engaging in off-label promotion, and made companies agree to onerous multi-year corporate integrity agreements. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

We are subject, directly or indirectly, to federal and state obligations and regulations applicable to our marketing practices. If we are unable to comply, or have not complied, with such laws, we could face substantial penalties.

Our marketing and sales operations are subject to various federal and state fraud and abuse laws, including, without limitation, the federal and state anti-kickback statutes and false claims laws. With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. We also are subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Federal Healthcare Program Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, most of our interactions with customers, including our proposed sales, marketing, and scientific/educational grant programs. We are also subject to complex laws and regulation regarding reporting and payment obligations as a result of our participation in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, and other government drug programs. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries. If investigated, we could be forced to incur substantial expense responding to the investigation and defending our actions. If unsuccessful in our defense, we could be found to be in violation and subject to substantial fines and penalties,

We currently do not have any long-term supply agreements or commercialization partnerships with third-party manufacturers for the production and distribution of our product candidates and intend to rely upon third parties to produce and distribute them.

We do not have a manufacturing infrastructure and do not intend to develop one. We do not have any long-term supply agreements with any manufacturers of CAD-1005 or frunexian. With respect to the drug candidates we acquired from eXIthera and Veralox, we intend to execute contracts with third-party CDMOs for the supply of drug substance and drug product in accordance with cGMP, but do not yet have such contracts in place.

We have recently completed the manufacturing of tecarfarin drug product in accordance with cGMP. We have executed contracts with third-party pharmaceutical CDMOs for the development of validated processes and the supply of active pharmaceutical ingredients and clinical trial material for tecarfarin in accordance with cGMP requirements. Such CDMOs have the capability to scale-up for commercial production of tecarfarin. However, we have not entered into any long-term supply agreements or commercialization partnerships with these vendors. Certain material suppliers and manufacturing sites for our product candidates are in locations outside of the U.S.

While the materials and substances used in our product candidates are manufactured by more than one supplier, the number of suppliers is limited. In the event it is necessary or advisable to acquire drug materials, substances, and products from alternative suppliers, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to transfer or redesign our manufacturing processes to work with another company. If approved by the FDA, we anticipate that we will be able to enter into agreements with third parties to manufacture and distribute our product candidates on commercially reasonable terms.

We intend to rely on third-party CDMOs to produce our product candidates for our clinical studies who are expected to purchase materials from third-party vendors and transport the materials necessary to produce them, such as the required reagents and containers. This reliance on CDMOs and third-party vendors that we do not own or operate exposes us to various risks, including:

- *Supply Disruptions*: Our CDMOs may experience difficulties in manufacturing, including shortages of raw materials, equipment failures, capacity constraints, or regulatory enforcement actions, any of which could result in delays or interruptions in supply.

- *Regulatory Compliance Risks*: Our CDMOs must comply with cGMP and other regulatory requirements enforced by the FDA and other regulatory authorities. Any failure to meet these standards could result in delays, batch failures, regulatory sanctions, or product recalls.

- *Loss of Key Manufacturing Partners*: If a CDMO terminates its relationship with us, fails to meet our supply needs, or becomes unable to fulfill its obligations due to financial difficulties, insolvency, or acquisition by a third party, we may not be able to obtain alternative manufacturing sources in a timely or cost-effective manner.

- *Limited Control Over Operations*: Because we do not own or operate these third-party facilities, we have limited control over their manufacturing processes, quality systems, and compliance efforts, which increases our exposure to risks outside of our direct control.

- *Capacity and Scalability Risks*: If our CDMO partners are unable to scale production to meet future clinical or commercial demands, we may experience supply shortages that could delay our development timelines or commercial launch.

If a third-party manufacturer was to experience any prolonged disruption for our manufacturing, or face enforcement scrutiny by regulatory authorities, we could be forced to seek additional third-party manufacturing contracts, thereby increasing our development costs and negatively impacting our timelines and any commercialization costs. If we change manufacturers at any point during the development process or after approval of a product candidate, we will be required to demonstrate comparability between the product manufactured by the old manufacturer and the product manufactured by the new manufacturer. If we are unable to do so, we may need to conduct additional studies or clinical trials with product manufactured by the new manufacturer, thereby delaying our NDA submission or approval.

If the manufacturer upon which we rely fails to comply with stringent regulations, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

Any problems or delays our contract manufacturers experience in preparing for commercial-scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Although we do not have day-to-day control over our contract manufacturers' compliance with these requirements, we are responsible for ensuring compliance with such requirements. Our failure, or the failure of our contract manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, revocation of licenses, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which would significantly and adversely affect supplies of our product candidates and our business. If a contract manufacturer's facilities do not pass a pre-approval inspection or do not have a cGMP compliance status acceptable to the FDA or a comparable foreign regulatory authority, our product candidate will not be approved.

In addition, application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. Moreover, in the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. In addition, our marketed products will have to comply with the Drug Supply Chain Security Act of 2013, which requires drug companies to enable electronic tracking of their products though the U.S. supply chain.

Any deviations from regulatory requirements may also require remedial measures that may be costly and/or time-consuming for us or a third-party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to product approvals, and commercialization. It may also require that we conduct additional trials.

We face substantial competition, which may result in others discovering, developing or commercializing competing products more successfully than we do, or, perhaps obtaining approval before our product and, potentially delaying our approval.

The development and commercialization of new drugs is highly competitive. We face competition with respect to developing our current product candidates, and we will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. If we succeed in developing our product candidates, we will face substantial competition. Our competitors include major multi-national pharmaceutical companies and biotechnology companies developing both generic and proprietary anticoagulant therapies, which have substantially more resources than we do and substantially more experience developing and marketing pharmaceuticals. Many of our competitors have drugs that have already been commercialized and therefore benefit from being first to market their products. Many of these companies are well-established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of competing drugs and potentially competing drugs. Our competitors are or may be attempting to develop therapeutics for our target indications. Although we are currently developing the only selective 12-LOX inhibitor at the clinical-stage; other companies may pursue alternative pathways or more effective 12-LOX candidates that could render our platform of assets obsolete.

Factors affecting competition in these markets include the financial, research and development, testing, and marketing strengths of individual competitors, trends in industry consolidation, consumers' product options, product quality, price and technology, reputation, customer service capabilities and access to market partners and customers. If approved, CAD-1005 would compete with existing non-heparin anticoagulants such as direct thrombin antagonists (bivalirudin and argatroban), fondaparinux (a direct Xa antagonist), and DOACS. Eliquis is manufactured and distributed by Bristol Myers Squibb, Pradaxa is manufactured and distributed by Boehringer Ingelheim, Xarelto is manufactured and distributed by Janssen Pharmaceuticals, and Savaysa is manufactured and distributed by Daiichi Sankyo, each of which is a competitor product of tecarfarin.

We may not be able to successfully compete with these existing products, including their current or future generic equivalents. Each of these organizations has a long operating history, extensive resources, strong brand recognition and large customer bases. As a result, we expect they will be able to devote greater resources than we can to the manufacture, promotion and sale of their products; receive greater resources and support than we will from market partners and independent distributors; initiate and withstand substantial price competition; and take advantage more readily than we could of acquisition and other strategic market opportunities. In addition, these or other organizations could succeed in developing new products that perform better or more cost-effectively than our products and product candidates in their respective markets. Moreover, changes in health trends, diet or other factors could substantially reduce the commercial attractiveness or viability of the markets for anti-anginal, anticoagulant, anti-arrhythmic and anti-platelet products.

The high level of competition in these markets could result in pricing pressure, reduced margins, the inability of our product candidates to achieve market acceptance and other impediments to commercial success. As a result, there can be no assurance that we will be able to complete the development of competitive products and commercialize them on a competitive basis.

Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If serious adverse effects are identified with respect to any of our product candidates or any of our approved products, we may need to modify or abandon our development of that product candidate, discontinue sale of an approved product, or change our labeling to reflect new safety risks.

It is impossible to guarantee when, or if, any of our product candidates will prove safe enough to receive regulatory approval. It is impossible to guarantee that safety issues that may arise during development will not significantly decrease the commercial potential of our product candidates. In addition, there can be no assurance that our clinical trials will identify all relevant safety issues. Known or previously unidentified adverse effects can adversely affect regulatory approvals or marketing of approved products. In such an event, we might need to abandon marketing efforts or development of that product or product candidate or enter into a partnership to continue development.

If a regulatory agency discovers adverse events of unanticipated severity or frequency it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. Among other legal and administrative actions, a regulatory agency may:

- mandate modifications to product labelling or promotional materials or require us to provide corrective information to healthcare practitioners;
- withdraw any regulatory approvals;
- place any ongoing clinical trials on clinical hold;
- refuse to approve pending applications or supplements to approved applications filed by us, our partners or our potential future partners;
- impose restrictions on operations, including costly new manufacturing, licensing or packaging requirements; or
- seize or detain products or require a product recall.

In addition, the occurrence of any of the foregoing, even if promptly remedied, could (1) negatively impact the perception of us or the relevant product among the medical community, patients or third-party payors and (2) result in product liability litigation that could result in the company paying substantial amounts of money in settlements or verdicts.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and to commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, under the Medicare Modernization Act ("MMA"), Medicare Part D provides coverage to the elderly and disabled for outpatient prescription drugs by approving and subsidizing prescription drug plans offered by private insurers. The MMA also authorizes Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. The Part D plans use their formulary leverage to negotiate rebates and other price concessions from drug manufacturers. Also under the MMA, Medicare Part B provides coverage to the elderly and disabled for physician-administered drugs on the basis of the drug's average sales price, a price that is calculated according to regulatory requirements and that the manufacturer reports to Medicare quarterly.

Both Congress and CMS, the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. For example, under the ACA, drug manufacturers are required to provide a 50% discount on prescriptions for branded drugs filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." The Bipartisan Budget Act of 2018 increased the manufacturer's subsidy under the program from 50% to 70% of the negotiated price, beginning in 2019. There have been legislative proposals to repeal the "non-interference" provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors.

In addition, healthcare reform legislation enacted in recent years has materially altered the post-approval commercial landscape for pharmaceutical products. The Inflation Reduction Act of 2022 ("IRA") grants the U.S. government authority to negotiate prices for certain drugs and biologics reimbursed under Medicare, imposes inflation-based rebate obligations, and modifies reimbursement structures under Medicare Part B and Part D. While these provisions generally apply a number of years after a product's initial approval, they may reduce long-term pricing flexibility, decrease the commercial value of approved products, influence development and launch strategies, and reduce the anticipated return on investment for one or more of our product candidates.

The ACA itself significantly reshaped the U.S. healthcare and pharmaceutical landscape. Among other things, it expanded access to health insurance coverage, increased utilization of healthcare services and prescription drugs, and imposed new transparency, pricing, and rebate obligations on pharmaceutical manufacturers. The ACA also included the Biologics Price Competition and Innovation Act, which established an abbreviated approval pathway for biosimilar biological products and a statutory exclusivity framework for reference biologics. This framework has materially affected competition dynamics, pricing pressure, and lifecycle management strategies for biologic products and may reduce the duration or magnitude of market exclusivity for any biologic product candidates we may develop or commercialize. The ACA also expanded mandatory manufacturer discounts and rebates under government healthcare programs, including Medicaid and the Medicare Part D coverage gap discount program, and increased reporting and compliance obligations under federal healthcare laws, such as the Physician Payments Sunshine Act. These provisions have increased the complexity and cost of compliance for pharmaceutical manufacturers and reduced net revenues derived from government-reimbursed sales. If any of our products are approved and become eligible for coverage under government healthcare programs, these requirements could materially reduce our realized revenue and profitability.

In addition, the ACA strengthened and expanded the federal 340B drug pricing program, which requires manufacturers to provide significant discounts to certain covered entities. Expansion of the 340B program, as well as continued regulatory and judicial developments affecting its scope and enforcement, may further reduce net pricing and create additional uncertainty regarding distribution channels, contracting arrangements, and compliance exposure.

Beyond the ACA, subsequent legislation has expanded FDA's authority over the development and approval of drug and biologic products. The Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA") created, among other programs, the breakthrough therapy designation and expanded FDA's expedited development and review tools for products intended to treat serious or life-threatening diseases. While these programs may offer the potential for accelerated development or approval, they also involve greater regulatory uncertainty, enhanced FDA interaction, and increased post-approval obligations, and FDA retains broad discretion in determining eligibility and requirements. The 21st Century Cures Act of 2016 further modified FDA approval standards by permitting the Agency, in appropriate circumstances, to consider real-world evidence, biomarkers, surrogate endpoints, and novel clinical trial designs in support of marketing approval or label expansions. Although these provisions were intended to increase flexibility and efficiency in drug development, they create uncertainty regarding how FDA will apply these evolving evidentiary standards to particular products or development programs, including ours.

More recently, the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), enacted as part of the Consolidated Appropriations Act, 2023, significantly expanded FDA's authority over products approved under accelerated or other expedited approval pathways. FDORA enhances FDA's ability to require that confirmatory clinical trials be underway prior to approval, mandates additional post-approval reporting and oversight, and provides FDA with greater authority to expedite withdrawal of approval if required post-approval studies fail to verify clinical benefit, are not conducted with due diligence, or do not meet regulatory expectations. As a result, even if one or more of our product candidates receives accelerated approval, we may be required to conduct additional costly and time-consuming studies, and FDA may ultimately withdraw approval.

Recent legislation has also imposed additional requirements on clinical development programs, including obligations to submit and implement diversity action plans for certain late-stage clinical trials. Compliance with these requirements may increase development costs, extend clinical timelines, complicate patient enrollment, and adversely affect our ability to complete studies, particularly for rare diseases or highly specialized patient populations.

Congress continues to consider additional legislative and regulatory reforms that could further amend the ACA, modify FDA approval pathways, expand government pricing controls, increase compliance and reporting requirements, or otherwise affect exclusivity, reimbursement, and commercialization. We cannot predict whether, when, or in what form such changes may be adopted, nor how FDA and other agencies may interpret or implement them. If we are unable to successfully adapt our development and commercialization strategies to this evolving legislative and regulatory environment, or if future changes under the ACA or other healthcare laws impose more stringent requirements, delay or prevent approvals, increase development or compliance costs, restrict pricing or reimbursement, or result in withdrawal of approval, our business, financial condition, results of operations, and prospects could be materially adversely affected.

If we market any of our products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA and other government authorities enforce laws and regulations that require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off-label" use under the practice of medicine, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct may be subject to significant liability. Similarly, industry codes in the European Union and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Federal Healthcare Program Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Federal Healthcare Program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the U.S. Federal Healthcare Program Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Federal Healthcare Program Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws, including the U.S. False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

Over the past few years, pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; using a charity as an illegal conduit to cover the copays of Medicare patients; and submitting inflated best price information to the Medicaid Drug Rebate Program to reduce liability for Medicaid rebates.

Other restrictions under applicable U.S. federal and state healthcare laws and regulations may include the following:

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH) Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report payments and other transfers of value to physicians and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family, which includes annual data collection and reporting obligations; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures to federal and state agencies. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Tracking and reporting may be burdensome and require a significant expenditure to comply with applicable requirements.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;

- private health maintenance organizations and health insurers; and

- other healthcare payers.

Patients generally expect that products such as ours are covered and reimbursed by third-party payors for all or part of the costs and fees associated with their use. If such products are not covered and reimbursed then patients may be responsible for the entire cost of the product, which can be substantial. Therefore, health care providers generally do not prescribe products that are not covered and reimbursed by third-party payors in order to avoid subjecting their patients to such financial liability. The existence of adequate coverage and reimbursement for the products by government and private insurance plans is central to the acceptance of our current product candidates and any future products we provide.

During the past several years, third-party payors have undertaken cost-containment initiatives including different payment methods, monitoring health care expenditures, and anti-fraud initiatives. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for our product candidates or any of our other products or may make no payment at all. Furthermore, the health care industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control health care costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that our services will be reimbursed at a level that is sufficient to meet our costs.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our current product candidates or any future product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our current product candidates or any future product candidates.

We intend to seek approval to market our current product candidates and future product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our current product candidates or any future product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for product candidates and may be affected by existing and future health care reform measures.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in the ACA, as amended by the Health Care and Education Affordability Reconciliation Act, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs, including product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

The impact of recent healthcare reform legislation, other changes in the healthcare industry, and in healthcare spending is currently unknown and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry, and new laws, regulations, judicial decisions, or new interpretations of existing laws, regulations, or decisions related to healthcare availability, the method of delivery, or payment for healthcare tests, products, and services could negatively impact our business, operations, and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including proposals aimed at lowering prescription drug prices and increasing competition for prescription drugs, as well as additional regulation on pharmaceutical transparency and reporting requirements, any of which could negatively impact our future profitability and increase our compliance burden. We cannot predict the initiatives that may be adopted in the future, including future challenges or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations, and other payors to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our therapeutic products, if we or our licensors obtain regulatory approval;
- the ability to set a price that we believe is fair for a therapeutic product;
- the ability to obtain coverage and reimbursement approval for a therapeutic product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, particularly in light of the new presidential administration in the United States, and any proposed changes to healthcare laws that could potentially affect our clinical development or regulatory strategy. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current product candidates, or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We will rely on third parties and consultants to conduct all of our clinical trials. If these third parties or consultants do not successfully carry out their contractual duties, comply with regulatory requirements, or meet expected deadlines, we may be unable to obtain regulatory approval for any future product candidates.

We will rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to conduct clinical trials on our product candidates. The third parties with whom we may contract for execution of any of our future clinical trials may play a significant role in the conduct of these trials and the subsequent collection and analysis of data. These third parties would not be our employees, and except for contractual duties and obligations, we would have limited ability to control the amount or timing of resources that they devote to any of our future programs. Although we may rely on these third parties to conduct our clinical trials, we would remain responsible for ensuring that each of our preclinical trials and clinical trials is conducted in accordance with applicable legal requirements, the investigational plan and the protocol. Moreover, whether we conduct trials ourselves or hire third parties to do so, the FDA and other similar regulatory authorities require us to comply with GCP when we conduct, monitor, record and report 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 clinical trials.

In addition, the execution of clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. If the third parties or consultants conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCP, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for and will not be able to, or may be delayed in our efforts to, successfully commercialize any future product candidates being tested in such trials.

We currently do not have any distribution, marketing, support and sales capabilities and plan to rely on third-party distribution partners for the distribution, marketing, support and sales of our products which could delay or limit our ability to generate revenue.

We plan to utilize third-party service providers for the distribution and marketing and sales of our product candidates, if approved. Upon launch, we intend to promote utilizing third party collaborations in addition to building our own commercial infrastructure in anticipation of the approval of our product candidates. Reliance on third-party service providers may prevent our direct control of key aspects of those critical functions including regulatory compliance, import and export operations, supply chain security, warehousing and inventory management, distribution, contract administration, invoicing, sales deductions administration, accounts receivable management and call center management. Any future distribution partners may hold significant control over important aspects of the commercialization of our products, including market identification, regulatory compliance, marketing methods, pricing, composition of sales force and promotional activities.

We may not be able to control the amount and timing of resources that any future third-party distribution partners may devote to our products, or prevent any third-party from pursuing the development of alternative technologies or products that compete with our products, except to the extent our contractual arrangements protect us against such activities. Also, we may not be able to prevent any other third-party from withdrawing its support of our products.

If third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, encounter natural or other disasters at their facilities or otherwise fail to perform their services to us in a satisfactory or predicted manner, or at all, our ability to deliver product to meet commercial demand could be significantly impaired. In addition, we may use third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions, and any indemnity we may receive from such third-party service providers could be limited by such provider's ability to pay and otherwise might not be sufficient to cover all losses we may experience.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: (i) comply with the laws of the FDA and other similar foreign regulatory bodies; (ii) provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; (iii) comply with manufacturing standards we have established; (iv) comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (v) report financial information or data accurately or to disclose unauthorized activities to us. Any such misconduct or noncompliance could negatively affect the FDA's review of our regulatory submission, including delaying approval or disallowance of certain information to support the submission, and/or delay a federal or state healthcare programs or a commercial insurer's determination regarding the availability of future reimbursement for product candidates. If we obtain FDA approval of any product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We intend to establish a sales force to market our product candidates. If we are not successful in doing so, our ability to generate sales and profits will be limited.

Although certain of our employees have commercialization experience, as a company we do not have an internal sales force and we currently have only limited commercial capabilities. We intend to establish an internal specialty sales force for the promotion and sale of our product candidates, if approved. Establishing a pharmaceutical sales force is a difficult undertaking. Experienced and competent sales representatives and sales managers must be recruited, hired, trained, assigned appropriate territories, managed and compensated in such a way that they can achieve success in selling products to a sophisticated audience of healthcare professionals who frequently have little or no time to spend with sales personnel. In addition, our prospective sales force must compete against the sales forces of some of the largest and most successful pharmaceutical companies in the world, who will be promoting competing products. If we fail to hire and field a high-quality sales force, we may be unable to generate expected revenues and profits.

In addition, there are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates. For example, if we recruit any sales representatives or establish marketing capabilities prior to commercial launch and the commercial launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

In addition to our own internal sales force, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. To the extent we commercialize our product candidates by entering into agreements with third-party collaborators, we may have limited or no control over the sales, marketing and distribution activities of these third parties, in which case our future revenues would depend heavily on the success of the efforts of these third parties. If we are not successful in commercializing our current product candidates or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we could incur significant additional losses.

We plan to rely on collaborations and license arrangements with third parties to commercialize, market and promote our marketed products which may limit our ability to generate revenue and adversely affect our profitability.

We plan to rely on collaboration and other agreements with third parties with respect to our product candidates and future marketed products. Our current or any future collaborations or license arrangements may not be successful. With respect to the product candidates we have out-licensed, including our rights to tecarfarin and frunexian in China, we depend upon collaborations with third parties to develop these product candidates in the licensed territories and we will depend substantially upon third parties to commercialize these product candidates. If we are unable to maintain current collaborations or enter into additional collaborations with established pharmaceutical or pharmaceutical service companies to provide the services we need, we may not be able to successfully commercialize our products.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Although our focus as this time is primarily on the U.S. market, our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;

- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import, export and foreign licensing requirements;
- different packaging and labeling requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- differing and/or reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

Global health crises may adversely affect our planned operations.

Our business and the businesses of our third-party pharmaceutical manufacturers could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis. If there is a global health crisis, we could experience delays in patient enrollment and significant disruptions to our clinical development timelines. If we experience delays in patient enrollment or patient dropouts and we deem it necessary or advisable to improve patient recruitment by, among other things, opening additional clinical sites, we could incur increased clinical program expenses. Any such disruptions or delays would, and any such increased clinical program expenses could, adversely affect our business, financial condition, results of operations and growth prospects. We may experience disruptions as a result of a global health crisis, including:

- unwillingness of potential study participants to enroll in our planned clinical trials and/or visit healthcare facilities;
- postponement of enrollment in our planned clinical trials;
- postponement of the initiation of our planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trial;
- interruption of key clinical trial activities, such as clinical site visits by study participants and clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our planned clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials;
- interruption in global shipping that may affect the manufacture and transport of clinical trial materials, such as investigational drug product used in our clinical trial;

- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our planned clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and

- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics during times of pandemics.

Our business and the business of the suppliers of our clinical product candidate may be materially and adversely affected by a global health crisis, including a resurgence of COVID-19, including the delay or complete or partial closure of clinical trial sites or one or more manufacturing facilities which could impact our supply of our clinical product candidate. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships.

In addition, a global health crisis could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office, or due to quarantines. A global health crisis could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

The extent to which a resurgence of COVID-19 or another global health crisis may impact our business and clinical trials is highly uncertain and cannot be predicted with confidence. While the original spread of COVID-19 has been mitigated, the continued emergence of novel virus strains means there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, or that the global economy will recover, either of which could seriously harm our business.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.

The Animal Welfare Act ("AWA"), is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

General Company-Related Risks

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our current product candidates or any future product candidates, conduct our clinical trials and commercialize our product candidates or any future products we develop.

Our management team has expertise in many different aspects of fundraising, drug development and commercialization. We believe that our future success is highly dependent upon the contributions of our senior management, particularly Quang X. Pham, our Chief Executive Officer. We do not have an insurance policy on the life of our Chief Executive Officer and we do not have "key person" life insurance policies for any of our other officers or advisors. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates or any other future products we develop, which could adversely affect our operating results.

We will need to hire additional personnel, including experienced marketing and sales representatives, as we expand our clinical development and commercial activities. We could experience difficulties attracting and retaining qualified employees in the future. For example, competition for qualified personnel in the pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information or that their former employers own their research output. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates could be limited.

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

We will need to continue to expand our managerial, operational, finance and other resources to manage our operations, commercialize our current product candidates or any other product candidates, if approved, and continue our development activities. Our management and personnel systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage any of our future clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our development and strategic objectives or disrupt our operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit the commercialization of any future products we develop.

We face an inherent risk of product liability as a result of the clinical testing of our current product candidates and any of our future product candidates. We will face further risk if we commercialize any of our product candidates. For example, we may be sued if any product we sell or any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial losses or be required to limit the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products we develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- significant costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- the inability to commercialize any products we develop; and
- a decline in our share price.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current product candidates or any future products that we develop. We currently carry product liability insurance covering our marketed products and our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidates, however, we may be unable to obtain this liability insurance on commercially reasonable terms.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusions, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our current or future product development programs. For example, the loss of clinical trial data from completed or any future ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our product candidates could be delayed.

We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information and will continue to do so once we commence clinical trials, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow.

Any failure to maintain the security of information relating to our patients, customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

In connection with the pre-clinical and clinical development, sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

Use of artificial intelligence in research, development, and commercial activities presents operational, regulatory, ethical, and reputational risks that could adversely affect our business.

We increasingly rely on artificial intelligence ("AI") and machine-learning systems across our research, development, clinical, manufacturing, and commercial operations. These tools support activities such as target identification, compound screening, biomarker discovery, clinical-trial design and recruitment, pharmacovigilance monitoring, supply-chain optimization, and commercial analytics. Because AI models—particularly those applied to biological and clinical datasets—can behave unpredictably or produce biased or inaccurate outputs, our reliance on such systems may expose us to operational and scientific risks. Any errors or limitations in AI-generated insights could delay discovery efforts, impair the design or execution of our clinical trials, misinform safety or efficacy assessments, or otherwise negatively impact the advancement of our pipeline candidates.

The regulatory environment applicable to AI remains highly uncertain and continues to evolve in the United States and globally. Regulators have begun scrutinizing AI applications in healthcare and life sciences, and we may face new obligations related to transparency, data provenance, model documentation, validation standards, or auditability. In particular, new or forthcoming requirements from U.S. federal agencies and international authorities could impose additional burdens on our R&D workflows or clinical-trial operations, limiting how we design studies, analyze endpoints, select patient populations, or interact with clinical investigators and regulatory bodies. As noted by recent legal and regulatory commentary, public companies must carefully assess and disclose material AI-related risks, and the SEC has emphasized that inaccurate or overstated claims about AI capabilities—commonly referred to as "AI-washing"—may give rise to enforcement actions and shareholder litigation. Any failure to provide accurate AI-related disclosures could subject us to reputational damage, regulatory proceedings, or securities claims.

Our use of AI may also introduce data-integrity and cybersecurity risks. AI systems used in drug development frequently involve sensitive clinical, genomic, or proprietary datasets, making them potential targets for data-poisoning attacks, model manipulation, or unauthorized access. Compromised AI tools could corrupt datasets, distort model outputs related to safety or efficacy, or expose confidential patient or trial information. Additionally, reliance on third-party AI vendors, cloud providers, or specialized platforms—some outside traditional pharmaceutical quality-system regulations—may increase our exposure to operational disruptions, confidentiality breaches, or compliance failures.

We also face competitive risks. AI-enabled research continues to transform discovery timelines, trial execution, and manufacturing processes within the biopharmaceutical industry. If competitors adopt more advanced AI systems, access higher-quality proprietary datasets, or integrate AI more efficiently into R&D or commercial processes, we may be placed at a competitive disadvantage. Conversely, over-reliance on emerging AI technologies that ultimately do not perform as expected could divert resources, impair strategic decision-making, or delay program progression.

As AI technologies and regulatory expectations evolve, we may incur significant additional costs to update systems, retrain personnel, validate models, modify documentation, or enhance governance and oversight. If we fail to appropriately manage these risks, our research productivity, clinical development timelines, regulatory interactions, commercial performance, financial condition, or reputation could be materially adversely affected.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our technology and industry experience to expand our offerings or other capabilities. Though certain company personnel have business development and corporate transaction experience, including with licensing, mergers and acquisitions, and strategic partnering, as a company we have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our Common Stock as consideration, which would dilute the ownership of our stockholders. If the price of our Common Stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Changes in general economic or business conditions, including tariff and customs regulations, may have a negative impact on our business.

Continuing concerns over U.S. health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence, could precipitate an economic slowdown and recession. Additionally, political changes in the U.S. and elsewhere in the world have created a level of uncertainty in the markets. If the economic climate does not improve or deteriorate, our business, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In an inflationary environment, such cost increases may outpace our expectations, causing us to use cash faster than forecasted. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks.

Changes in U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain trade partners. Tariffs, economic sanctions and other changes in U.S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U.S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer-driven) either in the United States or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U.S. economy or certain sectors thereof, the global economy, and our industry, and as a result, could have a material adverse effect on our business, financial condition and results of operations.

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems.

In addition, the global macroeconomic environment could be negatively affected by, among other things, pandemics or epidemics, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine, the war in the Middle East and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

We are actively monitoring the effects these disruptions and increasing inflation could have on our operations. These conditions make it extremely difficult for us to accurately forecast and plan future business activities.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient exclusivity and/or patent protection for our product candidates, or if the scope of the exclusivity or patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected.

Our success largely depends on our ability to obtain and maintain exclusivity for our proprietary product candidates through market and data exclusivity granted by regulatory agencies in the United States and other countries with respect to our proprietary product candidates as well as through patent protection. If we do not adequately protect our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business. The patent application and approval process are expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Generally, the patent position of pharmaceutical companies is highly uncertain. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Our future patent applications may not result in patents being issued which protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened compared to expectations and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease the use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our Common Stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Furthermore, while we have engaged intellectual property counsel to assist in protecting our patent ownership rights, to date, we have not had intellectual property counsel conduct a freedom to operate analysis regarding our product candidates. As a result, we cannot be certain that we will not be exposed to third-party legal claims, liabilities and/or litigation actions when we seek to develop our product candidates, and make and market products using our intellectual property.

If we are sued for infringing the intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our product candidates or their methods of use, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the pharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference and other administrative proceedings before the USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products, or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. In the United States, proving invalidity (except in proceedings before the USPTO) requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing, or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such a third party in order to use the infringing technology and continue developing, manufacturing, or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorney'' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the enforcement or defense of our or our collaboration partner's issued patents, all of which could harm our business, results of operations, and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO, and the relevant law-making bodies in other countries, the laws, and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payments and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

All of our issued U.S. and foreign patents with respect to tecarfarin expired in 2024 and, therefore, we no longer have patent protection for tecarfarin.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if we obtain additional patents covering our product candidates, once the patent life has expired for a product, we may be open to competition from other products. If the lives of our patents are not sufficient to effectively protect our products and business, our business and results of operations will be adversely affected. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

We have lost effective patent protection in the United States and in key countries outside of the United States. *See supra* the section entitled "Intellectual Property." With respect to tecarfarin, we had two issued U.S. patents directed to tecarfarin for composition of matter and method of treatment, both of which expired in 2024, and our foreign patents directed to tecarfarin, for composition of matter and use, expired in April 2025. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, we are no longer able to seek patent extensions for our U.S. patents since they have expired. If we were to be granted U.S. patents in the future, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

For non-biologic products, loss of exclusivity (whether by expiration of legal rights or by termination thereof as a consequence of litigation) typically results in the entry of one or more generic competitors, leading to a rapid and severe decline in revenues, especially in the United States. Historically, outside the United States, the market penetration of generics following loss of exclusivity has not been as rapid or pervasive as in the United States; however, generic market penetration is increasing in many markets outside the United States, including Japan, Europe, and many countries in the emerging markets. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented intellectual property.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

We anticipate that many of the people that we expect to hire as employees, including our one current employee, were previously employed at other pharmaceutical companies. Some of these employees may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third-party. Litigation may be necessary to defend against such claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third-party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may 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 we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. 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.

Risks Related to Ownership of Our Common Stock

An active public trading market for our Common Stock may not be maintained.

Prior to our initial public offering consummated on January 24, 2023, there was no public market or active private market for trading shares of our Common Stock. Our Common Stock is currently traded on the Nasdaq Capital Market, but we can provide no assurance that we will be able to maintain an active trading market. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the price of shares of Common Stock. An inactive market may impair our ability to raise capital by selling shares and our ability to use our capital stock to acquire other companies or technologies. We cannot predict the prices at which our Common Stock will trade.

We cannot be assured that we will be able to maintain our listing on the Nasdaq Capital Market.

Our securities are listed on The Nasdaq Capital Market, a national securities exchange. We cannot be assured that we will continue to comply with the rules, regulations or requirements governing the listing of our Common Stock on Nasdaq Capital Market or that our securities will continue to be listed on Nasdaq Capital Market in the future. If Nasdaq should determine at any time that we fail to meet Nasdaq requirements, we may be subject to a delisting action by Nasdaq.

On September 6, 2023, we received a letter from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Rule"), requiring listed securities to maintain a minimum bid price of $1.00 per share because our closing bid price for the last 30 consecutive business days was below $1.00 per share. On August 20, 2024 we effected a reverse stock split and on September 5, 2024 we were notified by Nasdaq that we had regained compliance with the Rule. However, there can be no assurance that we will continue to comply with the Rule or the other Nasdaq continued listing requirements.

The Nasdaq has recently proposed a new rule change to (i) adopt Listing Rule 5550(a)(6) to require issuers listed on the Nasdaq Capital Market to maintain a minimum Market Value of Listed Securities (as defined in Nasdaq Listing Rule 5005(a)(23)) of at least $5 million for a period of thirty (30) consecutive business days, and (ii) amend Rule 5810 to suspend trading and immediately delist from Nasdaq securities of issuers that do not satisfy the proposed new requirements, and Rule 5815 to set forth the procedures for requesting a hearing before a Hearings Panel and the scope of the Panel's discretion.

If Nasdaq delists our securities from trading on its exchange at some future date, we would take actions to restore our compliance with The Nasdaq Capital Market's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq Capital Market, minimum bid price requirement or prevent future non-compliance with The Nasdaq Capital Market's listing requirements. In the event of a delisting, we could face significant material adverse consequences, including:

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

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our Common Stock could incur substantial losses.

Investors should consider an investment in our Common Stock risky and invest only if they can withstand a significant loss and wide fluctuations in the market value of their investment. Investors who purchase our Common Stock may not be able to sell their shares at or above the purchase price. Our stock price has been volatile and may be volatile in the future. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our Common Stock. Some of the factors that may cause the market price of our Common Stock to fluctuate include:

- adverse results or delays in our clinical trials;
- the timing or delay of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the receipt of regulatory approval or the establishment or termination of a commercial partnership for one or more of our product candidates;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates, our clinical trials or our sales and marketing activities;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- any intellectual property infringement lawsuit involving us;
- announcements of technological innovations or new products by us or our competitors;

- announcements related to any device used in our clinical trials;
- market conditions for the biotechnology or pharmaceutical industries in general;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our Common Stock;
- sales of our Common Stock by our executive officers, directors and significant stockholders;
- direct sales of our Common Stock through financing arrangements;
- restatements of our financial results and/or material weaknesses in our internal controls;
- the loss of any of our key scientific or management personnel; and
- announcements regarding the ongoing exploration of the strategic options available to us.

These broad market and industry factors may seriously harm the market price of our Common Stock, regardless of our operating performance. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations, divert management's attention and resources, and possibly delay our clinical trials or commercialization efforts.

Even if our product candidates receive FDA approval, there is no guarantee that the trading price of our Common Stock will increase following approval, and in the past, some companies have not necessarily experienced such an increase.

The market price of our Common Stock may not increase following the approval of one or more of our product candidates by the FDA or other regulatory authorities and may instead remain flat or decline. Although FDA approval may be viewed as an important development milestone, historical experience in the biopharmaceutical industry demonstrates that regulatory approval does not necessarily result in an increase in a company's stock price, and in some cases has been followed by a decrease in market value.

Any stock price reaction to FDA approval may be negatively affected by a variety of factors, including investor expectations that exceeded the actual scope or conditions of approval, limitations or restrictions in the approved labeling, safety warnings or post-approval study requirements, lack of perceived differentiation from existing therapies, uncertainty regarding reimbursement or pricing, or concerns regarding market adoption and commercial execution. In addition, investors may shift their focus following approval from regulatory milestones to commercialization risks, including manufacturing scale-up, marketing capabilities, and competitive dynamics.

Moreover, approval of a product candidate does not guarantee commercial success or meaningful revenue generation. Our ability to generate value following approval will depend on numerous factors, including physician and patient acceptance, coverage and reimbursement decisions by third-party payors, the competitive landscape (including the availability of alternative or lower-cost therapies), our ability to effectively market and distribute any approved product, and our compliance with ongoing regulatory obligations. If our actual commercial performance or post-approval development plans fail to meet investor expectations, the market price of our Common Stock may decline.

In addition, broader factors unrelated to the regulatory status or underlying performance of our product candidates may adversely affect our stock price. These factors may include general volatility in the equity markets, changes in macroeconomic or geopolitical conditions, shifts in investor sentiment toward biotechnology or small-capitalization companies, analyst coverage or forecasts, and the trading behavior of institutional investors or other significant stockholders.

If financial or industry analysts do not publish research or reports about our business or if they issue inaccurate or unfavorable commentary or downgrade our Common Stock, our stock price and trading volume could decline.

The trading market for our Common Stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. We do not control these analysts or the content and opinions included in their reports. As a new public company, we may be slow to attract research coverage, and the analysts who publish information about our Common Stock will have had relatively little experience with our company, which could affect their ability to accurately forecast our results and make it more likely that we fail to meet their estimates. In the event any of the industry or financial analysts who cover us issue an inaccurate or unfavorable opinion regarding our stock price, our stock price would likely decline. In addition, the stock prices of many companies in the biopharmaceutical industry have declined significantly after those companies have failed to meet, or often times failed to exceed, the financial guidance publicly announced by the companies or the expectations of analysts. If our financial results fail to meet, or significantly exceed, our announced guidance or the expectations of analysts or public investors, analysts could downgrade our Common Stock or publish unfavorable research about us. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our officers and directors exercise significant control over our Company and may be able to control our management and operations, acting in their best interests and not necessarily those of other stockholders.

Our executive officers and directors, in the aggregate, beneficially own shares representing approximately 23% of our outstanding capital stock. Quang X. Pham, our Chief Executive Officer, beneficially owns approximately 17% of our outstanding capital stock. As a result, Mr. Pham alone and together with these other stockholders, acting together, may be able to significantly influence any matters requiring approval by our stockholders, including the election of directors, the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our Common Stock due to the perception that conflicts of interest may exist or arise. Therefore, you should not invest in reliance on your ability to have any control over our company.

Future sales and issuances of our Common Stock or rights to purchase Common Stock, including pursuant to our equity incentive plans and outstanding warrants, could result in additional dilution of the percentage ownership of our stockholders and could depress the market price of our Common Stock.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell Common Stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell Common Stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our Common Stock.

Pursuant to our 2022 Successor Equity Incentive Plan, our management is authorized to grant equity awards to our employees, officers, directors and consultants. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline. Further, the issuance of the shares of Common Stock underlying outstanding stock options and warrants will have a dilutive effect on the percentage ownership held by holders of our Common Stock.

Anti-takeover provisions in our charter documents, and under Delaware law, could make an acquisition of our company, which may be beneficial to our stockholders, more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our Common Stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock, thereby depressing the market price of our Common Stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our Common Stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, or our Chief Executive Officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- establish that our board of directors is divided into three classes — Class I, Class II, and Class III — with each class serving staggered three-year terms;
- provide that, so long as our board of directors is classified, directors may only be removed for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of two-thirds of our outstanding shares of voting stock to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our Common Stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that you would receive a premium for your shares of our Common Stock in an acquisition.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware or the federal district court for the District of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could result in increased costs for our stockholders to bring a claim and could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by, any director, officer, employee or agent of the Company to the Company or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or (iv) any action asserting a claim against us or any director, officer of employee that is governed by the internal affairs doctrine of the law of the State of Delaware; provided that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, or the Company consents in writing to the selection of an alternative forum, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America is the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Notwithstanding the foregoing, the exclusive forum provision will not apply to claims brought to enforce any liability or duty created by the Exchange Act. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, this choice of forum provision could result in increased costs for our stockholders to bring a claim and could may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that is contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated bylaws, provide that we will indemnify our directors and executive officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and the indemnification agreements that we have entered into with each of our current executive officers and intend to enter into with our directors and certain other officers, among other things provide that:

- We will indemnify our directors and executive officers for serving us in those capacities, or for serving as a director, officer, employee or agent of other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that we may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interest and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We will be required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- The rights conferred in our bylaws will not be exclusive. We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

As a result, claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

We do not intend to pay dividends in the foreseeable future. As a result, your ability to achieve a return on your investment will depend on appreciation in the price of our Common Stock.

We have never declared or paid any cash dividends on our Common Stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our Common Stock in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors. Consequently, your only opportunity to achieve a return on your investment in our company will be if the market price of our Common Stock appreciates and you sell your shares at a profit. There is no guarantee that the price of our Common Stock that will prevail in the market will ever exceed the price that you pay. For additional information about our dividend policy, see the "Dividend Policy" in Part II, Item 5 of this Annual Report.

Certain members of our management team have limited experience managing a public company.

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

We have incurred significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we have incurred and will continue to incur legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act, and are required to comply with the applicable requirements of SOX, and the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank"). The listing requirements of the Nasdaq Stock Market, and the rules of the SEC require that we satisfy certain corporate governance requirements. Our management and other personnel are required to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation.

To date, we have not identified any material weaknesses in our review of our internal controls for the purpose of providing the reports required by these rules. In the future, if we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of SOX in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our Common Stock could decline, and we could also become subject to investigations by the stock exchange on which our Common Stock is listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences that would materially harm our business and reputation.

For so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (i) following the fifth anniversary of the completion of our initial public offering, (ii) in which we have total annual gross revenue of at least $1.235 billion, or (iii) in which we are deemed to be a large accelerated filer, which means the market value of our Common Stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are an emerging growth company and we cannot be certain if (i) the reduced disclosure requirements or (ii) extended transition periods for complying with new or revised accounting standards applicable to emerging growth companies will make our Common Stock less attractive to investors. In addition, as a smaller reporting company we will also have reduced disclosure requirements.

We qualify as an emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company, or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

In addition, for as long as we continue to be an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our Common Stock less attractive because we will rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

We are also a "smaller reporting company" as defined in the Securities Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a "smaller reporting company" as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an "emerging growth company" may continue to be available to us as a "smaller reporting company," including exemption from compliance with the auditor attestation requirements pursuant to SOX and reduced disclosure about our executive compensation arrangements. We will continue to be a "smaller reporting company" until we have $250 million or more in public float (based on our Common Stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our Common Stock) or a public float (based on our Common Stock) that is less than $700 million, annual revenues of $100 million or more during the most recently completed fiscal year.

We have additional securities available for issuance, which, if issued, could adversely affect the rights of the holders of our Common Stock.

Our Amended and Restated Certificate of Incorporation, as amended, authorizes the issuance of 75,000,000 shares of our Common Stock and 7,500,000 shares of preferred stock. As of December 31, 2025, we had 2,338,127 shares of Common Stock outstanding, options exercisable to purchase 403,000 shares of Common Stock, and 1,044,167 warrants exercisable to purchase shares of Common Stock. In certain circumstances, the Common Stock, as well as the awards available for issuance under our equity incentive plans and shares of preferred stock, can be issued by our board of directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership of us held by holders of preferred stock and Common Stock. In addition, the issuance of certain securities, including pursuant to the terms of our stockholder rights plan, may be used as an "anti-takeover" device without further action on the part of our stockholders, and may adversely affect the holders of the Common Stock.

Future sales of our Common Stock could cause the market price for our Common Stock to decline.

We cannot predict the effect, if any, that market sales of shares of our Common Stock or the availability of shares of our Common Stock for sale will have on the market price of our Common Stock prevailing from time to time. Sales of substantial amounts of shares of our Common Stock in the public market, or the perception that those sales will occur, could cause the market price of our Common Stock to decline or be depressed.

There is no public market for the outstanding warrants.

There is no established public trading market for any outstanding warrants and we do not expect a market to develop. None of our warrants are listed on a national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the warrants will be limited.

Holders of the outstanding warrants will have no rights as common stockholders with respect to the shares our Common Stock underlying the warrants until such holders exercise their warrants and acquire our Common Stock, except as otherwise provided in the warrants.

Until holders of the outstanding warrants acquire shares of our Common Stock upon exercise thereof, such holders will have no rights with respect to the shares of our Common Stock underlying such warrants, except to the extent stated in the warrant. Upon exercise of the warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We maintain a cyber risk management protocol designed to identify, assess, manage, mitigate, and respond to cybersecurity threats.

The underlying processes and controls of our cyber risk management protocol incorporate recognized best practices and standards for cybersecurity and information technology, including the National Institute of Standards and Technology ("NIST") Cybersecurity Framework ("CSF"). We have undertaken, on an annual basis, to conduct an assessment of our cyber risk management processes and controls to identify, quantify, and categorize material cyber risks. In addition, we have developed a risk mitigation plan to address such risks, and where necessary, remediate potential vulnerabilities identified through the annual assessment process.

In addition, we maintain policies over areas such as information security, access on/offboarding, and access and account management, to help govern the processes put in place by management designed to protect our IT assets, data, and services from threats and vulnerabilities. We consult with a third-party specialist with regard to our cyber risk management processes and controls.

Our management team is responsible for oversight and administration of our cyber risk management protocol, and for informing senior management and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. Cadrenal's management team has prior experience selecting, deploying, and overseeing cybersecurity technologies, initiatives, and processes and relies on threat intelligence as well as other information obtained from governmental, public, or private sources. Our Audit Committee also provides oversight of risks from cybersecurity threats.

As part of its review of the adequacy of our system of internal controls over financial reporting and disclosure controls and procedures, the Audit Committee is specifically responsible for reviewing the adequacy of our computerized information system controls and security related thereof. The cybersecurity stakeholders, including member(s) of management assigned with cybersecurity oversight responsibility and/or third-party consultants providing cyber risk services, brief the Audit Committee on cyber vulnerabilities identified through the risk management process, the effectiveness of our cyber risk management program, and the emerging threat landscape and new cyber risks on at least an annual basis. This includes updates on Cadrenal's processes to prevent, detect, and mitigate cybersecurity incidents. In addition, cybersecurity risks are reviewed by our Board of Directors at least annually, as part of the Company's corporate risk oversight processes.

We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. Cadrenal acknowledges that the risk of cyber incidents is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of its business. To date, we have not had a cybersecurity incident. We proactively seek to detect and investigate unauthorized attempts and attacks against our IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal processes and tools and changes or updates to service delivery; however, potential vulnerabilities to known or unknown threats will remain. Further, there is increasing regulation regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject us to additional liability and reputational harm. See Item 1A. "Risk Factors" for more information on cybersecurity risks.

Item 2. Properties.

Our corporate headquarters are located at 822 A1A North, Suite 306, Ponte Vedra, Florida 32082, which are leased pursuant to a Lease Agreement, originally dated October 15, 2022 with Veranda III Partners, Ltd. (the "Lease Agreement"), as subsequently amended. The Lease Agreement, as most recently amended by an addendum dated October 14, 2025, has a term of 12 months commencing on November 1, 2025. The monthly rent is $2,346. We believe that these headquarters are adequate for our current operations and needs.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. We may, however, in the ordinary course of business face various claims brought by third parties, and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation. If this were to happen, the payment of any such awards could have a material adverse effect on our business, financial condition and results of operations. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our Common Stock has traded on the Nasdaq Capital Market under the symbol "CVKD" since January 20, 2023. The last price of our Common Stock as reported on the Nasdaq Capital Market on March 27, 2026 was $4.99 per share.

Stockholders

We have two classes of stock, undesignated preferred stock, par value $0.001 per share, and Common Stock, par value $0.001 per share. No shares of preferred stock have been issued or are outstanding. As of March 27, 2026, we had 17 Common Stock stockholders of record. The number of holders of record is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Dividend Policy

We have never paid any cash dividends on our Common Stock to date, and do not anticipate paying such cash dividends in the foreseeable future. Whether we declare and pay dividends is determined by our Board of Directors at their discretion, subject to certain limitations imposed under Delaware corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our Board of Directors.

Equity Compensation Plan Information

The Company adopted the Cadrenal Therapeutics, Inc. 2022 Equity Incentive Plan, (the "Initial Plan"), on July 11, 2022, which was later amended and restated on October 16, 2022, for purposes of clarifying the application of certain of the rules of the Initial Plan to awards approved before such amendment and restatement of the Initial Plan and to facilitate the transition to the Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan (the "Successor Plan") for the issuance and approval of awards after consummation of our initial public offering. On October 16, 2022, the Board adopted and the Company's stockholders approved the Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan (the "2022 Plan"), which is a successor to and continuation of the Initial Plan. The 2022 Plan became effective on January 19, 2023, at which time it replaced the Initial Plan, except with respect to awards outstanding under the Initial Plan. No further awards are available for grant under the Initial Plan.

The following table presents information as of December 31, 2025 with respect to shares of our Common Stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Equity Compensation Plan Options	Weighted-Average Exercise Price of Outstanding Equity Compensation Plan Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders	403,000	$ 17.41	67,813
Equity compensation plans not approved by security holders	-	-	-
Total	403,000	$ 17.41	67,813

Recent Sales of Unregistered Securities

We have not issued unregistered securities to any person during the year ended December 31, 2025 and up to the date of the filing of this Annual Report in transactions that were not previously disclosed in our filings with the SEC.

Item 6. [Reserved]

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

The following discussion of our financial condition and results of operations should be read in conjunction with the audited financial statements and notes thereto for the period ended December 31, 2025 found in this Annual Report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward-looking statements by using words such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report.

The Company

We are a late-stage biopharmaceutical company advancing novel therapies for life-threatening immune and thrombotic conditions. As a result of our acquisition of a 12-LOX platform of assets in December 2025, we transitioned our primary strategic focus to the development of CAD-1005 for the treatment of immune-mediated and thrombotic disorders. Our lead product candidate, CAD-1005, is a first-in-class selective 12-LOX inhibitor being developed to treat HIT, a deadly immune-mediated thrombotic disorder. CAD-1005 has been evaluated in a blinded, placebo-controlled study Phase 2 clinical trial of 24 patients as well as Phase 1 clinical trials in more than 100 patients. On March 26, 2026, we completed our EOP2 meeting with the FDA and clarified a potential registrational path for our planned Phase 3 pivotal trial of CAD-1005 in patients with HIT. Our Phase 3 trial protocol will still be subject to additional information which may be set forth in the final meeting minutes from the FDA and any further comments we may receive from the FDA upon their review of the protocol. CAD-1005 has an ODD from the FDA for prophylaxis of thrombosis in patients with HIT, as well as an FDA Fast Track designation for the treatment and prevention of HIT, and an orphan designation from the EMA for the treatment of platelet-activating factor 4 disorders.

Our broader pipeline includes two additional clinical-stage assets —tecarfarin and frunexian. Tecarfarin is an oral vitamin K antagonist ("VKA") (a warfarin replacement for patients with complex needs) designed to prevent heart attacks, strokes, and deaths due to blood clots in patients requiring chronic anticoagulation. Specifically, our focus for tecarfarin is for chronic use in patients with kidney dysfunction or left ventricular assist devices ("LVADs"). Tecarfarin has been specifically designed to overcome metabolic factors that can make warfarin less reliable. Frunexian is a first-in-class, Phase 2-ready intravenous ("IV") Factor XIa inhibitor designed for acute care settings where contact activation of coagulation by medical devices or artificial surfaces is significant. Frunexian is the only IV FXIa inhibitor in clinical development that targets the acute/critical care hospital setting exclusively.

Recent Developments

Registered Direct Offering

On December 15, 2025, we entered into a securities purchase agreement with certain investors named on the signature pages thereto, pursuant to which we sold to such investors an aggregate of: (i) in a registered direct offering, 207,374 shares of Common Stock and, (ii) in a concurrent private placement, unregistered common warrants to purchase up to 414,748 shares of Common Stock. The offering price per share was $10.85. The registered direct offering and concurrent private placement were consummated on December 16, 2025 and we received gross proceeds therefrom of approximately $2.2 million.

Veralox Asset Purchase

On December 10, 2025, we entered into the Veralox Purchase Agreement, pursuant to which Veralox sold to us all, or substantially all, of its right title and interest in assets owned or otherwise used or held for use by Veralox in connection with the compound known as CAD-1005, and all back-up and follow-on compounds, including the CAD-2000 series (the "Compounds"), including, without limitation, all intellectual property related to the Compounds, all inventory related to the Compounds, certain contracts including a license agreement, all Permits and other Governmental Authorizations and Books and Records (as such terms are defined in the Veralox Purchase Agreement), free and clear of any liens (the Veralox Assets). The transactions contemplated by the Veralox Purchase Agreement were consummated on December 10, 2025.

The purchase price for the Veralox Assets consisted of (i) a cash payment of $200,000, (ii) the assumption by us of certain assumed liabilities; (iii) contingent milestone payments in an amount not to exceed $15 million, and (iv) royalty payments.

ATM Facility

During the year ended December 31, 2025, we sold 307,727 shares of our Common Stock through our at-the-market (ATM) facility with H.C.W., generating gross proceeds of approximately $4.9 million and net proceeds of approximately $4.6 million.

From January 1, 2026 through March 30, 2026, we sold 168,690 shares of our Common Stock through our at-the-market (ATM) facility with H.C.W., generating gross proceeds of approximately $1.4 million and net proceeds of approximately $1.3 million.

Results of Operations

The following table summarizes our results of operations for the fiscal year ended December 31, 2025 and 2024.

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Operating expenses:				
General and administrative expenses	$ 9,354,135	$ 6,753,726	$ 2,600,409	39%
Research and development expenses	4,100,168	4,205,013	(104,845)	(2)%
Depreciation expense	6,874	1,880	4,994	266%
Total operating expenses	13,461,177	10,960,619	2,500,558	23%
Loss from operations	(13,461,177)	(10,960,619)	(2,500,558)	23%
Other income				
Interest and dividend income	223,815	309,251	(85,436)	(28)%
Total other income	223,815	309,251	(85,436)	(28)%
Net loss and comprehensive loss	$ (13,237,362)	$ (10,651,368)	$ (2,585,994)	(5)%

General and administrative expenses

General and administrative expenses for the years ended December 31, 2025, and 2024 were $9.4 million and $6.8 million, respectively, representing an increase of approximately $2.6 million, or 39%. The increase is primarily attributable to a $1.6 million increase in expenses related to being a public company, a $0.4 million increase in stock-based compensation, a $0.4 million increase in consulting expenses, and a $0.1 million increase in professional fees.

Research and development expenses

Research and development expenses for the years ended December 31, 2025, and 2024 were $4.1 million and $4.2 million, respectively, representing a decrease of $0.1 million, or 2%. The decrease was primarily attributable to a $0.8 million reduction in consulting expenses, partially offset by a $0.5 million increase in expenses associated with the asset purchase agreements completed in September and December 2025, which were expensed as in-process research and development (IPR&D), a $0.2 million increase in personnel expenses, primarily associated with former Chief Medical Officer's severance agreement entered into in February 2025, a $0.1 million in clinical trial preparation costs, and a $0.1 million increase in stock-based compensation expense. We anticipate research and development expenses to increase when we commence clinical trials.

Interest and dividend income

Interest and dividend income for the years ended December 31, 2025, and 2024 were $0.2 million and $0.3 million, respectively. This represents the interest and dividend income earned from our investments in money market funds.

Liquidity and Capital Resources

Since inception, we have incurred losses and utilized cash in operations. To date, we have funded our operations from the proceeds of the sale of convertible and promissory notes, our IPO completed in January 2023, our Private Placement completed in July 2023, our Warrant Inducement completed in November 2024, our December 2025 Registered Offering, and the sale of Common Stock through our ATM facility. We recognized a net loss of $13.2 million for the year ended December 31, 2025 which included $1.9 million of non-cash expenses. Cash used in operating activities for the year ended December 31, 2025 totaled $12.6 million.

We expect to continue to incur operating losses and negative cash flows for the foreseeable future as we advance our clinical and regulatory activities. Based on our current operating plan, we believe that our existing cash resources will not be sufficient to fund our operating and capital requirements for the next 12 months. To meet anticipated funding needs, we plan to seek additional capital through strategic partnerships, equity offerings, and/or debt financings. However, there can be no assurance that additional funding will be available on acceptable terms or at all. These factors raise substantial doubt about our ability to continue as a going concern for at least one year following the issuance of the accompanying financial statements. If we are unable to obtain additional financing, we may be required to delay or reduce the scope of our development programs, implement cost-saving measures, or cease operations entirely. The accompanying financial statements do not include any adjustments that might result from this uncertainty.

Cash Flows

The following table summarizes our cash flow for the period presented:

	Years Ended December 31,	
	2025	**2024**
Cash used in operating activities	$ (12,601,666)	$ (7,357,550)
Cash used in investing activities	(5,104)	(6,537)
Cash provided by financing activities	6,596,617	8,979,529
Net change in cash	(6,010,153)	1,615,442
Cash and cash equivalents, beginning of period	10,017,942	8,402,500
Cash and cash equivalents, end of period	$ 4,007,789	$ 10,017,942

Operating activities

During the year ended December 31, 2025, cash used in operating activities was $12.6 million. Net loss adjusted for the non-cash items as detailed on the statement of cash flows, used $11.3 million in cash, and the changes in operating assets and liabilities, as detailed on the statement of cash flows, used $1.3 million in cash primarily from a $0.9 million decrease in accounts payable, a $0.2 million decrease in accrued liabilities, and a $0.2 million increase in prepaid expenses.

During the year ended December 31, 2024, cash used in operating activities was $7.4 million. Net loss adjusted for the non-cash items as detailed on the statement of cash flows, used $9.2 million in cash, and the changes in operating assets and liabilities, as detailed on the statement of cash flows, provided $1.9 million in cash primarily from a $1.3 million increase in accounts payable and a $0.5 million increase in accrued liabilities.

Financing activities

Net cash provided by financing activities was $6.6 million for the year ended December 31, 2025. This consisted primarily of net proceeds of $4.6 million from sales of common stock under our at-the-market equity program and net proceeds of $2.0 million from our December 2025 registered direct offering, with additional proceeds from the exercise of stock options.

Net cash provided by financing activities was $9.0 million for the year ended December 31, 2024. This consisted of net proceeds of $4.8 million from sales of common stock under our at-the-market equity program and net proceeds of $4.2 million from our warrant inducement agreement.

Critical Accounting Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Significant estimates and assumptions made in the accompanying financial statements include but are not limited to the fair value of financial instruments, the fair value of stock-based awards, deferred tax assets and valuation allowance, income tax uncertainties, and certain accruals. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimated under different assumption or conditions.

Stock-Based Compensation

We measure our stock-based awards granted to employees, consultants and directors based on the estimated grant-date fair values of the awards and recognize the compensation over the requisite service period. We use the Black-Scholes option-pricing model to estimate the fair value of our stock option awards. Stock-based compensation is recognized using the straight-line method. As the stock compensation expense is based on awards ultimately expected to vest, it is reduced by forfeitures. We account for forfeitures as they occur.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable because we are a smaller reporting company.

Item 8. Financial Statements and Supplementary Data.

CADRENAL THERAPEUTICS, INC.
FINANCIAL STATEMENTS
Contents

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Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders of
Cadrenal Therapeutics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Cadrenal Therapeutics, Inc. (the "Company") as of December 31, 2025 and 2024, and the related statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years ended December 31, 2025 and 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with the accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring operating losses and negative cash flows from operating activities since inception and expects to continue incurring operating losses and negative cash flows in the future. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2022.

East Brunswick, New Jersey

March 30, 2026

PCAOB ID No. 100

CADRENAL THERAPEUTICS, INC.
BALANCE SHEETS

	December 31, 2025	December 31, 2024
Assets:		
Current assets:		
Cash and cash equivalents	$ 4,007,789	$ 10,017,942
Interest receivable	5,096	38,153
Prepaid expenses and other current assets	200,140	42,257
Deferred offering costs	106,342	14,445
Total current assets	4,319,367	10,112,797
Property, plant and equipment, net	5,174	6,944
Other assets	2,167	3,792
Total assets	$ 4,326,708	$ 10,123,533
Liabilities and Stockholders' Equity:		
Current liabilities:		
Accounts payable	$ 650,663	$ 1,502,468
Accrued liabilities	937,319	1,181,490
Total current liabilities	1,587,982	2,683,958
Total liabilities	1,587,982	2,683,958
Stockholders' equity:		
Preferred stock, $0.001 par value, 7,500,000 shares authorized, no shares issued and outstanding as of December 31, 2025 and 2024	-	-
Common stock, $0.001 par value; 75,000,000 shares authorized, 2,338,127 shares issued and outstanding as of December 31, 2025; 1,782,486 shares issued and outstanding as of December 31, 2024	2,338	1,782
Additional paid-in capital	41,696,533	33,160,576
Accumulated deficit	(38,960,145)	(25,722,783)
Total stockholders' equity	2,738,726	7,439,575
Total liabilities and stockholders' equity	$ 4,326,708	$ 10,123,533

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

CADRENAL THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years Ended December 31,	
	2025	**2024**
Operating expenses:		
General and administrative expenses	$ 9,354,135	$ 6,753,726
Research and development expenses	4,100,168	4,205,013
Depreciation expense	6,874	1,880
Total operating expenses	13,461,177	10,960,619
Loss from operations	(13,461,177)	(10,960,619)
Other income		
Interest and dividend income	223,815	309,251
Total other income	223,815	309,251
Net loss and comprehensive loss	$ (13,237,362)	$ (10,651,368)
Net loss per common share, basic and diluted	$ (6.64)	$ (8.73)
Weighted average number of common shares used in computing net loss per common share, basic and diluted	1,993,757	1,219,550

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

CADRENAL THERAPEUTICS, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

For the year ended December 31, 2025

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2024	1,782,486	$ 1,782	$33,160,576	$ (25,722,783)	$ 7,439,575
Equity-based compensation - options	-	-	1,806,521	-	1,806,521
Issuance of common stock for consulting services	35,000	35	133,340	-	133,375
Proceeds from the sale of common stock and warrants, net of transaction costs of $291,883	207,374	208	1,957,917	-	1,958,125
Proceeds from sale of common stock under the ATM, net of issuance costs of $271,214	307,727	308	4,590,184	-	4,590,492
Exercise of stock options	5,540	5	47,995	-	48,000
Net loss	-	-	-	(13,237,362)	(13,237,362)
Balance, December 31, 2025	2,338,127	$ 2,338	$41,696,533	$ (38,960,145)	$ 2,738,726

For the year ended December 31, 2024

	Common Stock (1)		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital (1)	Deficit	Equity
Balance, December 31, 2023	868,184	$ 868	$22,762,922	$ (15,071,415)	$ 7,692,375
Issuance of common shares from exercise of pre-funded warrants	199,047	199	99	-	298
Rounding of fractional shares from reverse stock split	(36)	-	-	-	-
Equity-based compensation - options	-	-	747,005	-	747,005
Issuance of common stock for consulting services	38,333	38	671,996	-	672,034
Proceeds from sale of common stock under the ATM, net of issuance costs of $337,639	391,243	391	4,805,564	-	4,805,955
Proceeds from warrant inducements, net of issuance costs of $541,022	285,715	286	4,172,990	-	4,173,276
Net loss	-	-	-	(10,651,368)	(10,651,368)
Balance, December 31, 2024	1,782,486	$ 1,782	$33,160,576	$ (25,722,783)	$ 7,439,575

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

CADRENAL THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2025	**2024**
Cash flows used in operating activities:		
Net loss	$ (13,237,362)	$ (10,651,368)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	6,874	1,880
Equity-based compensation	1,939,896	1,419,039
Non-cash lease expense	-	(352)
Changes in operating assets and liabilities:		
Interest receivable	33,057	(905)
Prepaid expenses	(157,883)	10,168
Deferred offering costs	(91,897)	(14,445)
Other assets	1,625	-
Accounts payable	(851,805)	1,335,149
Accrued liabilities	(244,171)	543,284
Net cash used in operating activities	(12,601,666)	(7,357,550)
Cash flows used in investing activities:		
Investment in property and equipment	(5,104)	(6,537)
Net cash used in investing activities	(5,104)	(6,537)
Cash flows from financing activities:		
Proceeds from warrant inducements	-	4,714,298
Issuance costs from warrant inducement	-	(541,022)
Proceeds from sale of common stock under ATM	4,861,706	5,143,594
Issuance costs for sale of common stock under ATM	(271,214)	(337,639)
Proceeds from the sale of common stock and warrants	2,250,008	-
Issuance costs for the sale of common stock and warrants	(291,883)	-
Proceeds from exercise of warrants	-	298
Proceeds from exercise of stock options	48,000	-
Net cash provided by financing activities	6,596,617	8,979,529
Net change in cash and cash equivalents	(6,010,153)	1,615,442
Cash and cash equivalents – beginning of the period	10,017,942	8,402,500
Cash and cash equivalents – end of the period	$ 4,007,789	$ 10,017,942

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

Note 1. Description of Business and Summary of Significant Accounting Policies

Cadrenal Therapeutics, Inc. (the "Company" or "Cadrenal") was incorporated on January 25, 2022, in the State of Delaware and is headquartered in Ponte Vedra, Florida. Cadrenal is a late-stage biopharmaceutical company advancing novel therapies for life-threatening immune and thrombotic conditions. Its lead program, CAD-1005, is a first-in-class 12-LOX inhibitor for the treatment of heparin-induced thrombocytopenia (HIT), a deadly immune-mediated thrombotic disorder. CAD-1005 has received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration, and orphan drug status from the European Medicines Agency. Second-generation 12-LOX oral therapeutics are also under development for chronic conditions.

The Company's broader pipeline includes tecarfarin, a Phase 3-ready oral vitamin K antagonist for patients with end-stage kidney diseases and left ventricular assist devices, and frunexian, a parenteral Factor XIa inhibitor designed for use in acute hospital settings.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for the fair presentation of the Company's financial statements for the periods presented. The Company's fiscal year-end is December 31.

Liquidity

The accompanying financial statements have been prepared on the assumption that the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. Since its inception, the Company has incurred operating losses and negative cash flows from operations. For the year ended December 31, 2025, the Company had a net loss of $13.2 million, which included $1.9 million of non-cash expenses. Cash used in operations totaled $12.6 million. As of December 31, 2025, the Company had cash and cash equivalents of $4.0 million, net working capital of $2.7 million, and an accumulated deficit of $39.0 million.

The Company is projecting that its operating losses and expected capital needs will exceed its existing cash balances and cash expected to be generated from operations for the foreseeable future. In order to meet the Company's expected obligations, management intends to raise additional funds through partnering, the sale of equity, and debt financings. However, there can be no assurance that the Company will be able to complete partnering transactions or financings on terms acceptable to the Company or at all. As a result, there is uncertainty as to the Company's ability to meet its current operating and capital expenses. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the date the accompanying financial statements are issued. If the Company is unable to raise additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Emerging Growth Company Status

As an "emerging growth company" ("EGC") under the Jumpstart Our Business Startups Act ("JOBS Act"), the Company may elect to take advantage of certain forms of relief from various reporting requirements that apply to public companies. The relief afforded under the JOBS Act includes an extended transition period for implementing new or revised accounting standards. The Company has elected to take advantage of this extended transition period and, as a result, the Company's financial statements may not be comparable to those of companies that implement accounting standards as of the effective dates for public companies. The Company may take advantage of the relief afforded under the JOBS Act up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that it is no longer an EGC.

Use of Estimates

Preparing financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include but are not limited to the fair value of stock-based awards, deferred tax assets and valuation allowance, income tax uncertainties, and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances change. Actual results could differ from those estimates.

Concentration of Credit and Other Risks and Uncertainties

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents. Cash is maintained at high-credit-quality financial institutions; at times, balances may exceed federally insured limits. All interest-bearing and non-interest-bearing cash balances are insured up to $250,000 at each financial institution. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

The Company is subject to several risks common for early-stage biopharmaceutical companies including, but not limited to, dependency on the clinical and commercial success of its product candidate, ability to obtain regulatory approval of its product candidate, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and patients, significant competition and untested manufacturing capabilities.

Segment Reporting

Operating segments are defined as components of an entity where separate financial information is evaluated regularly by the chief operating decision maker (CODM) in deciding how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, who reviews financial information on a company-wide basis for purposes of allocating resources and assessing financial performance. The Company manages its business activities as a single entity and operates in one reportable segment.

The CODM assesses the performance of its one reportable segment and decides how to allocate resources based on loss from operations and net loss. The CODM utilizes loss from operations and net loss, as presented on the Company's statements of operations and comprehensive loss, to evaluate the Company's business plan, which includes clinical development roadmaps and long-range financial models as key inputs to decisions on resource allocation and its assessment of the performance of the business.

Significant expenses within loss from operations and net loss include research and development and general and administrative expenses, which are each separately presented on the Company's statements of operations and comprehensive loss. Other segment items include depreciation expense and interest and dividend income as presented on the Company's statements of operations and comprehensive loss. The accounting policies used to measure the segment's profit and loss are the same as those described in the summary of significant accounting policies.

The measure of segment assets is reported on the balance sheets as total assets.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash and cash equivalents include cash and money market funds.

Stock-Based Compensation

The Company measures its stock-based awards granted to employees, consultants, and directors based on the estimated grant-date fair values of the awards and recognizes the compensation over the requisite service period using the straight-line method. The Company uses the Black-Scholes option-pricing model to estimate the fair value of its stock option awards. The Company accounts for forfeitures as they occur.

The Black-Scholes model requires the use of highly subjective and complex assumptions, which determine the fair value of stock-based payment awards, including the option's expected term and the price volatility of the underlying stock. The Company estimates the fair value of options granted by using the Black-Scholes model with the following assumptions:

- Expected Volatility—The Company estimated volatility for option grants by evaluating the historical volatility of a peer group of companies for the period immediately preceding the option grant for a term that is approximately equal to the options' expected term.

- Expected Term—The expected term of the Company's options represents the period that the stock-based payment awards are expected to be outstanding. The expected term was estimated using the simplified method for employee stock options since the Company does not have adequate historical exercise data to estimate the expected term.

Deferred Offering Costs

The Company capitalizes certain legal, professional, and other third-party costs that are directly associated with in-process equity financings until such financings are consummated, at which time such costs are recorded against the gross proceeds of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss.

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine 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 so, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Acquisitions that meet the definition of a business combination are accounted for under the acquisition method, which requires allocating the purchase price to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

For asset acquisitions, a cost-accumulation model is used to determine the cost of an asset acquisition. Direct transaction costs are recognized as part of the cost of an asset acquisition. The Company also evaluates which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. When a transaction accounted for as an asset acquisition includes an in-process research and development ("IPR&D") asset, the IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. For an IPR&D asset to have an alternative future use: (a) the Company must reasonably expect that it will use the asset acquired in an alternative manner and anticipate economic benefit from that alternative use, and (b) the Company's use of the asset acquired is not contingent on the further development of the asset subsequent to the acquisition date (that is, the asset can be used in an alternative manner in the condition in which it existed at the acquisition date). Otherwise, amounts allocated to IPR&D that have no alternative use are expensed to research and development. Asset acquisitions may include contingent consideration arrangements that encompass obligations to make future payments to sellers contingent upon the achievement of future financial targets. Contingent consideration is not recognized until all contingencies are resolved and the consideration is paid or probable of payment, at which point the consideration is allocated to the assets acquired on a relative fair value basis.

Income Taxes

Income taxes are accounted for under the asset-and-liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and net losses, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of the provision for income taxes.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock and pre-funded warrants outstanding for the period, without consideration for potential dilutive shares of common stock. Diluted net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock and common stock equivalents of potentially dilutive securities outstanding for the period determined using the treasury stock or if-converted methods. Since the Company was in a loss position for all periods presented, basic net loss per common share is the same as diluted net loss per common share since the effects of potentially dilutive securities are anti-dilutive. Shares of common stock subject to repurchase are excluded from the weighted-average shares.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events or circumstances from non-owner sources. Net loss and comprehensive loss were the same for the periods presented in the accompanying financial statements.

Research and Development Expenses

Research and development costs are expensed as incurred and consist of fees paid to other entities that conduct certain research and development activities on the Company's behalf. Acquired intangible assets are expensed as research and development costs if, at the time of payment, the technology is under development; is not approved by the United States Food and Drug Administration ("FDA") or other regulatory agencies for marketing; has not reached technical feasibility; or otherwise has no foreseeable alternative future use. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and then expensed as the related goods are delivered or the services are performed.

Patents

Patent costs are comprised primarily of external legal fees, filing fees incurred to file patent applications, and periodic renewal fees to keep the patent in force. They are expensed as incurred as a component of general and administrative expenses.

Note 2. Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update, or ASU, 2023-09, Improvements to Income Tax Disclosures. The ASU requires greater disaggregation of information about a reporting entity's effective tax rate reconciliation and information on income taxes paid. The ASU applies to all entities subject to income taxes and is intended to help investors better understand an entity's exposure to potential changes in jurisdictional tax legislation and assess income tax information that affects cash flow forecasts and capital allocation decisions. The ASU is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted ASU 203-09 during the year ended December 31, 2025 using a retrospective approach and is complying with the related disclosure requirements in Note 10, Income Taxes.

Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03 Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40). The ASU aims to improve financial reporting by requiring that public business entities disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. In January 2025, the ASU was subsequently amended by ASU 2025-01 to clarify the effective date of which all public business entities are required to adopt the guidance in annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption of ASU 2024-03 is permitted. The Company is currently evaluating the impact of this guidance on its financial statements.

Note 3. Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- Level 1 — Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 — Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type are presented in the following table:

	December 31, 2025			
	Level 1	Level 2	Level 3	Fair Value
Financial Assets:				
Money market funds	$ 1,702,062	$ -	$ -	$ 1,702,062
Total financial assets	$ 1,702,062	$ -	$ -	$ 1,702,062

	December 31, 2024			
	Level 1	Level 2	Level 3	Fair Value
Financial Assets:				
Money market funds	$ 9,946,189	$ -	$ -	$ 9,946,189
Total financial assets	$ 9,946,189	$ -	$ -	$ 9,946,189

The carrying amounts of cash and cash equivalents, prepaid expenses, deferred offering costs, accounts payable, and accrued liabilities approximate their fair values due to their short-term nature. There were no transfers of liabilities among the fair value measurement categories during any of the periods presented.

Note 4. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2025	December 31, 2024
Accrued compensation	$ 733,196	$ 966,575
Accrued research and development	34,582	-
Accrued consulting fees	-	162,606
Accrued professional fees	130,770	5,565
Other	38,771	46,744
Total accrued liabilities	$ 937,319	$ 1,181,490

Note 5. Asset Purchase Agreements

eXIthera Pharmaceuticals, Inc.

On September 12, 2025, the Company entered into an Asset Purchase Agreement (the "eXIthera APA") with eXIthera Pharmaceuticals, Inc. (the "Seller of eXIthera"). Pursuant to the terms of the eXIthera APA, the Company acquired all of the rights, title and interests in assets owned or held for use by it in connection with the compounds known as frunexian (EP-7041) and EP-7327 and certain other compounds including all intellectual property, regulatory filings, clinical and non-clinical data, market analyses, commercialization plans, all inventory related to the compounds and other rights. In addition, the Company acquired the exclusive license agreement (the "Haisco License Agreement") with Sichuan Haisco Pharmaceutical Co., Ltd. ("Haisco"), which relates to the development and commercialization of frunexian in the People's Republic of China. In consideration of the purchase of the assets, the Company paid $50,000 at closing. As additional consideration, the eXIthera APA provides for contingent milestone payments by the Company to the Seller of eXIthera upon achievement of development milestones in an amount not to exceed $15 million.

Development Milestones	Milestone payment
First Patient Dosed in Phase 2 Initiated with Frunexian or EP-7327	$500,000 per compound
First Patient Dosed in Phase 1 Initiated with EP-7327	$500,000 per compound
First Patient Dosed in Phase 3 Initiated with Frunexian or EP-7327	$1,000,000 per compound
FDA Approval of New Drug Application for Frunexian or EP-7327	$6,000,000 per compound

As additional consideration, the Company agreed to pay the Seller of eXIthera royalties equal to 2% of annual net sales of the pharmaceutical products containing any compounds that are subject to the eXIthera APA. In addition, the Company agreed to pay the Seller of eXIthera 50% of all royalties received by the Company from the Haisco Licensing Agreement following the potential future commercialization of frunexian by Haisco. The contingent milestone payments and royalty payments are payable in cash, common stock, or in any combination thereof at the Company's discretion.

The Company accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified in-process research and development asset, the frunexian asset, thus satisfying the requirements of the screen test in accordance with the criteria under ASC 805-10-55-5C. The assets acquired in the transaction were measured based on the fair value of the consideration paid of $50,000 plus direct transaction costs of $151,216, as the fair value of the consideration paid was more readily determinable than the fair value of the assets acquired. The following table summarizes the initial purchase price of the assets acquired:

In process research and development	$	50,000
Transaction costs		151,216
Total	$	201,216

All costs the Company incurred in connection with the eXIthera APA were recognized as research and development expenses in the Company's statement of operations and comprehensive loss as these assets had no alternative future use at the time they were acquired. Due to the nature of the development, regulatory, and sales-based milestones, the contingent consideration was not included in the initial cost of assets purchased, as they are contingent upon events that are outside the Company's control.

However, upon achievement or anticipated achievement of each milestone, the Company will recognize the related appropriate payment as additional research and development expense. Contingent consideration will not be recorded until it is probable that the milestone events will occur.

Veralox Therapeutics Inc.

On December 10, 2025, the Company entered into an Asset Purchase Agreement (the "Veralox APA") with Veralox Therapeutics, Inc. (the "Seller of Veralox"). Pursuant to the terms of the Veralox APA, the Company acquired all of the rights, title and interests in assets owned or held for use by it in connection with the compound known as VLX-1005 ("VLX-1005"), and all back-up and follow-on compounds, including the VLX-2000 series (the "Compounds"), including, without limitation, all intellectual property related to the Compounds, all inventory related to the Compounds, certain contracts including a license agreement, all Permits and other Governmental Authorizations and Books and Records (as such terms are defined in the Veralox APA), free and clear of any liens. In consideration of the purchase of the assets, the Company paid $200,000 at closing and assumed certain liabilities (as defined in the Veralox APA). As additional consideration, the Veralox APA provides for contingent milestone payments upon achievement of development milestones in an amount not to exceed $15 million.

Development Milestones	Milestone payment
First Patient Dosed in the First Clinical Trial with VLX-1005	$ 2,000,000
First regulatory filing approval to market a pharmaceutical product for human use containing a Compound that is covered by a patent owned or licensed by the Seller of Verilox (the "Product") in the United States	$ 8,000,000
First regulatory filing approval to market a Product outside the United States	$ 2,000,000
Regulatory filing approval to market a Product for a subsequent indication in the United States	$ 2,000,000
Regulatory filing approval to market a Product for a subsequent indication outside the United States	$ 1,000,000

As additional consideration, the Company agreed to pay the Seller of Veralox royalties equal to 5% of annual net sales of each product containing any of the compounds that are the subject to the Veralox APA. The contingent milestone payments and royalty payments are payable in cash, common stock, or in any combination thereof at the Company's discretion.

The Company accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified in-process research and development asset, the VLX-1005 compound asset, thus satisfying the requirements of the screen test in accordance with the criteria under ASC 805-10-55-5C. The assets acquired in the transaction were measured based on the fair value of the consideration paid of $200,000 plus direct transaction costs of $131,797, as the fair value of the consideration paid was more readily determinable than the fair value of the assets acquired. The following table summarizes the initial purchase price of the assets acquired:

In process research and development	$ 200,000
Transaction costs	131,797
Total	$ 331,797

All costs the Company incurred in connection with the Veralox APA were recognized as research and development expenses in the Company's statement of operations and comprehensive loss as these assets had no alternative future use at the time they were acquired. Due to the nature of the development, regulatory, and sales-based milestones, the contingent consideration was not included in the initial cost of assets purchased, as they are contingent upon events that are outside the Company's control.

However, upon achievement or anticipated achievement of each milestone, the Company will recognize the related appropriate payment as additional research and development expense. Contingent consideration will not be recorded until it is probable that the milestone events will occur.

In addition, the Company acquired the assignment of an amended and restated exclusive license agreement between the Seller of Veralox and Old Dominion University, as successor in interest to Eastern Virgina Medical School (the "Licensor"), to which the Licensor grants the Seller an exclusive worldwide license under the EVMS Patent Rights related to the development and commercialization as 12-Lipoxygenase Inhibitors (12-LOX) (collectively the "Assets"). Pursuant to the License Agreement, the Company will pay Licensor milestone payments in the aggregate amount of $300,000 upon regulatory approval to market a Licensed Product in: (i) Japan or the European Union; and (ii) the United States, provided however that irrespective of whether such milestones are met, such milestone payments will be due in 2031 and 2032, respectively. Additionally, the Company will pay to Licensor royalties of 2% on worldwide net sales of a Licensed Product or Licensed Service less than or equal to $200,000,000 and royalties of 3% on worldwide sales greater than $200,000,000. Regardless of the commercialization status of any Licensed Product or Licensed Service, the License Agreement requires a minimum annual royalty payment to be paid to Licensor within (30) days of May 1st of each year beginning May 1, 2025, ranging between $10,000 and $50,000 per year. Such annual royalty payments have been waived by Licensor for fiscal years 2026, 2027 and 2028, with the first payment to be made by the Company due May 1, 2029. As of December 31, 2025, these milestones are not deemed probable, and therefore, no liability has been recognized.

Note 6. Stockholders' Equity and Warrants

Reverse Stock Split

On July 29, 2024, the Company's stockholders approved an amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of its shares of common stock, and its Board of Directors subsequently approved a final reverse stock split ratio of 1-for-15. The reverse stock split became effective on August 20, 2024 (the "Effective Date"). On the effective date, every 15 shares of issued and outstanding common stock were combined and converted into one issued and outstanding share of common stock. The number of authorized shares of common stock was not reduced and the par value per share of common stock remained unchanged. Fractional shares were canceled, and stockholders received cash in lieu thereof. A proportionate adjustment was also made to the maximum number of shares of common stock issuable under the Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan. As a result, the number of shares of common stock, stock options, warrants, net loss per share, and exercise prices disclosed throughout these notes to the financial statements, as well as the Annual Report on Form 10-K to which these financial statements and notes thereto are attached, have been retrospectively adjusted to reflect the reverse stock split.

Common Stock

The Company is authorized to issue a total of 75,000,000 shares of common stock, par value of $0.001 per share, and 7,500,000 shares of preferred stock, par value $0.001 per share.

Holders of common stock are entitled to one vote for each share of common stock held of record for the election of the Company's directors and all other matters requiring stockholder action. Holders of common stock will be entitled to receive such dividends, if any, as may be declared from time to time by the Company's Board in its discretion out of funds legally available therefor.

Warrant Inducement

On November 1, 2024, the Company entered into a warrant inducement letter agreement (the "Inducement Agreement") with a holder of the Company's warrants to purchase shares of the Company's Common Stock, issued in a private placement offering that closed on July 14, 2023 (the "Existing Warrants"). Pursuant to the Inducement Agreement, the holder of the Existing Warrants agreed to exercise, for cash, the Existing Warrants to purchase up to an aggregate of 285,715 registered shares of common stock, at the adjusted exercise price of $16.50 per share (reduced from the initial exercise price of $26.25 per share).

In consideration of the holder's agreement to exercise the Existing Warrants at the reduced exercise price per share in accordance with the Inducement Agreement, the Company issued to the holder new unregistered Series A-1 Common Stock warrants (the "Series A-1 Warrants") to purchase 285,715 shares of common stock and new unregistered Series A-2 Common Stock warrants (the "Series A-2 Warrants" and, together with the Series A-1 Warrants, the "New Warrants") to purchase an aggregate of 285,715 shares of common stock, at an exercise price of $16.50 per share. The Series A-1 Warrants were immediately exercisable for a term of five years from the date of issuance, and the Series A-2 Warrants were immediately exercisable for a term of 18 months from the date that the Company's registration statement on Form S-3, has been declared effective by the Securities and Exchange Commission, which occurred on November 22, 2024. The New Warrants contain customary provisions for anti-dilution adjustments to the exercise price, including stock splits, stock dividends, rights offerings, and pro rata distributions.

On November 4, 2024, the transactions contemplated by the Inducement Agreement closed, and the Company received aggregate gross proceeds of approximately $4.7 million for the exercise of the Existing Warrants, before deducting placement agent fees and other expenses totaling $0.5 million.

H.C. Wainwright & Co., LLC ("H.C.W.") acted as the placement agent in the Inducement Agreement, and as part of its compensation, the Company issued to designees of H.C.W. placement agent warrants (the "Placement Agent Warrants") to purchase up to 18,571 shares of common stock at an exercise price of $20.625. The Placement Agent Warrants expire five years after issuance and contain customary provisions for anti-dilution adjustments to the exercise price, including for stock splits, stock dividends, rights offerings, and pro rata distributions.

The Series A-1 Warrants, Series A-2 Warrants, and Placement Agent Warrants were classified as equity, and the offering costs were recorded as debit to additional paid-in capital.

All of the Company's outstanding warrants provide that the holder thereof has the right to participate in distributions or dividends paid on the Company's shares of common stock on an as-converted basis.

2025 Direct Registered Offering

On December 15, 2025, the Company entered into a securities purchase agreement with certain investors. The agreement provided for the sale and issuance by the Company of an aggregate of: (i) in a registered direct offering, 207,374 shares (the "2025 Shares") of the Company's common stock (the "2025 Common Stock"), and, (ii) in a concurrent private placement, unregistered warrants (the "2025 Common Warrants") to purchase up to 414,748 shares of Common Stock (collectively, the "December 2025 Registered Offering").

The offering price was $10.85 per 2025 Share. The 2025 Offering closed on December 16, 2025. The Company received gross proceeds of approximately $2.2 million.

The 2025 Common Warrants have an exercise price of $10.60 per share. The shares of 2025 Common Stock issuable upon the exercise of the 2025 Common Warrants are referred to as the "2025 Common Warrant Shares." The 2025 Common Warrants are exercisable immediately upon issuance and will expire two years following the effective date of the registration statement registering the resale of the 2025 Common Warrant Shares. The registration statement on Form S-1 went effective on December 31, 2025.

H.C.W. acted as the placement agent for the Company in connection with the December 2025 Registered Offering, and as part of its compensation, the Company issued to designees of H.C.W. placement agent warrants (the "Placement Agent Warrants") to purchase up to 13,479 shares of common stock at an exercise price of $13.5625. The Placement Agent Warrants expire on December 31, 2027, and contain customary provisions for anti-dilution adjustments to the exercise price, including for stock splits, stock dividends, rights offerings, and pro rata distributions.

The 2025 Common Warrants and Placement Agent Warrants were classified as equity, and the offering costs were recorded as a debit to additional paid-in capital.

ATM Facility

During the year ended December 31, 2025, the Company sold 307,727 shares of its common stock through its at-the-market (ATM) facility with H.C.W. These sales were made at a weighted average price of $15.80 per share, resulting in total gross proceeds of $4.9 million and net proceeds of $4.6 million.

Warrant Summary

The following table summarizes the total warrants outstanding at December 31, 2025:

	Issue Date	Exercise Price Per Share	Expiration Date	Outstanding as of December 31, 2024	New Issuance	Exercised	Outstanding as of December 31, 2025
Placement agent warrants	July - Sept 2022	$ 45.00	July - Sept 2027	767	-	-	767
Placement agent warrants	Nov 2022	$ 15.00	Nov 2027	1,000	-	-	1,000
Representative warrants	Jan 2023	$ 90.00	Jan 2028	5,600	-	-	5,600
Placement agent warrants	July 2023	$ 32.81	Jan 2029	18,572	-	-	18,572
New Series A-1 warrants	Nov 2024	$ 16.50	Nov 2029	285,715	-	-	285,715
New Series A-2 warrants	Nov 2024	$ 16.50	May 2026	285,715	-	-	285,715
Placement agent warrants	Nov 2024	$ 20.625	Nov 2029	18,571	-	-	18,571
Investor Warrants 2025	Dec 2025	$ 10.60	Dec 2027	-	414,748	-	414,748
Placement agent warrants	Dec 2025	$ 13.5625	Dec 2027	-	13,479	-	13,479
				615,940	428,227	-	1,044,167

Issuance of Restricted Common Stock

In October 2024, the Company engaged consultants to perform certain public and investor relations services and issued 50,000 shares of restricted common stock as partial consideration of such services. The Company issued 25,000 shares of fully vested, nonrefundable restricted common stock on October 9, 2024 and the remaining 25,000 shares of restricted common stock were issued on January 8, 2025. On June 29, 2025, the Company issued an additional 10,000 shares of fully vested, nonrefundable restricted common stock, in partial consideration of services performed.

Note 7. Equity-Based Compensation

The Company adopted the Cadrenal Therapeutics, Inc. 2022 Equity Incentive Plan (the "Initial Plan"), on July 11, 2022, which was later amended and restated on October 16, 2022, for purposes of clarifying the application of certain of the rules of the Initial Plan to awards approved before such amendment and restatement of the Initial Plan and to facilitate the transition to the Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan (the "Successor Plan") for the issuance and approval of awards after consummation of the IPO. On October 16, 2022, the Board adopted and the Company's stockholders approved the Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan (the "2022 Plan"), which is a successor to and continuation of the Initial Plan and became effective on January 19, 2023. Upon the effectiveness of the 2022 Plan, it replaced the Initial Plan, except with respect to awards outstanding under the Initial Plan, and no further awards will be available for grant under the Initial Plan.

Subject to certain adjustments, the maximum number of shares of common stock that could have been issued under the Initial Plan and 2022 Plan was initially 133,333 shares. The maximum number of shares of common stock that may be issued under the 2022 Plan will automatically increase on January 1 of each calendar year for a period of ten years commencing on January 1, 2024 and ending on (and including) January 1, 2033, to a number of shares of common stock equal to 20% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; provided, however that the board of directors, or the compensation committee, may act prior to January 1 of a given calendar year to provide that the increase for such year will be a lesser number of shares of common stock. On January 1, 2024, the maximum number of shares of common stock that may be issued under the 2022 Plan increased to 173,636. On July 29, 2024, the Company held its 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting"). At the 2024 Annual Meeting, the Company's stockholders approved an amendment to the 2022 Plan to increase the number of shares of the Company's common stock that will be available for awards under the 2022 Plan by 133,333 shares to 306,969 shares and to amend the "evergreen provision" such that the number of reserved shares of common stock available for issuance each year will be 20% of: (i) the shares of common stock outstanding at December 31; plus (ii) the shares of common stock issuable upon exercise of warrants and pre-funded warrants outstanding at December 31. As of December 31, 2025, 67,813 remained available for future issuance. All available shares may be utilized toward the grant of any type of award under the 2022 Plan.

Weighted average assumptions used in the Black-Scholes model are set forth below:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Risk-free interest rate	3.54% - 4.40%	4.09% - 4.83%
Dividend yield	-	-
Expected term (years)	5.27 - 5.89	5.27 - 5.31
Volatility	73.0% - 75.4%	76.4% - 77.7%

Activity under the Plans for the period from December 31, 2024 to December 31, 2025 is set forth below:

	Number Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2024	156,334	$ 13.20	8.35	$ 420,720
Granted	285,000	19.58	8.45	-
Exercised	(6,667)	9.60	-	-
Canceled/forfeited/expired	(31,667)	17.84	-	-
Outstanding at December 31, 2025	403,000	$ 17.41	8.51	$ 299,096
Options vested and exercisable at December 31, 2025	167,305	$ 15.45	7.83	$ -
Options vested and expected to vest as of December 31, 2025	403,000	$ 17.41	8.51	$ -

The weighted average grant date fair value of options granted during the year ended December 31, 2025 was $12.80. At December 31, 2025, the Company had $2.3 million of unrecognized stock-based compensation expense related to stock options which will be recognized over the weighted average remaining requisite service period of 1.9 years. The Company settles employee stock option exercises with newly issued shares of common stock.

Total stock-based compensation expense and the allocation of stock-based compensation for the periods presented were as follows:

	Years Ended December 31,	
	2025	2024
General and administrative	$ 1,459,585	$ 1,030,657
Research and development	480,311	388,382
Total equity-based compensation	$ 1,939,896	$ 1,419,039

Note 8. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per common share:

	Years Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (13,237,362)	$ (10,651,368)
Denominator:		
Weighted average common shares outstanding	1,993,757	1,219,550
Net loss per common share, basic and diluted	$ (6.64)	$ (8.73)

Since the Company was in a loss position for the periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive securities would have been anti-dilutive. For the periods presented, there were no potential dilutive securities other than stock options and warrants.

The following common stock equivalents were excluded from the calculation of diluted net loss per share applicable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of December 31,	
	2025	2024
Anti-dilutive common stock equivalents:		
Stock options to purchase common stock	403,000	156,334
Warrants to purchase common stock	1,044,167	615,940
Total anti-dilutive common stock equivalents	1,447,167	772,274

Note 9. Leases, Commitments, and Contingencies

Leases

In accordance with ASC 842, Leases, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

At lease inception, the Company determines whether an arrangement is an operating or capital lease. For operating leases, the Company recognizes rent expense, inclusive of rent escalation, on a straight-line basis over the lease term.

The Company classifies leases at the lease commencement date as operating or finance leases and records a right-of-use asset and a lease liability on the balance sheet for all leases with an initial lease term of greater than 12 months. Leases with an initial term of 12 months or less are not recorded in the balance sheet pursuant to the practical expedient available under ASC 842, but payments are recognized as expenses on a straight-line basis over the lease term.

Finance and operating right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. Operating lease assets are further adjusted for prepaid or accrued lease payments. Operating lease expense is recognized on a straight-line basis over the lease term.

In October 2025, the Company amended its office space lease to extend the term by one additional year. The lease agreement (as amended in October 2025) has a term that extends through October 31, 2026. Operating lease expenses were $26,875 and $26,559 for the years ended December 31, 2025 and 2024, respectively. Cash paid for the office lease were $26,875 and $22,319 for the years ended December 31, 2025 and 2024, respectively.

Future annual lease payments under non-cancellable operating leases as of December 31, 2025 were as follows:

2026	$ 23,438
Total lease payments	$ 23,438

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown, because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Indemnification

In accordance with the Company's certificate of incorporation and bylaws, the Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. In addition, the Company has entered into indemnification agreements with its officers and directors. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Note 10. Income Taxes

The Company's loss before provision (benefit) for income taxes for the years ended December 31, 2025 and 2024 was generated in the following jurisdictions:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Domestic	$ (13,237,362)	$ (10,651,368)
Foreign	-	-
Loss before income taxes	$ (13,237,362)	$ (10,651,368)

The Company's provision is $0, which is primarily driven by the federal and state statutory income tax rates on current-year losses, offset by the Company's full valuation allowance.

The components of income tax expense (benefit) were as follows for the years ended December 31, 2025 and 2024:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Current:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total current provision	-	-
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
Total deferred provision	-	-
Provision for income taxes	$ -	$ -

A reconciliation of income tax expense (benefit) to the amount computed by applying the statutory federal income tax rate to the loss from operations is summarized for the years ended December 31, 2025 and 2024, as follows:

	Year Ended December 31, 2025		Year Ended December 31, 2024	
Tax benefit at statutory rate	$ (2,779,846)	21.0%	$ (2,236,787)	21.0%
Effects of changes in tax laws or rates enacted in the current period	(1)	0.0%	-	0.0%
Permanent differences	26,754	-0.2%	5,601	-0.1%
Equity-based compensation	(22,479)	0.2%	89,753	-0.8%
Other	(1,557)	0.0%	5	0.0%
Increase in valuation allowance	2,777,129	-21.0%	2,141,428	-20.1%
	$ -	$ 0.0%	$ -	$ 0.0%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, 2025 and 2024 are shown below. The Company has established a full valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of its deferred tax assets. At such time as it is determined that it is more likely than not that the deferred tax asset will be realized, the valuation allowance will be reduced. The increase in the valuation allowances of approximately $3,188,000 for the year ended December 31, 2025 was primarily due to an increase in the Company's net operating losses and capitalized research costs occurring during the current year.

The components of deferred tax assets and liabilities consisted of the following at December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Net operating loss carryforwards	$ 5,589,000	$ 2,748,000
Equity-based compensation	646,000	286,000
Capitalized research costs	1,520,000	1,475,000
Accruals and other temporary differences	177,000	235,000
Total deferred tax assets	7,932,000	4,744,000
Valuation allowance for deferred tax assets	(7,932,000)	(4,744,000)
Net deferred tax assets	$ -	$ -

As of December 31, 2025, the Company has net operating loss carryforwards of approximately $23.3 million and $15.9 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. As of December 31, 2024, the Company has net operating loss carryforwards of approximately $11.3 million and $8.7 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The Company's US federal and state net operating loss carryovers of $23.3 million and $11.3 million as of December 31, 2025 and 2024, respectively, can be carried forward indefinitely, but the deduction related to these net operating losses is limited to 80% of taxable income when utilized in future years.

The utilization of net operating loss carryforwards and tax credit carryovers could be subject to annual limitations under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state tax provisions, due to ownership change limitations that may have occurred previously or that could occur in the future. These ownership changes limit the amount of net operating loss carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. The Company has not conducted an analysis of an ownership change under section 382. To the extent that a study is completed and an ownership change is deemed to occur, the Company's net operating losses and tax credits could be limited.

The Company applies the two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained upon audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount, which is more than 50% likely of being realized upon ultimate settlement. Income tax positions must meet a more likely than not recognition threshold to be recognized under ASC 740 upon initial measurement and in subsequent periods. ASC 740-10 also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

At December 31, 2025, the Company did not have any significant uncertain tax positions. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2025, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations and comprehensive loss. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

All of the Company's tax years will remain open for examination by the federal and state taxing authorities to the extent that the Company's tax attributes are utilized in future years to offset income or income taxes.

Note 11. Subsequent Events

The Company has evaluated events that occurred through March 30, 2026, the date that the financial statements were issued, and determined that there have been no events that have occurred that would require adjustments to its disclosures in the financial statements except for the transactions described below.

From January 1, 2026 through March 30, 2026, the Company sold 168,690 shares of its common stock through its at-the-market (ATM) facility generating gross proceeds of approximately $1.4 million and net proceeds of approximately $1.3 million.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We have adopted and maintain disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report, is collected, recorded, processed, summarized, and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such a date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

As required by SEC rules and regulations implementing Section 404 of SOX, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with GAAP. 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 the transactions and dispositions of the assets of our company,

2. provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, 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 the prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our financial statements. 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 or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on our assessments and those criteria, management determined that our internal controls over financial reporting were effective as of December 31, 2025.

This Annual Report does not include an attestation report of internal controls from our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Changes in Internal Control over Financial Reporting

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

Report of Independent Registered Public Accounting Firm

This Annual Report does not include an attestation report by WithumSmith+Brown, PC, our independent registered public accounting firm, regarding internal control over financial reporting. As a smaller reporting company, our internal control over financial reporting was not subject to audit by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report.

Item 9B. Other Information.

During the three months ended December 31, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "nonRule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

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

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information About our Executive Officers and Directors

The following table sets forth information concerning our directors and executive officers, including their ages, as of March 30, 2026. There are no family relationships among any of our directors or executive officers.

Name	Age	Position
Executive Officers and Directors		
Quang X. Pham	61	Chairman and Chief Executive Officer
Matthew Szot	51	Chief Financial Officer
James Ferguson	72	Chief Medical Officer
Jeffrey Cole	58	Chief Operating Officer
Non-Employee Directors		
John R. Murphy	75	Director
Glynn Wilson	79	Director
Steven Zelenkofske	67	Director
Lee Golden	58	Director

Quang X. Pham, Chairman and Chief Executive Officer

Quang X. Pham has served as our Chief Executive Officer since he formed the Company in 2022. He previously served as Chairman & CEO of Espero BioPharma ("Espero"), which he also founded, and which previously advanced tecarfarin, a Phase 3-ready, orphan-designed blood thinner, since its formation in March 2015 until July 2020, at which time a petition for assignment for the benefit of creditors was filed in the Delaware Chancery Court, seeking an assignment of Espero's assets. Under his leadership, Cadrenal has also acquired frunexian, a fast-acting Factor XIa anticoagulant in Phase 2 for coronary artery bypass grafting (CABG), and VLX-1005, a 12-LOX inhibitor (Phase 2 complete) for the treatment of heparin-induced thrombocytopenia (HIT). Prior to Espero, he founded and served as Chairman and CEO of Lathian Systems, a venture-backed digital and database marketing company serving the pharmaceutical industry until it was acquired by D&R Communications. Mr. Pham is a graduate of UCLA. He is a recipient of the EY® Entrepreneur of the Year, BioFlorida's Executive of the Year Awards, and a bestselling author. He also served as a U.S. Marine Corps aviator in two overseas conflicts. We believe Mr. Pham is qualified to serve on our Board of Directors because of his significant business, mergers and acquisitions, and fundraising experience, numerous interactions with the FDA, continuous eight-year history with tecarfarin development, and his extensive knowledge of the pharmaceutical industry and our competitors.

Matthew Szot, Chief Financial Officer

Matthew Szot has served as our Chief Financial Officer since May 2022. From March 2010 to November 2021, Mr. Szot served as Executive Vice President and Chief Financial Officer of S&W Seed Company, a Nasdaq-listed agricultural seed biotechnology company. Since September 2020, Mr. Szot has served on the Board of Directors and as Chairman of the Audit Committee of INVO Fertility, Inc., a Nasdaq-listed commercial-stage fertility company. He also serves on the Board of Directors and as Chairman of the Audit, Compensation, and Nominating and Governance Committees of SenesTech, Inc., a Nasdaq-listed life science company with next-generation technologies for managing animal pest populations through fertility control. From June 2018 to August 2019, Mr. Szot served on the Board of Directors and as Chairman of the Audit Committee of Eastside Distilling, a Nasdaq-listed craft spirits company. From 2007 until 2011, Mr. Szot served as the Chief Financial Officer for Cardiff Partners, LLC, a strategic consulting company that provided executive financial services to various publicly traded and privately held companies. From 2003 to 2006, he served as Chief Financial Officer of Rip Curl, Inc., a market leader in wetsuit and action sports apparel products. From 1996 to 2003, Mr. Szot was a Certified Public Accountant with KPMG in the San Diego and Chicago offices and served as an Audit Manager for various publicly traded companies. Mr. Szot graduated from the University of Illinois, Champaign-Urbana with a BS in Agricultural Economics/Accountancy. He is a Certified Public Accountant in the State of California. Mr. Szot brings a wealth of knowledge in equity and debt financings, mergers and acquisitions, scaling global organizations through rapid growth, corporate strategy, corporate governance, and SEC reporting and compliance. He also has extensive experience in international operations, joint ventures, and technology license agreements.

James J. Ferguson III, Chief Medical Officer

James Ferguson has served as our Chief Medical Officer since February 2025. Dr. Ferguson is a well-recognized, industry-leading academic and clinical expert with over 25 years of experience in the cardiovascular space. Prior to joining Cadrenal, he served as the Chief Medical Officer of Matinas BioPharma Holdings, Inc. from February 2019 until October 2024 and as the Cardiovascular and Bone Therapeutic Area Head for U.S. Medical Affairs, at Amgen, multinational biopharmaceutical company, from 2016 to 2019. Prior to Amgen, Dr. Ferguson held a number of senior positions at AstraZeneca, a multinational pharmaceutical and biopharmaceutical company, including Vice President of U.S. Cardiovascular Medical and Scientific External Relations, Therapeutic Area Vice President of Cardiovascular Global Medical Affairs, U.S. Development Brand Leader for BRILINTA®, and Senior Director, Clinical Research. Before joining AstraZeneca, he was Vice President of Surgical and Critical Care for The Medicines Company. In addition, Dr. Ferguson had more than 20 years of academic experience as the Associate Director of Clinical Cardiology Research at the Texas Heart Institute, Co-Director of the Cardiology Fellowship Training Program at St. Luke's Episcopal Hospital in Houston, where he was an Associate Professor of Medicine at Baylor College of Medicine, and a Clinical Assistant Professor at the University of Texas Health Science Center at Houston. Dr. Ferguson has served on the Editorial Board of numerous peer-reviewed journals and has over 400 publications and book chapters. Dr. Ferguson received his B.A. (cum Laude) in Biology from Harvard University, his M.D. from the University of Pennsylvania School of Medicine and completed his post-graduate training at the University of Michigan Medical Center, Ann Arbor, Michigan and Beth Israel Hospital, Boston, Massachusetts.

Jeffrey Cole, Chief Operating Officer

Jeffrey Cole has served as our Chief Operating Officer since February 2024. Mr. Cole brings over 25 years of experience in global pharmaceutical manufacturing and commercial operations, finance, and corporate development. Prior to his appointment as Chief Operating Officer, he served as a consultant to the Company beginning in July 2022. Since August 2010, Mr. Cole has served as Principal of J. Scott Capital, LLC, a firm that provides executive and capital resources to emerging growth life science organizations, including Cadrenal prior to his appointment as Chief Operating Officer. From March 2015 to July 2020, he served as President, Chief Financial Officer and co-founder of Espero, where he also served as a director from April 2016 until August 2018. From August 2010 to February 2015, he served as President and co-founder of MarcasUSA, LLC, a marketer and distributor of over-the-counter pharmaceuticals.

From May 2008 to August 2010, Mr. Cole was Chief Financial Officer of Legacy Pharmaceuticals International GmbH, a global contract manufacturing organization, and founding President of its generic pharmaceuticals subsidiary Solco Healthcare U.S., Inc. From February 2002 to May 2008, Mr. Cole held various executive positions at Valeant Pharmaceuticals International, Inc. (now Bausch Health Companies), including General Manager, Vice President of Corporate Development, and Chief Financial Officer for North America. Prior to the pharmaceutical industry, Mr. Cole worked in the technology industry from January 2000 to January 2002. Mr. Cole also served as Principal in the Financial Management Consulting practice at PricewaterhouseCoopers from July 1994 to January 2000. Mr. Cole holds an MBA with honors from the University of Michigan and a BS in accounting from the University of Southern California.

John R. Murphy, Director

John R. Murphy has served on our Board of Directors since January 2023. Since 2003, John R. Murphy has served on the Board of Directors of O'Reilly Automotive, Inc., where he served as Chairman of the Audit Committee from 2003 until 2019. Currently, he serves on the Audit Committee and Human Capital and Compensation Committee (Chair). Mr. Murphy also served on the Board of Directors of Summit Materials, Inc. from 2012 to 2024, where he was the Chair of the Audit Committee. Previously he served as a Director, Audit Committee Chairman, and Member of the Nominating and Governance Committee of Apria, Inc. ("Apria") from August 2019 until April 2022. He also served on the Board of Directors of Alight Solutions LLC and was the Audit Committee Chairman from February 2020 until May 2022 and DJO Global, Inc. from 2012 until 2019. Mr. Murphy also previously served on the Board of Directors of Graham Packaging, Inc. and Accuride Corporation, Inc. He previously served as Interim Chief Financial Officer of Summit Materials, Inc. in 2013, Senior Vice President and Chief Financial Officer of Smurfit-Stone Container Corporation from 2009 to 2010, and Chief Financial Officer, then President and Chief Operating Officer, then President and Chief Executive Officer with Accuride Corporation, Inc. from 1998 to 2008. Mr. Murphy holds a Bachelor of Science in Accounting from Pennsylvania State University and a Master of Business Administration from the University of Colorado, and is a Certified Public Accountant. We believe Mr. Murphy is qualified to serve on our Board of Directors due to his substantial experience guiding public company boards and knowledge and experience as chief financial officer.

Glynn Wilson, Ph.D., Director

Dr. Glynn Wilson has served on our Board of Directors since January 2023. He is currently Chief Executive Officer and Director of Caring Brands, Inc. He was on the Board of Directors of Jupiter Wellness, Inc. ("Jupiter") since November 2018, serving as Chairman since October 2019. Dr. Wilson also served as Jupiter's Chief Scientific Officer since April 2021 and served as its Head of Research and Development from October 2019 to July 2021. Dr. Wilson previously served as a Director of TapImmune, Inc. from February 2005 until October 2018 and as Chief Executive Officer from July 2009 through September 2017. Dr. Wilson also served as President of Auriga Laboratories, Inc. from June 1, 2005 through March 13, 2006, and as Chief Scientific Officer from March 13, 2016 through August 25, 2006. He was the Chief Scientific Officer at Tacora Corporation from 1994 to 1997 and was the Vice-President, R&D, at Access Pharmaceuticals from 1997 to 1998. Dr. Wilson was Research Area Head, Cell and Molecular Biology in Advanced Drug Delivery at Ciba-Geigy Pharmaceuticals from 1984 – 1989 and Worldwide Head of Drug Delivery at SmithKline Beecham from 1989 to 1994. He was a faculty member at Rockefeller University, New York, in the laboratory of the Nobel Laureates, Sanford Moore and William Stein, from 1974 to 1979. Dr. Wilson is a recognized leader in the development of drug delivery systems and has been involved in taking lead products & technologies from concept to commercialization. Dr. Wilson has a Ph.D. in Biochemistry and conducted medical research at The Rockefeller University, New York. We believe that Dr. Wilson's extensive background of success in corporate management and product development, with tenures in both multinational and start-up biotech organizations, will assist us as we work to complete our drug development and commercialization activities.

Steven Zelenkofske, D.O., Director

Dr. Steven Zelenkofske has served on our Board of Directors since January 2023. Dr. Zelenkofske served on the Board of Directors of Dinaqor AG from May 2020 until June 2025. He is currently serving as President of SLZ Consulting, LLC. He is currently a SR Medical Advisor to SSI Strategy. He has served as Chief Medical Officer of SwanBio Therapeutics since June 1, 2020 until September 2022. Dr. Zelenkofske was also an advisor to Veralox Therapeutics, Inc., as Chair of the Scientific Advisory Board, a position he held from March 2020 until November 2025. Previously, he served as Executive Vice President and Chief Medical Officer of Achillion Pharmaceuticals, Inc. from August 2018 until April 2020. Dr. Zelenkofske also served as Chief Medical Officer of uniQure N.V., from June 2017 to August 2018. Prior to joining uniQure, N.V., Dr. Zelenkofske was Vice President and Therapeutic Head of Cardiovascular/Metabolism for AstraZeneca, a biopharmaceutical company, from November 2014 to June 2017. From January 2009 to November 2014, Dr. Zelenkofske was Senior Vice President Clinical and Medical Affairs and Chief Medical Officer of Regado Biosciences, Inc., a biotechnology company. Dr. Zelenkofske has held leadership positions at Sanofi Pharmaceuticals, a global healthcare company, Boston Scientific, a medical device company, and Novartis Pharmaceuticals, a global healthcare company. Dr. Zelenkofske holds Bachelor of Science and Master of Science degrees from Emory University and a Doctor of Osteopathic Medicine degree from the Philadelphia College of Osteopathic Medicine. He conducted his graduate medical education at the Philadelphia College of Osteopathic Medicine and is board-certified in internal medicine, cardiology and cardiac electrophysiology. We believe that Dr. Zelenkofske is qualified to serve on our Board of Directors due to his knowledge and experience working in the biotech and pharmaceutical space will assist us as we work to complete our drug development and commercialization activities.

Lee Golden, Director

Dr. Lee Golden has served on our Board of Directors since November 2025. Dr. Golden currently serves as Executive Vice President and Chief Medical Officer at PTC Therapeutics, Inc., a Nasdaq-listed company, where he leads global clinical development across a broad rare disease pipeline. Before joining PTC, Dr. Golden served as the Chief Medical Officer at Espero BioPharma, Inc., a development-stage cardiovascular pharmaceutical company focused on developing drugs for unmet needs in thrombosis and cardiac rhythm control, and as Chief Medical Officer at Gemphire Therapeutics, Inc. He also serves as Chairman of the Advisory Board for Coagulation Sciences LLC. Previously, Dr. Golden held senior roles at Pfizer, Actelion, Eisai, Mesoblast, and others, with a long-standing focus on cardiovascular and hematologic drug development. Dr. Golden has more than 25 years of industry experience, with increasing responsibilities, managing global, cross-functional teams responsible for creating and deploying strategic and clinical development plans. He has extensive experience across multiple therapeutic areas and with orphan diseases. Dr. Golden received a B.S. from the University of Michigan and an MD from New York University School of Medicine, where he also completed his Internal Medicine residency. He then completed Fellowships in Cardiology at the University of Miami and Interventional Cardiology at George Washington University Hospital, where he also served as an adjunct instructor. We believe that Dr. Golden is qualified to serve on our Board of Directors due to his knowledge and experience in cardiovascular drug development and with public companies, which will assist us as we work to complete our drug development and commercialization activities.

Selection of Officers

Our executive officers serve at the discretion of our Board of Directors. There are no familial relationships among our directors and executive officers.

Board Composition

Pursuant to our amended and restated certificate of incorporation, our Board of Directors is divided into three classes — Class I, Class II, and Class III — with each class serving staggered three-year terms and subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws, our Board of Directors consists of five members, as a classified board of directors. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held in 2026 for the Class I directors, 2027 for the Class II directors, and 2028 for the Class III director. Our directors are divided among the three classes as follows:

- the Class I directors are Quang X. Pham and Dr. Glynn Wilson and their terms will expire at the annual meeting of stockholders to be held in 2026;
- the Class II directors are John Murphy and Dr. Lee Golden and their terms will expire at the annual meeting of stockholders to be held in 2027; and
- the Class III director is Steven Zelenkofske and his term will expire at the annual meeting of stockholders to be held in 2028.

Upon expiration of the term of a class of directors, new directors for that class will be elected for three-year terms at the annual meeting of stockholders during the year in which that term expires. Each director's term shall continue until the election and qualification of his or her successor, or the director's earlier death, resignation or removal. Any additional directorships resulting from an increase in the number of authorized directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The classification of our Board of Directors may have the effect of delaying or preventing a change of our management, a change of control or other corporate actions. Under Delaware law, our amended and restated certificate of incorporation our directors may be removed only for cause.

Director Independence

Under the rules of the Nasdaq Stock Market, independent directors must comprise a majority of our Board of Directors. The rules of the Nasdaq Stock Market, as well as those of the SEC, impose several requirements with respect to the independence of our directors. Our Board of Directors has conducted a review of its proposed composition, the composition of its proposed committees and the independence of each director in accordance with these rules. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our Board of Directors has determined that John R. Murphy, Dr. Steven Zelenkofske, Dr. Glynn Wilson and Dr. Lee Golden do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of the Nasdaq Stock Market and the SEC. In making this determination, our Board of Directors considered relationships that each director has with the Company, including the transactions described under the section entitled "Certain Relationships and Related Party Transactions."

Committees of the Board of Directors

Our Board of Directors has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, each of which has the composition and responsibilities described below. Each committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Stock Market, copies of which are available on our website at *www.cadrenal.com*. From time to time, our Board of Directors may establish other committees to facilitate the management of our business as it sees fit and in accordance with applicable law and our corporate governance documents. In April 2025, our Board of Directors established a Science and Technology Committee, which operates under a written charter and has the composition and responsibilities described below. Members will serve on these committees until their resignation or until otherwise determined by our Board of Directors.

Audit Committee. Our Audit Committee consists of John Murphy, Dr. Steven Zelenkofske and Dr. Glynn Wilson, with John Murphy serving as the Chair of the Audit Committee. Our Board of Directors has determined that all of the directors who serve on our Audit Committee are independent within the meaning of the rules and regulations of the Nasdaq Stock Market and Rule 10A-3 under the Exchange Act. In addition, our Board of Directors has determined that John Murphy qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Stock Market. The primary purpose of the Audit Committee is to oversee the quality and integrity of our accounting and financial reporting processes and the audit of our financial statements. Specifically, the Audit Committee:

- selects and hires the independent registered public accounting firm to audit our financial statements;
- helps to ensure the independence and performance of the independent registered public accounting firm;
- approves audit and non-audit services and fees;
- reviews financial statements and discusses with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal controls over financial reporting and disclosure controls;
- prepares the audit committee report that the SEC requires to be included in our annual proxy statement;
- reviews reports and communications from the independent registered public accounting firm;
- reviews the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- reviews our policies on risk assessment and risk management;
- reviews and approves related party transactions; and
- establishes and oversees procedures for the receipt, retention and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Compensation Committee. Our Compensation Committee consists of Dr. Steven Zelenkofske and John Murphy, with Dr. Steven Zelenkofske serving as the Chair of the Compensation Committee. Our Board of Directors has determined that all of the directors who serve on our Compensation Committee are independent under the listing standards, are “non-employee directors” as defined in rule 16b-3 promulgated under the Exchange Act and are “outside directors” as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended (the “Code”). Our Compensation Committee oversees our compensation policies, plans and benefits programs. The Compensation Committee also:

- oversees our overall compensation philosophy and compensation policies, plans and benefit programs;
- reviews and recommends to our Board of Directors for approval compensation for our executive officers and directors;
- Will prepare the compensation committee report that the SEC would require to be included in our annual proxy statement if we were no longer deemed to be an emerging growth company or a smaller reporting company; and
- administers our equity compensation plans.

Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee consists of Dr. Glynn Wilson and Dr. Steven Zelenkofske, with Dr. Glynn Wilson serving as the Chair of the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee oversees and assists our Board of Directors in reviewing and recommending nominees for election as directors. All members who serve on the Nominating and Corporate Governance Committee are independent directors as defined under the listing standards of the Nasdaq Stock Market. Specifically, the Nominating and Corporate Governance Committee:

- identifies, evaluates and makes recommendations to our Board of Directors regarding nominees for election to our Board of Directors and its committees, including consideration of recommendations for election to the Board of Directors by stockholders if submitted in a timely manner in accordance with the procedures set forth in our bylaws;
- considers and makes recommendations to our Board of Directors regarding the composition of our Board of Directors and its committees;
- reviews developments in corporate governance practices;
- evaluates the adequacy of our corporate governance practices and reporting; and
- evaluates the performance of our Board of Directors and of individual directors.

Science and Technology Committee. Our Science and Technology Committee (the "S&T Committee") consists of Dr. Steven Zelenkofske, Dr. Glynn Wilson and Dr. Lee Golden, with Dr. Steven Zelenkofske serving as the Chair of the S&T Committee. The primary purpose of the S&T Committee is to periodically examine management's strategic direction and investment in our research and development and technology initiatives. Specifically, the S&T Committee:

- reviews, evaluates and reports to the Board regarding the performance of the research and development leaders in achieving long-term strategic goals and objectives and the quality, direction and competitiveness of our research and development programs;
- identifies and discusses significant emerging science and technology issues and trends;
- reviews and advises the Board on the acquisition and/or in license of other potential assets;
- determines whether there is sufficient and ongoing external review from world-class experts across both research and development, pertaining to our therapeutic areas;
- reviews our approaches to acquiring and maintaining a range of distinct technology positions;
- evaluates the soundness/risks associated with the technologies in which we are investing;
- periodically reviews our overall patent strategies; and
- monitors the progress of our research and development pipeline.

Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee will be serving, or will have ever served, as an officer or employee of ours. None of our executive officers currently serves, or has served during the last completed year, as a member of the Board of Directors, Compensation Committee or other board committee performing equivalent functions of any entity that has one or more executive officers who served as a member of our Board of Directors during the last completed year.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that applies to all officers, directors and employees, including those officers responsible for financial reporting. The full text of the Code of Conduct is posted on our website at *www.cadrenal.com* and a copy will be made available to stockholders without charge, upon request, in writing to the Corporate Secretary at 822 A1A North, Suite 306, Ponte Vedra, Florida 32082. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website or by filing with the SEC a Current Report on Form 8-K, in each case if such disclosure is required by SEC or the Nasdaq rules.

Insider Trading/Anti-Hedging/Anti-Pledging

We have adopted an insider trading policy (the "Trading Policy") that is designed to promote compliance with federal securities laws, rules and regulations, as well as the rules and regulations of the Nasdaq Stock Market. The Trading Policy provides Cadrenal's standards on trading and causing the trading of our securities or securities of other publicly traded companies while in possession of confidential information. It prohibits trading in certain circumstances and applies to us and all of our directors, officers and employees as well as independent contractors or consultants who have access to material nonpublic information of Cadrenal. Additionally, our Trading Policy imposes special additional trading restrictions applicable to all of our directors and executive officers. The Trading Policy also prohibits, among other things, short-term trading, short sales, options trading, hedging and pledging. Consequently, no employee, executive officer or director may enter into a hedge or pledge of the Company's Common Stock, including short sales, derivatives, put options, swaps and collars. A copy of our Trading Policy is available on our website at *www.cadrenal.com* and is annexed as an exhibit to this Annual Report.

Limitation of Liability and Indemnification

Our amended and restated bylaws provide indemnification for our directors and executive officers to the fullest extent permitted by the Delaware General Corporation Law. The indemnification agreements that we have entered into with each of our current executive officers and directors may, in some cases, be broader than the specific indemnification provisions contained under Delaware law.

In addition, as permitted by Delaware law, our amended and restated certificate of incorporation includes provisions that eliminate the personal liability of our directors and officers for monetary damages resulting from breaches of certain fiduciary duties as a director or officer, as applicable, except to the extent such an exemption from liability thereof is not permitted under the Delaware General Corporation Law. The effect of these provisions is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director or officer for breach of fiduciary duties as a director or officer, subject to certain exceptions in which case the director or officer would be personally liable. An officer may not be exculpated for any action brought by or in the right of the corporation. A director may not be exculpated for improper distributions to stockholders. Further, pursuant to Delaware law a director or officer may not be exculpated for:

- any breach of his or her duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; and
- any transaction from which the director or officer derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of directors and officers, then the liability of our directors and officers will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our certificate of incorporation does not eliminate the duty of care owed by our directors and officers and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect the responsibilities of directors and officers under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In the case of an action or proceeding by or in the right of our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these charter and bylaw provisions are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors and officers for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. Moreover, a stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

We have entered into separate indemnification agreements with each of our current executive officers and intend to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification that will be provided for in our amended and restated bylaws. The indemnification agreements and our amended and restated bylaws require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2025, which consist of our principal executive officer and the next two most highly compensated executive officers, are:

- Quang X. Pham, Chairman and Chief Executive Officer
- Matthew Szot, Chief Financial Officer
- James Ferguson, Chief Medical Officer

Summary Compensation Table

The following table shows compensation awarded to or earned by our named executive officers, for the fiscal year ended December 31, 2025 and 2024.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Stock Award ($)[2]	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Quang X. Pham	2025	$ 751,275	$ 296,754	—	$ 847,665	—	$ 14,000	$ 1,909,694
Chief Executive Officer	2024	$ 708,750	$ 407,531	—	$ 93,300	—	$ 13,800[3]	$ 1,223,381
Matthew Szot	2025	$ 459,716	$ 181,588	—	$ 652,050	—	$ 13,665	$ 1,307,019
Chief Financial Officer	2024	$ 435,850	$ 263,126	—	$ 155,503	—	$ 13,800[4]	$ 868,279
James J. Ferguson	2025	$ 457,414	$ 136,350	—	$ 778,920	—	$ 23,125[5]	$ 1,395,809
Chief Medical Officer	2024	—	$ —	—	$ —	—	$ —	$ —

(1) Bonuses for 2025 were accrued as of December 31, 2025, but such bonuses were paid in the first quarter of 2026.

(2) In accordance with SEC rules, this column reflects the aggregate fair value of the stock and option awards granted as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). The valuation assumptions used in determining such amounts are described in Note 1 and Note 7 to our audited financial statements included elsewhere in this Annual Report. These amounts do not correspond to the actual value that may be realized by the Named Executive Officers upon vesting or exercise of such awards.

(3) All other compensation for Mr. Pham included $14,000 and $13,800 of 401K employer match contributions for 2025 and 2024, respectively.

(4) All other compensation for Mr. Szot in 2025 included $13,665 of 401K employer match contributions. All other compensation for Mr. Szot in 2024 included $ 13,800 of 401K employer match contributions.

(5) All other compensation for Dr. Ferguson in 2025 included $12,625 of 401K employer match contributions and $10,500 of consulting fees earned prior to his appointment as Chief Medical Officer effective February 5, 2025.

Agreements with Our Named Executive Officers

Quang X. Pham Employment Agreement

We entered into an employment agreement with Quang X. Pham, our Chief Executive Officer, on March 1, 2022. Mr. Pham's employment is at-will. Mr. Pham's annual base salary pursuant to the employment agreement was initially $420,000, which increased to $675,000 upon the completion of our initial public offering. On January 1, 2024, his salary was increased to $708,750, on January 1, 2025, his salary was increased to $751,275 and on January 1, 2026, his salary was increased to $777,570. Mr. Pham is eligible for an annual target bonus of up to 50% of his base salary, with the actual amount of the bonus, if any, based upon the achievement by Mr. Pham and us of the applicable performance targets and goals as set by our board of directors or our compensation committee, with individual performance targets determined in consultation with Mr. Pham.

Pursuant to Mr. Pham's employment agreement, we will need to provide 90 days' written notice to terminate his employment without cause. If Mr. Pham resigns for Good Reason, as such term is defined in the employment agreement, or is terminated without cause (as such terms are defined below), he is entitled to (i) a lump sum payment equal to 24 months of his base salary, (ii) a lump sum payment equal to his target bonus for the calendar year in which his termination date occurs, (iii) full acceleration of any outstanding equity or equity-based awards that he has with respect to us or any of our affiliates as of his termination date, (iv) extension of exercisability for the full term of any stock option, and (v) payment of his full COBRA premiums for 24 months following his termination date, if applicable conditions are met.

Mr. Pham is required to provide us 90 days' written notice of the condition that qualifies as a Good Reason for his resignation and we will have 30 days from receipt of such notice to remedy such condition. If Mr. Pham fails to provide the required notice such that we have the opportunity to cure the condition prior to his resignation, or if he resigns more than nine months after the initial existence of the condition, his resignation shall not be deemed for Good Reason.

If we terminate Mr. Pham's employment for Cause, as such term is defined in the employment agreement, or if Mr. Pham voluntarily terminates his employment without Good Reason upon 30 days written notice to us, Mr. Pham shall be entitled to receive Accrued Obligations, as such term is defined in the employment agreement and which includes earned, but unpaid, base salary, accrued, but unused, vacation, and vested benefits, as of the date of termination.

Pursuant to Mr. Pham's employment agreement, if his employment is terminated due to his death or disability (as defined in the employment agreement), he is entitled to (i) a lump sum payment equal to twelve months of his base salary, (ii) full acceleration of any outstanding equity or equity-based awards that he has with respect to us or any of our affiliates as of his termination date, and (iii) Accrued Obligations.

Matthew Szot Employment Agreement

Upon completion of the initial public offering, we entered into an employment agreement with Matthew Szot, our Chief Financial Officer, dated January 24, 2023. He initially received an annual salary of $375,000, which was increased to $415,000 effective June 1, 2023, $435,750 effective January 1, 2024, $459,716 effective January 1, 2025 and $475,806 effective January 1, 2026. Mr. Szot is eligible for an annual target bonus of up to 50% of his base salary, with the actual amount of the bonus, if any, based upon the achievement of Mr. Szot and us of the applicable performance targets and goals as set by our board of directors.

Pursuant to Mr. Szot's employment agreement, we will need to provide 90 days' written notice to terminate his employment without Cause, as such term is defined in the employment agreement. If Mr. Szot resigns for Good Reason, as such term is defined in the employment agreement, or is terminated without Cause, unrelated to a Change of Control, as such term is defined in the employment agreement, he is entitled to (i) continuation of his base salary in effect immediately prior to termination for a period of 12 months, (ii) a lump sum payment equal to his target bonus for the calendar year in which his termination date occurs, (iii) full acceleration of any outstanding equity or equity-based awards as of his termination date, (iv) extension of exercisability for the full term of any stock option, and (v) payment of his full COBRA premiums for 12 months following his termination date, if applicable conditions are met.

Mr. Szot will be required to provide us 90 days' written notice of the condition that qualifies as a Good Reason for his resignation and we will have 30 days from receipt of such notice to remedy such condition. If Mr. Szot fails to provide the required notice such that we do not have the opportunity to cure the condition prior to his resignation, or if he resigns more than nine months after the initial existence of the condition, his resignation shall not be deemed for Good Reason.

If at any time during a Change of Control Period, as such term is defined in the employment agreement, Mr. Szot's employment is terminated without Cause or Mr. Szot resigns for Good Reason, he is entitled to: (i) a lump sum payment equal to 12 months of his base salary in effect immediately prior to termination plus his target bonus for the fiscal year in which his termination date occurs; (ii) full acceleration of any outstanding equity or equity-based awards as of his termination date; (iii) extension of exercisability for the full term of any stock option; and payment of his full COBRA premiums for 12 months following his termination date, if applicable conditions are met.

If we terminate Mr. Szot's employment for Cause, or if Mr. Szot voluntarily terminates his employment without Good Reason upon 30 days written notice to us, Mr. Szot shall be entitled to receive Accrued Obligations, as such term is defined in the employment agreement, as of the date of termination.

Pursuant to Mr. Szot's employment agreement, if his employment is terminated due to his death or Disability (as defined in the employment agreement), he is entitled to (i) a lump sum payment equal to twelve months of his base salary, (ii) full acceleration of any outstanding equity or equity-based awards that he has with respect to us or any of our affiliates as of his termination date; and (iii) Accrued Obligations.

James Ferguson Employment Agreement

On February 4, 2025, we entered into an employment agreement with James Ferguson, our Chief Medical Officer, effective as of February 5, 2025, which provides for: (i) an initial annual salary of $505,000, (ii) a discretionary annual target bonus of up to 40% of his base salary, with the actual amount of the bonus, if any, based upon the achievement of Dr. Ferguson and us of the applicable performance targets and goals as set by our board of directors; and (iii) a stock option award for 60,000 shares of our Common Stock, which options shall vest 25% on March 1, 2026, with the balance vesting pro rata over thirty-six (36) months. Effective January 1, 2026, Dr. Ferguson's salary was increased to $512,575. Dr. Ferguson is also bound by confidentiality provisions.

If Dr. Ferguson's employment agreement is terminated by us without Cause or by Dr. Ferguson for Good Reason, he will be entitled to receive continuation of payment of his base salary and the payment of his COBRA premiums for a period of 12 months.

Dr. Ferguson will be required to provide us 90 days' written notice of the condition that qualifies as a Good Reason for his resignation and we will have 30 days from receipt of such notice to remedy such condition. If Dr. Ferguson fails to provide the required notice such that we do not have the opportunity to cure the condition prior to his resignation, or if he resigns more than 15 days after expiration of our 30 day period to remedy the condition, his resignation shall not be deemed for Good Reason.

If at any time during a Change of Control Period, as such term is defined in the employment agreement, Dr. Ferguson's employment is terminated without Cause or Dr. Ferguson resigns for Good Reason, he is entitled to: (i) a lump sum payment equal to 12 months of his base salary in effect immediately prior to termination plus his target bonus for the fiscal year in which his termination date occurs; (ii) full acceleration of any outstanding equity or equity-based awards as of his termination date; (iii) extension of exercisability for the full term of any stock option; and payment of his full COBRA premiums for 12 months following his termination date, if applicable conditions are met.

If we terminate Dr. Ferguson's employment for Cause, or if Dr. Ferguson voluntarily terminates his employment without Good Reason upon 30 days written notice to us, Dr. Ferguson shall be entitled to receive Accrued Obligations, as such term is defined in the employment agreement, as of the date of termination.

Pursuant to Dr. Ferguson's employment agreement, if his employment is terminated due to his death or Disability (as defined in the employment agreement), he is entitled to (i) a lump sum payment equal to twelve months of his base salary, (ii) full acceleration of any outstanding equity or equity-based awards that he has with respect to us or any of our affiliates as of his termination date; and (iii) Accrued Obligations.

Jeffrey Cole Employment Agreement

On February 12, 2024, we entered into an employment agreement with Jeffrey Cole, our Chief Operating Officer, effective February 8, 2024. He initially received an annual salary of $405,000, which was increased to $425,250 effective January 1, 2025 and $440,134 effective January 1, 2026. Mr. Cole is eligible for an annual target bonus of up to 40% of his base salary, with the actual amount of the bonus, if any, based upon the achievement of Mr. Cole and us of the applicable performance targets and goals as set by our board of directors.

Pursuant to Mr. Cole's employment agreement, we will need to provide 90 days' written notice to terminate his employment without Cause, as such term is defined in the employment agreement. If Mr. Cole resigns for Good Reason, as such term is defined in the employment agreement, or is terminated without Cause, unrelated to a Change of Control, as such term is defined in the employment agreement, he is entitled to (i) continuation of his base salary in effect immediately prior to termination for a period of 12 months, (ii) a lump sum payment equal to his target bonus for the calendar year in which his termination date occurs, (iii) full acceleration of any outstanding equity or equity-based awards as of his termination date, (iv) extension of exercisability for the full term of any stock option, and (v) payment of his full COBRA premiums for 12 months following his termination date, if applicable conditions are met.

Mr. Cole will be required to provide us 90 days' written notice of the condition that qualifies as a Good Reason for his resignation and we will have 30 days from receipt of such notice to remedy such condition. If Mr. Cole fails to provide the required notice such that we do not have the opportunity to cure the condition prior to his resignation, or if he resigns more than 15 days after expiration of our 30 day period to remedy the condition, his resignation shall not be deemed for Good Reason.

If at any time during a Change of Control Period, as such term is defined in the employment agreement, Mr. Cole's employment is terminated without Cause or Mr. Cole resigns for Good Reason, he is entitled to: (i) a lump sum payment equal to 12 months of his base salary in effect immediately prior to termination plus his target bonus for the fiscal year in which his termination date occurs; (ii) full acceleration of any outstanding equity or equity-based awards as of his termination date; (iii) extension of exercisability for the full term of any stock option; and payment of his full COBRA premiums for 12 months following his termination date, if applicable conditions are met.

If we terminate Mr. Cole's employment for Cause, or if Mr. Cole voluntarily terminates his employment without Good Reason upon 30 days written notice to us, Mr. Cole shall be entitled to receive Accrued Obligations, as such term is defined in the employment agreement, as of the date of termination.

Pursuant to Mr. Cole's employment agreement, if his employment is terminated due to his death or Disability (as defined in the employment agreement), he is entitled to (i) a lump sum payment equal to twelve months of his base salary, (ii) full acceleration of any outstanding equity or equity-based awards that he has with respect to us or any of our affiliates as of his termination date; and (iii) Accrued Obligations.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth information concerning the number of shares of Common Stock underlying outstanding equity incentive awards for each of our named executive officers as of December 31, 2025:

	Option Awards					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock not yet Vested (#)	Market Value of Shares or Units not yet Vested ($)
Quang X. Pham	01/18/2024 [1]	4,583	5,417	$ 14.10	01/17/2034	-	-
Quang X. Pham	01/23/2025[2]	0	65,000	$ 19.79	01/22/2035	-	-
Matthew Szot	01/18/2024 [1]	7,639	9,028	$ 14.10	01/17/2034	-	-
Matthew Szot	01/23/2025[2]	0	50,000	$ 19.79	01/22/2035	-	-
James J. Ferguson	07/11/2022 [3]	0	60,000	$ 19.75	07/10/2032	-	-

(1) These options vest 25% on February 1, 2025 and thereafter pro rata on a monthly basis for the next 36 months.

(2) These options vested monthly for one year and are fully vested.

(3) These options vest 25% on March 1, 2026 and thereafter pro rata on a monthly basis for the next 36 months.

Equity Incentive Plans

2022 Successor Equity Incentive Plan

In October 2022, the Board adopted, and our stockholders approved, the 2022 Plan, as a successor to and continuation of the Initial Plan, which became effective on January 19, 2023, upon the effectiveness of the Registration Statement. All outstanding awards under the Initial Plan remain outstanding but no further grants will be made under the Initial Plan. The shares of Common Stock underlying any awards under the 2022 Plan and the Initial Plan that are forfeited, canceled or otherwise terminated, other than by exercise, will be added back to the shares of Common Stock available for issuance under the 2022 Plan. In addition, if any shares subject to an award under the 2022 Plan and the Initial Plan are tendered or withheld by the Company to satisfy any exercise price or tax withholding obligation, such tendered or withheld shares will be added back to the shares of Common Stock available for issuance under the 2022 Plan. Shares of Common Stock repurchased on the open market will not be added back to the shares of Common Stock available for issuance under the 2022 Plan. The principal purpose of the 2022 Plan is to attract, retain and incentivize the Company's employees and other service providers through the granting of certain stock-based awards, including performance-based awards.

2022 Initial Equity Incentive Plan

We adopted the Initial Plan on July 11, 2022, which was later amended and restated on October 16, 2022, for purposes of clarifying the application of certain of the rules of the Initial Plan to awards approved before such amendment and restatement of the Initial Plan and to facilitate the transition to the Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan (the "Successor Plan") for the issuance and approval of awards. The principal provisions of the Initial Plan are summarized below. On October 16, 2022, the Board adopted, and our stockholders approved, the Cadrenal Therapeutics, Inc. 2022 Plan, as a successor to and continuation of the Initial Plan, which became effective on January 19, 2023. The 2022 Plan replaced the Initial Plan, except with respect to awards outstanding under the Initial Plan, and no further awards will be available for grant under the Initial Plan.

Clawback Policy

The Board has adopted a clawback policy which allows us to recover performance-based compensation, whether cash or equity, from a current or former executive officer in the event of an Accounting Restatement. The clawback policy defines an Accounting Restatement as an accounting restatement of our financial statements due to our material noncompliance with any financial reporting requirement under the securities laws. Under such policy, we will reasonably and promptly recoup incentive-based compensation previously received by an executive officer that exceeds the amount of incentive-based compensation that otherwise would have been received had it been determined based on the restated amounts in the Accounting Restatement.

The Board has the sole discretion to determine the form and timing of the recovery, which may include repayment, forfeiture and/or an adjustment to future performance-based compensation payouts or awards. The remedies under the clawback policy are in addition to, and not in lieu of, any legal and equitable claims available to the Company. The clawback policy is incorporated by reference in this Annual Report as an exhibit.

Equity Compensation Policy and Practices

While we do not have a formal written policy in place with regard to the timing of awards of options in relation to the disclosure of material nonpublic information, the Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. It has been our practice to grant equity awards to our officers and directors upon their appointment. We intend to issue equity grants to our officers and/or directors at the same time each year, in connection with our first meeting of the Board of Directors each fiscal year. Option grants are effective on the date the award determination is made by the Compensation Committee, and the exercise price of options is the closing market price of our Common Stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day.

During the fiscal year ended December 31, 2025, we did not award any options to a named executive officer in the period beginning four business days before the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a current report on Form 8-K that discloses material nonpublic information, and ending one business day after the filing or furnishing of such report other than as set forth in the table below:

Name	Grant date	Number of securities underlying the award	Exercise price of the award per share	Grant date fair value of the award	Percentage change in the closing market price of the securities underlying the award between the trading day ending immediately prior to the disclosure of material nonpublic information and the trading day beginning immediately following the disclosure of material nonpublic information
James Ferguson	02/05/25	60,000	$ 19.75	$ 778,920	(6.44)%

Director Compensation

For the fiscal year ended December 31, 2025, our directors received annual cash compensation in the amount of $35,000. In addition, the Chair of the Audit Committee received additional annual cash compensation of $25,000, the Chair of the Compensation Committee and Nominating and Corporate Governance Committee each received additional annual cash compensation of $10,000, the Chair of the Science and Technology Committee received additional annual cash compensation of $25,000 (pro rated) and members of the Science and Technology Committee each received additional annual cash compensation of $15,000 (pro rated). From time to time, we may grant additional stock options to certain of our non-employee directors as compensation for their services as directors.

The following table shows certain information with respect to the compensation of all of our non-employee directors for the fiscal year ended December 31, 2025:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(3)(4)	Option Awards ($)(3)(4)	Total ($)
John R. Murphy	$ 60,000	$ -	$ 253,840	$ 313,840
Steven Zelenkofske, D.O.	$ 63,750	$ -	$ 253,840	$ 317,590
Glynn Wilson, Ph.D.	$ 56,250	$ -	$ 253,840	$ 310,090
Robert Lisicki [(1)]	$ 17,500	$ -	$ 253,840	$ 271,340
Lee Golden [(2)]	$ 5,163	$ -	$ 27,970	$ 33,133

(1) Mr. Lisicki resigned from the Board of Directors on July 15, 2025.

(2) Dr. Golden was appointed to the Board of Directors on November 24, 2025.

(3) In accordance with SEC rules, this column reflects the aggregate fair value of the stock and option awards granted as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). The valuation assumptions used in determining such amounts are described in Note 1 and Note 7 to our audited financial statements included elsewhere in this Annual Report. These amounts do not correspond to the actual value that may be realized by the Directors upon vesting or exercise of such awards.

(4) The table below shows the aggregate number of option awards outstanding at fiscal year-end of our non-employee directors.

Name	Number of Shares Subject to Outstanding Options as of December 31, 2025
John R. Murphy	33,334
Steven Zelenkofske, D.O.	30,000
Glynn Wilson, Ph.D.	28,000
Robert Lisicki	0
Lee Golden	5,000

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

The following table sets forth the beneficial ownership of our Common Stock as of March 27, 2026, by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our Common Stock;
- each of the named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group

As of March 27, 2026, we had 2,506,817 shares of Common Stock outstanding, held by approximately 17 stockholders of record. This number does not include stockholders for whom shares are held in a "nominee" or "street" name.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Exchange Act.

We have based our calculation of the percentage of beneficial ownership on 2,506,817 shares of our Common Stock outstanding as of March 27, 2026. We have deemed shares of our Common Stock subject to securities that are currently convertible or exercisable into shares of Common Stock, or convertible or exercisable into shares of our Common Stock within 60 days of March 27, 2026, to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Cadrenal Therapeutics, Inc., 822 A1A North, Suite 306, Ponte Vedra, Florida 32082.

Name of Beneficial Owner	Shares Beneficially Owned	Percentage
Named Executive Officers and Directors		
Quang X. Pham	419,110[(1)]	16.57%
Matthew Szot	22,570[(2)]	*
James Ferguson	16,250[(3)]	*
John Murphy	74,320[(4)]	2.93%
Steven Zelenkofske	32,666[(5)]	1.29%
Glynn Wilson	31,333[(6)]	1.24%
Lee Golden	1,667[(7)]	*
All current executive officers and directors as a group (8 persons)	611,770	22.87%
5% Stockholders other than executive officers and directors		
The PVBQ Living Trust	200,000[(1)]	7.98%

* Represents beneficial ownership of less than one percent.

(1) Includes (i) 196,089 shares of Common Stock owned by Quang X. Pham; (ii) 200,000 shares of Common Stock owned by The PVBQ Living Trust; and (iii) 23,021 shares of Common Stock issuable upon the exercise of options held by Mr. Pham that are exercisable within the 60-day period following March 27, 2026. The beneficiary of The PVBQ Living Trust (the "Trust") is Mr. Pham's child and Mr. Pham is the trustee of the Trust and has sole voting and disposition power with respect to the shares owned by the Trust. The address for the Trust is 822 A1A North, Suite 306, Ponte Vedra, Florida 32082.

(2) Includes 22,570 shares of Common Stock issuable upon the exercise of options held by Mr. Szot that are exercisable within the 60-day period following March 27, 2026.

(3) Includes 16,250 shares of Common Stock issuable upon the exercise of options held by Dr. Ferguson that are exercisable within the 60-day period following March 27, 2026.

(4) Includes: (i) 40,986 shares of Common Stock; and (ii) 33,334 shares of Common Stock issuable upon the exercise of options held by Mr. Murphy that are exercisable within the 60-day period following March 27, 2026.

(5) Includes: (i) 2,666 shares of Common Stock; and (ii) 30,000 shares of Common Stock issuable upon the exercise of options held by Dr. Zelenkofske that are exercisable within the 60-day period following March 27, 2026.

(6) Includes (i) 3,333 shares of Common Stock; and (ii) 28,000 shares of Common Stock issuable upon the exercise of options held Dr. Wilson that are exercisable within the 60-day period following March 27, 2026.

Changes In Control

None.

Equity Compensation Plan Information

See Part II, Item 5— "Equity Compensation Plan Information" for certain information regarding our equity compensation plans.

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

Other than the compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections titled "Management" and "Executive Compensation," we have not engaged in any transaction since January 1, 2024 and are not currently engaged in any transaction in which:

- we have been or are to be a party to;
- the amount involved exceeded or exceeds $120,000 or 1% of the average of our total assets as of the end of the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

For information on our compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, see the sections titled "Management" and "Executive Compensation."

Indemnification Agreements

We have entered into separate indemnification agreements with each of our current executive officers and intend to enter into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification that will be provided for in our amended and restated bylaws. The indemnification agreements and our amended restated bylaws require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. See the section titled "Description of Securities — Limitations on Liability and Indemnification of Officers and Directors" for additional information.

Our Policy Regarding Related Party Transactions

Our board of directors recognizes the fact that transactions with related persons present a heightened risk of conflicts of interest and/or improper valuation (or the perception thereof). Our board of directors adopted a written policy on transactions with related persons that is in conformity with the requirements for issuers having publicly held common stock that is listed on the Nasdaq Stock Market. Under the new policy:

- any related person transaction, and any material amendment or modification to a related person transaction, must be reviewed and approved or ratified by the Audit Committee; and
- any employment relationship or transaction involving an executive officer and any related compensation must be approved by the compensation committee of the board of directors or recommended by the compensation committee to the board of directors for its approval.

In connection with the review and approval or ratification of a related person transaction:

- management must disclose to the committee or disinterested directors, as applicable, the name of the related person and the basis on which the person is a related person, the material terms of the related person transaction, including the approximate dollar value of the amount involved in the transaction, and all the material facts as to the related person's direct or indirect interest in, or relationship to, the related person transaction;

- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction complies with the terms of our agreements governing our material outstanding indebtedness that limit or restrict our ability to enter into a related person transaction;

- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction will be required to be disclosed in our applicable filings under the Securities Act or the Exchange Act, and related rules, and, to the extent required to be disclosed, management must ensure that the related person transaction is disclosed in accordance with the Securities Act and the Exchange Act and related rules; and

- management must advise the committee or disinterested directors, as applicable, as to whether the related person transaction constitutes a "personal loan" for purposes of Section 402 of SOX.

In addition, the related person transaction policy provides that the committee or disinterested directors, as applicable, in connection with any approval or ratification of a related person transaction involving a non-employee director, should consider whether such transaction would compromise the director's status as an "independent," "outside," or "non-employee" director, as applicable, under the rules and regulations of the SEC, the Nasdaq Stock Market, and the Code.

Director Independence

The information included under the heading "Directors, Executive Officers and Corporate Governance—Director Independence" in Part III, Item 10 is hereby incorporated by reference into this Item 13.

Item 14. Principal Accountant Fees and Services.

WithumSmith+Brown, P.C. serves as our independent registered public accounting firm.

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2025 and 2024 by our auditors:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Audit Fees	$ 129,772	$ 185,007
Tax Fees	-	-
Audit-Related Fees	$ 27,278	$ 29,930
All Other Fees	-	-
Total	$ 157,050	$ 214,937

*** Audit-related fees represent charges for work on registration statements including comfort letters and consents.

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the PCAOB. The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with our business, people, culture, accounting systems, risk profile, and whether the services enhance our ability to manage or control risks, and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements. The financial statements required to be filed in this Annual Report are included in Part II, Item 8 hereof.

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Financial Statements or related notes included in Part II, Item 8 hereof.

(a)(3) Exhibits. The exhibits listed below are required by Item 601 of Regulation S-K. Each management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report has been identified

Item 16. Form 10-K Summary.

Not Applicable.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (Incorporated by reference as Exhibit 3.3 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
3.2	Amended and Restated Bylaws (Incorporated by reference as Exhibit 3.2 to the Registration Statement on Form S-1 (333-267562) filed on December 6, 2022)
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Cadrenal Therapeutics, Inc. (Incorporated by reference as Exhibit 3.1 to the Current Report on Form 8-K filed on August 20, 2024)
4.1	Specimen Common Stock Certificate (Incorporated by reference as Exhibit 4.1 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
4.2#	Convertible Promissory Note dated March 1, 2022 issued to John Murphy (Incorporated by reference as Exhibit 4.3 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
4.3	Form of Convertible Note dated June 13, 2022 (Incorporated by reference as Exhibit 4.4 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
4.4	Form of Private Placement Convertible Note (Incorporated by reference as Exhibit 4.5 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
4.5	Form of November Private Placement Promissory Note (Incorporated by reference as Exhibit 4.6 to the Registration Statement on Form S-1 (333-267562) filed on December 6, 2022)
4.6	Form of Amended and Restated November Warrant (Incorporated by reference as Exhibit 4.7 to the Registration Statement on Form S-1 (333-267562) filed on December 6, 2022)
4.7	Form of Amended and Restated Placement Agent Warrant from Private Placement (Incorporated by reference as Exhibit 4.8 to the Registration Statement on Form S-1 (333-267562) filed on December 6, 2022)
4.8	Form of Placement Agent Warrant from November Private Placement (Incorporated by reference as Exhibit 4.9 to the Registration Statement on Form S-1 (333-267562) filed on December 6, 2022)
4.9	Form of Amendment to Convertible Promissory Note (Incorporated by reference as Exhibit 4.10 to the Registration Statement on Form S-1 (333-267562) filed on December 6, 2022)
4.10	Representative's Warrant issued to Boustead Securities, LLC dated January 19, 2023 (Incorporated by reference as Exhibit 4.1 to the Current Report on Form 8-K (001-41596) filed with the SEC on January 25, 2023)
4.11	Description of Securities (Incorporated by reference as Exhibit 4.11 to the Annual Report on Form 10-K (001-41596) filed with the SEC on March 30, 2023)
4.12	Form of Pre-Funded Warrant (Incorporated by reference as Exhibit 4.1 to the Current Report on Form 8-K 001-41596), as filed with the SEC on July 14, 2023)
4.13	Form of Warrant (Incorporated by reference as Exhibit 4.2 to the Current Report on Form 8-K 001-41596), as filed with the SEC on July 14, 2023)
4.14	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.3 to the Current Report on Form 8-K 001-41596), as filed with the SEC on July 14, 2023)
4.15	Form of New Warrant (Incorporated by reference as Exhibit 4.1 to the Current Report on Form 8-K filed on November 4, 2024)
4.16	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Current Report on Form 8-K filed on November 4, 2024)
4.17	Form of Common Stock Purchase Warrant (Incorporated by reference as Exhibit 4.1 to the Current Report on Form 8-K filed on December 16, 2025)
4.18	Form of Placement Agent Warrant (Incorporated by reference as Exhibit 4.2 to the Current Report on Form 8-K filed on December 16, 2025)

10.1#	Cadrenal Therapeutics, Inc. 2022 Equity Incentive Plan and form of Incentive Stock Option Agreement, Non-Qualified Stock Option Agreement for Officers and Other Employees, Non-Qualified Stock Option Agreement for Directors and Consultants, Restricted Stock Agreement, and Restricted Stock Unit Agreement (Incorporated by reference as Exhibit 10.1 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
10.2#	Consulting Agreement, dated January 25, 2022, with Phamace LLC (Quang Pham) from company formation until initiation of payroll (Incorporated by reference as Exhibit 10.2 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
10.3#	Employment Agreement, dated March 1, 2022 with Quang Pham (Incorporated by reference as Exhibit 10.3 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
10.4#	Restricted Stock Purchase Agreement with Matthew Szot (Incorporated by reference as Exhibit 10.5 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
10.5	Asset Purchase Agreement dated as of April 1, 2022, between Cadrenal Therapeutics, Inc. and HESP LLC (Incorporated by reference as Exhibit 10.7 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
10.6	Patent Assignment Agreement dated as of April 1, 2022, between Cadrenal Therapeutics, Inc. and HESP LLC (Incorporated by reference as Exhibit 10.8 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
10.7	Subscription Agreement with Quang Pham, dated January 25, 2022 (Incorporated by reference as Exhibit 10.9 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
10.8	Form of Investor Rights and Lockup Agreement (Incorporated by reference as Exhibit 10.10 to the Registration Statement on Form S-1 (333-267562) filed on September 22, 2022)
10.9+	License, Development and Commercialization Agreement Effective as of September 16, 2015 by and between Armetheon, Inc. and China Cardiovascular Focus Ltd. (Incorporated by reference as Exhibit 10.13 to the Registration Statement on Form S-1 (333-267562) filed on October 11, 2022)
10.10#	Cadrenal Therapeutics, Inc. 2022 Amended and Restated Equity Incentive Plan (Incorporated by reference as Exhibit 10.14 to the Registration Statement on Form S-1 (333-267562) filed on October 17, 2022)
10.11#	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the 2022 Amended and Restated Equity Incentive Plan (Incorporated by reference as Exhibit 10.15 to the Registration Statement on Form S-1 (333-267562) filed on October 17, 2022)
10.12#	Form of Indemnification Agreement (Incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K (001-41596) filed with the SEC on January 25, 2023)
10.13	Amendment to Asset Purchase Agreement, dated as of August 18, 2022, between Cadrenal Therapeutics, Inc. and HESP LLC (Incorporated by reference as Exhibit 10.2 to the Current Report on Form 8-K (001-41596) filed with the SEC on January 25, 2023)
10.14#	Employment Agreement with Matthew Szot (Incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K (001-41596) filed with the SEC on January 25, 2023)
10.15#	Employment Agreement with Douglas Losordo (Incorporated by reference as Exhibit 10.4 to the Current Report on Form 8-K (001-41596) filed with the SEC on January 25, 2023)
10.16#	Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan (Incorporated by reference as Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-267562) filed with the SEC on January 17, 2023)
10.17#	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the 2022 Successor Equity Incentive Plan (Incorporated by reference as Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-267562) filed with the SEC on January 17, 2023)
10.18#	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2022 Successor Equity Incentive Plan (Incorporated by reference as Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-267562) filed with the SEC on January 17, 2023)
10.19#	Amendment No. 1 to Employment Agreement by and between Cadrenal Therapeutics, Inc. and Matthew Szot, dated May 25, 2023 (Incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K (001-41596) filed with the SEC on May 26, 2023)
10.20	Form of Securities Purchase Agreement (Incorporated herein by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (001-41596), as filed with the SEC on July 14, 2023)
10.21	Form of Registration Rights Agreement (Incorporated herein by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (001-41596), as filed with the SEC on July 14, 2023)
10.22#	Offer Letter dated, February 6, 2024, between Cadrenal Therapeutics, Inc. and Jeffrey Cole (Incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K filed on February 12, 2024)
10.23#	Employment Agreement, effective as of February 8, 2024, between Cadrenal Therapeutics, Inc. and Jeffrey Cole (Incorporated by reference as Exhibit 10.2 to the Current Report on Form 8-K filed on February 12, 2024)
10.24#	Amendment to the Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan (Incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K filed on July 31, 2024)
10.25	Form of Warrant Inducement Agreement (Incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K filed on November 4, 2024)
10.26#	Employment Agreement between Cadrenal Therapeutics, Inc. and James J. Ferguson III, effective February 5, 2025 (Incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K filed on February 7, 2025)

10.27#	Severance and Release Letter Agreement, dated February 7, 2025, between Cadrenal Therapeutics, Inc. and Douglas Losordo (Incorporated by reference as Exhibit 10.2 to the Current Report on Form 8-K filed on February 7, 2025)
10.28	Collaboration Agreement between Abbott Global Enterprises Limited and Cadrenal Therapeutics, Inc. (Incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K filed on March 4, 2025)
10.29	Purchase Agreement between Cadrenal Therapeutics, Inc. and eXIthera Pharmaceuticals, Inc. (incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K filed on September 15, 2025)
10.30	Asset Purchase Agreement between Cadrenal Therapeutics, Inc. and Veralox Therapeutics, Inc., dated December 10, 2025 (incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K filed on December 12, 2025)
10.31	Amended and Restated Exclusive License Agreement by and between Eastern Virginia Medical School and Veralox Therapeutics, Inc., dated May 1, 2020 (incorporated by reference as Exhibit 10.2 to the Current Report on Form 8 K filed on December 12, 2025)
10.32	First Amendment to Amended and Restated Exclusive License Agreement by and between Old Dominion University, as successor in interest to Eastern Virgina Medical School, and Veralox Therapeutics, Inc., effective as of December 9, 2025 (incorporated by reference as Exhibit 10.3 to the Current Report on Form 8 K filed on December 12, 2025)
10.33	Form of Securities Purchase Agreement, dated as of December 15, 2025, by and among Cadrenal Therapeutics, Inc. and the Purchasers named therein (Incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K filed on December 16, 2025)
19.1	Amended and Restated Insider Trading Policy (Incorporated by reference as Exhibit 19.1 to the Annual Report on Form 10-K filed on March 13, 2025)
21.1	Subsidiaries of Registrant (Incorporated by reference as Exhibit 21.1 to the Annual Report on Form 10-K filed on March 11, 2024)
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of the Principal Executive Officer Pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Principal Financial Officer and Principal Accounting Officer Pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification by the Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification by the Principal Financial Officer and Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Clawback Policy (Incorporated by reference as Exhibit 97.1 to the Annual Report on Form 10-K filed on March 11, 2024)
101.INS	Inline XBRL Instance*
101.SCH	Inline XBRL Taxonomy Extension Schema*
101.CAL	Inline XBRL Taxonomy Extension Calculation*
101.DEF	Inline XBRL Taxonomy Extension Definition*
101.LAB	Inline XBRL Taxonomy Extension Labeled*
101.PRE	Inline XBRL Taxonomy Extension Presentation*
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

* Filed herewith.
\# Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this Annual Report.
\+ Certain portions of this exhibit indicated therein by [***] have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

NOTE: This 2025 Annual Report to Shareholders does not contain the exhibits filed or furnished with the Company's annual report on Form 10-K for the fiscal year ended December 31, 2025. Copies of these exhibits are available electronically at www.sec.gov or www.cadrenal.com or by writing to Cadrenal Therapeutics, Inc., 822 A1A North, Suite 306, Ponte Vedra, Florida 32082, Attention: Corporate Secretary.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 31st day of March, 2026.

Cadrenal Therapeutics, Inc.
(Registrant)

Dated: March 31, 2026

/s/ Quang X. Pham
Quang X. Pham
Chairman of the Board and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Quang Pham, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the registrant, Cadrenal Therapeutics, Inc., in the capacities and on the date indicated.

Signature	Title	Date
/s/ Quang X. Pham Quang X. Pham	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 31, 2026
/s/ Matthew Szot Matthew Szot	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2026
/s/ John R. Murphy John R. Murphy	Director	March 31, 2026
/s/ Glynn Wilson Glynn Wilson	Director	March 31, 2026
/s/ Steven Zelenkofske Steven Zelenkofske	Director	March 31, 2026
/s/ Lee Golden Lee Golden	Director	March 31, 2026

NASDAQ: CVKD

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