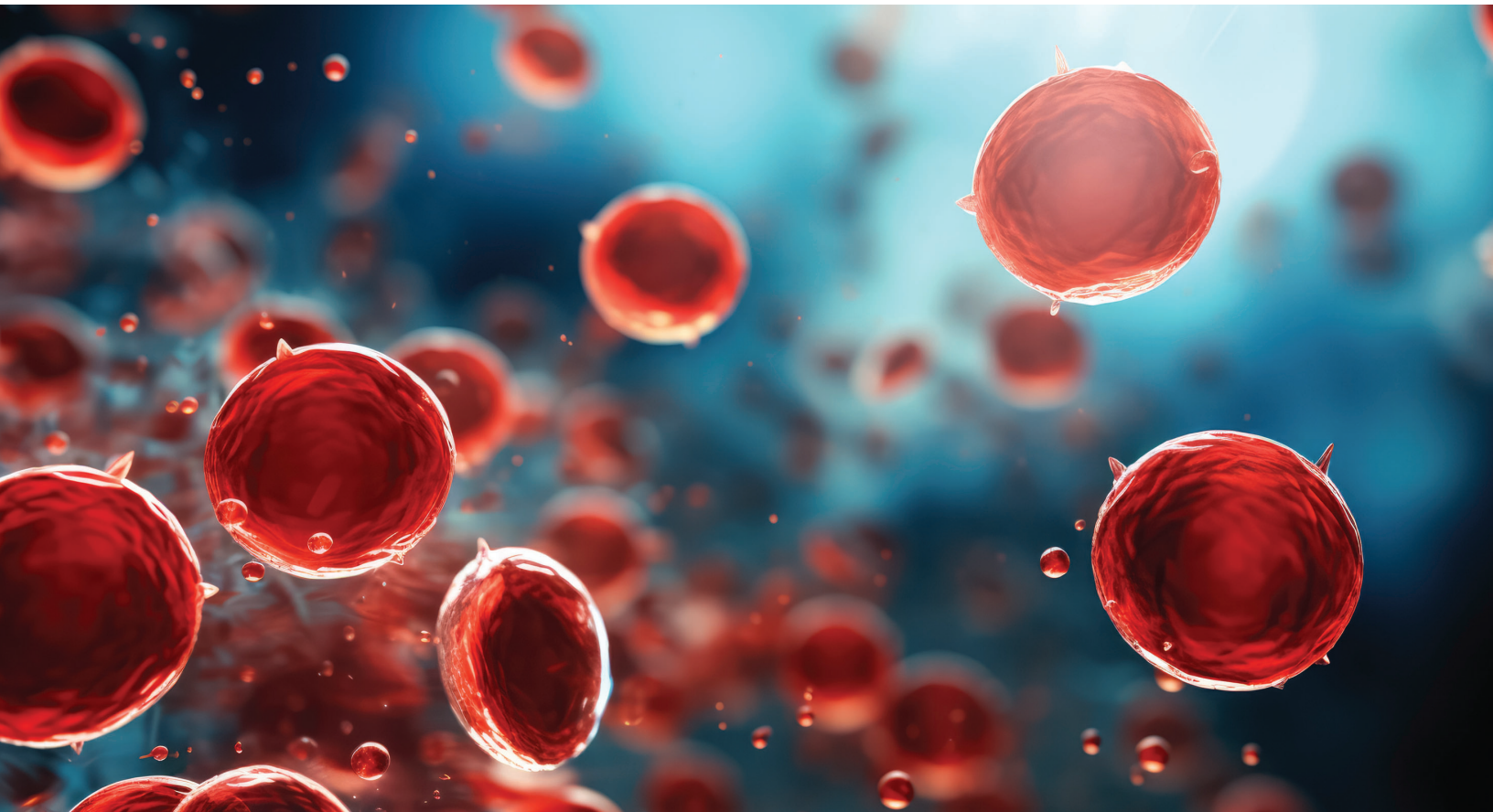
CARDIORENAL THERAPEUTICS™

NASDAQ: CVKD

2023 ANNUAL REPORT



DEAR SHAREHOLDERS

In 2023, Cadrenal embarked on our exciting journey as a publicly traded company. We set our unwavering mission: bring to market our next-generation Vitamin K Antagonist (VKA), tecarfarin, for patients in need. Tecarfarin is our late-stage novel oral and reversible anticoagulant (more commonly referred to as a blood thinner) to prevent heart attacks, strokes, and deaths due to blood clots in patients with rare cardiovascular conditions who require lifelong anticoagulation.

While the anticoagulant market is extremely large, our focus is to develop tecarfarin as a therapy for patients with certain unmet needs where the only drug used, warfarin, has failed to achieve reliable results, and the newer class of medications commonly called DOACs (Eliquis, Xarelto, Pradaxa, and Savaysa) have not shown clinical benefit. This unmet sector of the anticoagulant market presents a significant commercial opportunity that is estimated to be at $2 billion per year.

Specifically, we have identified three areas where we believe tecarfarin can be the lead therapy for patients requiring lifelong anticoagulation. These include patients with:

- Implanted mechanical circulatory support devices, which include the left ventricular assist device (LVAD);
- End-stage kidney disease (ESKD) with Atrial Fibrillation (AFib); and
- Thrombotic Antiphospholipid Syndrome (APS).

We have received orphan drug designation from the U.S. Food and Drug Administration (FDA) for the first two indications mentioned above (LVADs and ESKD + AFib), and have submitted our orphan drug application to the FDA for APS. These are critical designations as they provide potential seven-year marketing exclusivities after approval, and clarity regarding the pathway to approval. We also received a Fast Track designation for ESKD + AFib.

During the past year, an increasing number of scientific articles and medical meeting presentations underscore the deficiencies of warfarin and the need for a new VKA therapy for patients with rare cardiovascular conditions. For example, in April 2024, a groundbreaking presentation was made discussing an analysis of the Abbott-sponsored ARIES-HM3 trial data. One key point from the data was the importance of LVAD patients maintaining targeted time in therapeutic range (TTR), a quality measure for VKAs. Dr. Mandeep Mehra, who chaired the ARIES-HM3 study, holds the William Harvey Distinguished Chair in Advanced Cardiovascular Medicine and is Executive Director of the Center for Advanced Heart Disease at Brigham and Women's Hospital, recently commented, "…Tecarfarin could potentially be an important therapy for patients with LVADs who all require chronic anticoagulation since it does not get affected by drug-drug interactions or changes in kidney function like warfarin and deserves further study." We believe our VKA tecarfarin, with its unique retrometabolic design that provides for more stable anticoagulation than warfarin, is the much-needed replacement therapy for this patient population.

As we look to the rest of 2024 and beyond, we intend to pursue a pivotal trial to evaluate tecarfarin's effectiveness for LVAD patients. To prepare for this trial, we are simultaneously advancing our pharmaceutical contract development and manufacturing organizations to supply active pharmaceutical ingredients, drug products, and clinical trial materials while exploring strategic partnerships, co-development, and licensing agreements for tecarfarin to help us accelerate clinical development.

While we are proud of our progress, the Cadrenal team is working hard to advance these critical clinical imperatives and continue to build value for our shareholders. Thank you for your continued patience and support of Cadrenal. We are excited about our future as we look to bring a much-needed blood thinner solution to these underserved patients.

Respectfully,

Quang X. Pham

Quang X. Pham
Chairman & Chief Executive Officer

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, 2023

OR

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

For the transition period from ___ to ___

Commission file number 001-41596

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	**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 a share of the registrant's common stock on June 30, 2023, as reported by the Nasdaq Capital Market on such date was approximately $6,399,323. Shares of the registrant's common stock held by each executive officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 8, 2024, there were 16,008,469 shares of Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None

CADRENAL THERAPEUTICS, INC.

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. and its subsidiaries.

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.

Note Regarding Company References

Throughout this Annual Report, "Cadrenal," "the Company," "we" and "our" refer to Cadrenal Therapeutics, Inc.

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

- We have a limited operating history, a history of losses and expect to continue to incur losses;
- Our cash and the proceeds from our initial public offering and July 2023 private placement offering will only fund our operations for a limited time;
- We will need to raise additional capital.

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

- Our business is dependent upon the success of tecarfarin, which requires additional clinical testing;
- All of our current data for tecarfarin 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 may require additional clinical testing resulting in additional costs and delays;

- Even if we complete our clinical trials, we may not receive regulatory approval for tecarfarin;
- Fast Track designation and Orphan Drug Designation by the FDA does not assure FDA approval;
- Even if we obtain regulatory approval, we may not enjoy marketing exclusivity and we may face development, regulatory or labeling 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 tecarfarin is approved, our success depends on our commercialization efforts and market acceptance;
- We have never submitted an NDA to the FDA or comparable applications to other regulatory authorities;
- After approval of tecarfarin, it will remain subject to regulatory obligations and other restrictions;
- We are subject to federal and state obligations and regulations applicable to our marketing practices;
- We rely on a third-party manufacturer to produce tecarfarin;
- 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, which may harm our business;
- Recently enacted and future legislation may affect marketing approval and commercialization of tecarfarin;
- 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;
- We will rely on third parties to conduct all of our clinical trials;
- We currently have limited distribution, marketing, support and sales capabilities;
- Our employees, contractors, consultants, commercial partners and vendors may engage in misconduct;
- If we are not successful establishing a sales force, our ability to generate sales and profits will be limited;
- We plan to rely on collaborations with 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; and
- Compliance with regulations regarding the treatment of animals could increase our costs.

Risks Related to Our Intellectual Property

- We may be unable to obtain and maintain market exclusivity or patent protection for tecarfarin;
- We may become involved in intellectual property lawsuits, which could be costly and time consuming;
- 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; and
- Our patents expire in 2024 and 2025 and therefore we will lose protection from such patents in the next couple years.

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;
- If favorable research or reports about us are not published our stock price could decline;
- Our officers, directors, and principal stockholders exercise significant control over our Company;
- Future sales of Common Stock could result in dilution and could depress the market price of our Common Stock;
- Our charter documents have anti-takeover provisions;
- 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;
- 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; and
- 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.

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, including cybersecurity and data leakage risks;
- Acquisitions of other businesses could harm our operating results; and
- Declining general economic or business conditions may have a negative impact on our business.

Item 1. Business.

Overview —

We are developing tecarfarin, our drug candidate, for unmet needs in anticoagulation therapy. Tecarfarin is a late-stage novel oral and reversible anticoagulant (blood thinner) to prevent heart attacks, strokes, and deaths due to blood clots in patients with rare cardiovascular conditions requiring chronic anticoagulation.

There is a lack of approved anticoagulation therapies for certain rare cardiovascular conditions requiring chronic anticoagulation, such as patients with left ventricular assist devices (LVADs), patients with mechanical heart valves, patients with end-stage kidney disease (ESKD) and atrial fibrillation (AFib), and patients with thrombotic anti-phospholipid syndrome (APS). For patients with these conditions, treatment guidelines, not randomized controlled trials, direct the recommended use of a vitamin K antagonist (VKA) such as warfarin, despite warfarin's failure to

achieve sufficiently stable anticoagulation in these patients. Additionally, direct-acting oral anticoagulants (DOACs) like Eliquis and Xarelto have either not shown clinical benefits in these and certain other patient populations, or their efficacy and safety remains uncertain.

At the time the investigation new drug application (IND) for tecarfarin was filed by its initial sponsor, warfarin was the only other marketed oral anticoagulant, and the strategy was to develop tecarfarin as an alternative VKA with superior efficacy and safety over warfarin for a broad range of indications including AFib, deep vein thrombosis (DVT), pulmonary embolism (PE), prevention of pulmonary embolism in patients with venous thrombosis, DVT prevention in patients undergoing certain surgical procedures, thrombosis prevention in patients with mechanical heart valves, and prevention of thrombotic complications in patients after a myocardial infarction (heart attack), among others.

When tecarfarin clinical trials were being conducted by the initial IND sponsors, the DOACs were advancing through clinical trials and ultimately approved by demonstrating that they were non-inferior to warfarin in certain indications, including AFib in the general population, prevention of pulmonary embolism in patients with venous thrombus, prevention of deep vein thrombosis in patients undergoing certain surgical procedures, among others. These DOAC clinical studies resulted in a change in the standard of care for a large percentage of the population that had been previously treated with existing VKAs, the same population also initially targeted by prior tecarfarin IND sponsors. Thus, the original broad-label development plan for tecarfarin was challenged.

Accordingly, we are focusing the development of tecarfarin on rare cardiovascular conditions where patients are unable to achieve sufficiently reliable chronic anticoagulation with warfarin, and where DOACs have either failed or their efficacy and safety remain unproven. This includes patients with LVADs, patients with ESKD and AFib, and patients with thrombotic APS, among others, where the need for VKA-dependent chronic anticoagulation has been underscored by recent clinical studies. While warfarin-treated patients have fared better than DOAC-treated patients in comparative studies in certain of these cardiovascular conditions, the event rates in these studies remain unacceptably high and the quality of anticoagulation in warfarin-treated patients has repeatedly been shown to be sub-optimal.

The quality of anticoagulation provided by VKA has been defined by the assessment of "time in therapeutic range" (TTR) blood tests. This measurement quantifies the percentage of time that a patient's International Normalized Ratio (INR), a measure of the degree of anticoagulation achieved, is in the target range. The target INR is 70%, however most studies have shown that warfarin fails to achieve this target, even in carefully controlled clinical trials. A major contributing factor to the failure of warfarin is its metabolism. Warfarin is metabolized via the cytochrome p450 (CYP450) pathway which results in unstable and variable pharmacokinetics (PK) due to 1) a large number of drugs that use this pathway (i.e. competition for the pathway which has limited capacity), 2) genetic variability in components of the pathway that result in altered rates of metabolism and 3) a number of drugs alter the activity of components of the pathway, either increasing or decreasing activity and therefore increasing or decreasing clearance of drugs metabolized by the pathway. The result is highly variable PK which translates into unstable levels of anticoagulation.

In 2019, tecarfarin was granted an orphan drug designation (ODD) by the United States Food and Drug Administration (FDA) for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with ESKD and Afib, and a fast-track designation was granted by the FDA in 2023. 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 benefit of any anticoagulant. There are more than 809,000 Americans with ESKD, with approximately 70% on dialysis. Approximately 100,000 to 150,000 ESKD patients also have AFib. AFib nearly doubles the anticipated mortality and increases the stroke risk by approximately five-fold in these patients. There are currently no effective anticoagulation treatment options for patients with ESKD and AFib. Commonly prescribed medications, such as warfarin and apixaban (Eliquis), may cause substantial harm, leading to outcomes such as hemorrhagic stroke, major bleeding, or death. Yet most trials of anticoagulant therapy to reduce the risk of such events have excluded these patients. These patients have typically been excluded from randomized clinical trials because approved therapies for AFib have metabolic profiles that may increase drug exposures in patients, thereby increasing known risks and challenges in managing patients with ESKD and AFib.

We have also applied for an orphan drug designation for the prevention of thrombosis and thromboembolism in patients with LVADs. There are approximately 15,000 patients in the U.S. with LVADs, and recent randomized controlled trials in LVAD patients have documented that currently available VKAs yield poor quality anticoagulation despite the tight management of anticoagulation in the clinical trial setting. Implantable LVAD therapy is used to improve quality of life, alleviate symptoms, and extend survival rates in patients with advanced heart failure, irrespective of eligibility for cardiac transplant. Patients with LVADs require chronic anticoagulation to reduce the risk of thromboembolic complications, and under the currently available anticoagulants, they commonly experience bleeding events. Recent

data reveals that the current standard of care anticoagulant, warfarin, yields suboptimal levels of anticoagulation, leading to excess bleeding complications. LVAD patients require life-long anticoagulant therapy to reduce the risk of pump thrombosis and anticoagulation management in patients with LVADs continues to be a challenge. Patients and their clinicians are faced with the daily challenge of balancing the need for adequate anticoagulation versus the bleeding risks that are associated with excess anticoagulation. Warfarin is the only available oral anticoagulant for all currently available LVAD devices, however, warfarin is known to be a difficult medication to manage due to its labile metabolism, and its many drug-drug interactions which also impacts the stability of anticoagulation.

The FDA grants ODD status to drugs that are intended for the treatment, diagnosis, or prevention of rare diseases or conditions, which are defined as a disease or condition that affect fewer than 200,000 people in the U.S. The ODD program provides a drug developer with certain benefits and incentives, including a seven-year period of U.S. marketing exclusivity from the date of marketing authorization, waiver of FDA user fees, and tax credits for clinical research. The granting of an orphan drug designation does not alter the FDA's regulatory requirements to establish safety and effectiveness of a drug through adequate and well-controlled studies to support approval and commercialization. Furthermore, orphan drug designation does not indicate or guarantee FDA approval of the New Drug Application, or NDA, and we might not receive exclusivity. On January 13, 2023, the FDA designated a Fast Track development program for the investigation of tecarfarin for the prevention of systemic thromboembolism of cardiac origin in patients with ESKD and AFib. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

In patients with LVADs, recent data also highlights the need for a next generation VKA anticoagulant. 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 time in the therapeutic range was only 56% with warfarin, far below the target of 70%, and that, despite the superior design of the HM3 device, poor quality anticoagulation was associated with excess thrombotic and bleeding events.

Tecarfarin has been evaluated in eleven (11) human clinical trials conducted by its previous owners and other third parties 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, or CKD. In the Phase 2/3 trial, EMBRACE-AC, the largest tecarfarin trial with 612 patients having completed it, only 1.6% of the blinded tecarfarin subjects suffered from major bleeding.

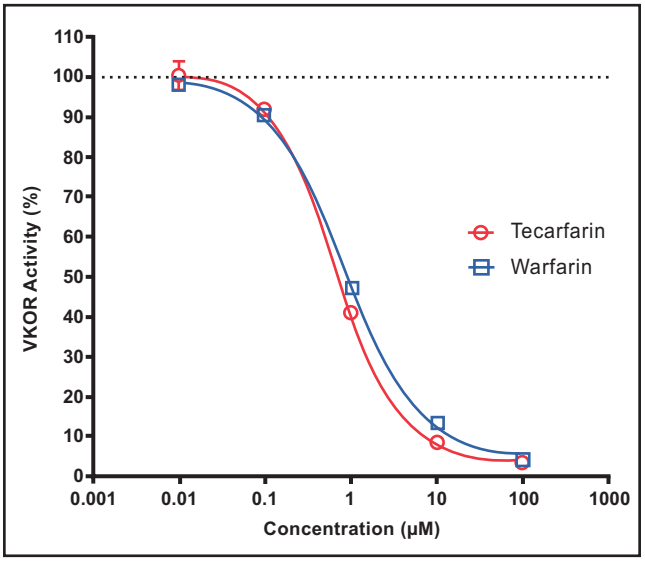
Tecarfarin is specifically designed to target a different metabolism pathway than warfarin, utilizing the human carboxylesterase 2 pathway, which is abundant, and although it has genetic variability, the variants have not been shown to significantly alter drug clearance. This has been shown in clinical studies to result in more reliable levels of anticoagulation. In the EMBRACE-AC study of 612 patients, the time in therapeutic range (TTR) was used to compare tecarfarin to warfarin. TTR quantifies the percentage of International Normalized Ratio (INR) values that are in the appropriate range. When the INR values collected in tecarfarin and warfarin were compared, tecarfarin TTR was significantly better than warfarin. This was especially notable because a blinded team of experts reviewed all INR values and made dose adjustments which resulted in the TTR of warfarin being much higher than in a "real world" setting.

Tecarfarin was developed by researchers using a retrometabolic drug design process which specifically targeted a different metabolic pathway than the most commonly prescribed drug for the treatment of thrombosis and AFib. "Drug metabolism" refers to the process by which a drug is inactivated by the body and rendered easier to eliminate or to be cleared by the body. Most approved drugs, including warfarin, the only FDA-approved Vitamin K antagonists, or VKAs, are metabolized in the liver through a pathway known as the Cytochrome 450 system, or CYP450. This pathway has more than 50 enzymes, however 6 of these enzymes are involved in the metabolism (elimination) of 90% of drugs. For example, CYP3A4 is responsible for the metabolism of more than 50% of medicines, and this enzyme is part of warfarin's metabolism.

By design, tecarfarin utilizes a different metabolic pathway, thereby eliminating CYP450 metabolism in the liver. 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 that are well documented with warfarin use.

Our product candidate, tecarfarin, was designed to follow a metabolic pathway distinct from the CYP450 pathway and is metabolized by both CYP450 and non-CYP450 pathways. We believe this may allow elimination by large capacity and non-saturable tissue esterase pathways that exist throughout the body rather than just in the liver. The evidence generated in clinical studies indicates that the design of tecarfarin results in more reliable anticoagulation than the currently available VKA.

VKAs block the production of vitamin K-dependent blood clotting factors, such that the blood is "thinned," preventing clots, while DOACs directly block the activity of single clotting factors. Vitamin K epoxide Reductase Complex subunit 1 (VKORC1) is a significant enzyme for effective clotting. VKORC1 reduces vitamin K epoxide to its active form (Vitamin K), which is the rate-limiting step in the physiological process of vitamin K recycling. Vitamin K serves as a cofactor for normal function of several clotting/anticoagulation factors including Factors II, VII, IX and X and Proteins C, S, and Z. VKORC1 genetic deficiencies result in increased sensitivity to VKAs, which results in an increase in the risk of significant hemorrhaging. We believe tecarfarin has potency for VKORC1 inhibition similar to warfarin, but it is an investigational new drug, and we must demonstrate it is safe and effective for its proposed indication.



AFib is the most common 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 2021 estimates by the Centers for Disease Control and Prevention, or CDC, approximately 15% of the U.S. adult population, or 37 million people, have CKD. An estimated 0.4% of people in the U.S. suffer from Stage 4 CKD and 0.1% of people in the U.S. have ESKD.

There are more than 809,000 Americans with ESKD, with approximately 70% on dialysis, according to the United States Renal Data System. Approximately 100,000 to 150,000 ESKD patients also have AFib. AFib nearly doubles the anticipated mortality and increases the stroke risk by approximately five-fold 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 Annual Data Report published by the United States Renal Data System, total Medicare spending for patients with ESKD reached $51 billion in 2019, accounting for approximately 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. These patients have typically been excluded from randomized clinical trials because the approved therapies for AFib have metabolic profiles that may increase drug exposures, thereby increasing the known risks and challenges in managing these patients. 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, but there are no approved treatment options for patients with ESKD and AFib. Warfarin may cause substantial harm in these patients. Low-dose apixaban (Eliquis) was approved by the FDA for use in ESKD patients on hemodialysis based upon

limited pharmacokinetic data from 8 subjects. Although randomized trials of apixaban versus warfarin for AFib have been conducted, those studies excluded patients with severe and end-stage kidney disease. The RENAL-AF (Trial to Evaluate Anticoagulation Therapy in Hemodialysis Patients With Atrial Fibrillation) was terminated early in 2019 by its sponsor. Accordingly, there is no evidence to support the use of any drug for the prevention of thromboembolic events in patients with ESKD and AFib.

Clinical Trials

Tecarfarin has been evaluated in 11 human clinical trials in over 1,000 individuals, which includes eight Phase 1 trials, two Phase 2 trials, and one Phase 2/3 trial evaluating the efficacy and safety of tecarfarin.

In a Phase 2/3 randomized and blinded trial sponsored by ARYx Therapeutics, Inc. in 2008 (EMBRACE-AC study), 612 patients with a variety of indications for chronic anticoagulation were treated with either tecarfarin or warfarin. The primary endpoint of the study was the Time in Therapeutic Range, or TTR, which quantifies the percentage of time a patient is at the desired level of anticoagulation. The degree of anticoagulation is measured by the INR (international normalized ration) which measures the clotting ability of the blood. Individuals with normal clotting ability have an INR of ~1. When a patient is on anticoagulation with a VKA such as warfarin the target range of the INR is usually from 2-3. In clinical practice, the dose of a VKA is adjusted based on periodic measurement of the INR. If he INR is too low then the dose of VKA is increased and if it is too high then the dose of VKA is decreased. Studies of warfarin have shown that the TTR is typically around 50-55%, while the target TTR is at least 70%.

In the EMBRACE-AC study comparing warfarin to tecarfarin, there was a committee of experts that reviewed every INR in every patient. As a result, the TTR's in this study were higher than in general practice. However, despite this intense oversight of dose adjustment, the INRs actually measured were evaluated and the TTR for tecarfarin was significantly higher than the TTR in warfarin-treated patients. Interestingly the study design called for a method that interpolated INR values for missing data (for example when patients were not taking any medication) and this method resulted in the values looking similar. Tecarfarin appeared to have a favorable safety profile and be well tolerated with only 1.6% of the blinded tecarfarin subjects suffering from major bleeding and no thrombotic events. When thrombotic and major bleeding events during the blinded period were combined, a numerical imbalance favoring tecarfarin over warfarin was seen (warfarin 11 subjects, 3.6%; tecarfarin 5 subjects, 1.6%). The trial however did not meet its primary endpoint of superiority of tecarfarin over warfarin using the interpolation method of calculating TTR.

In a subsequent Phase 1 study with 23 patients with CKD sponsored by Armetheon, Inc. in 2016, the metabolism of warfarin was shown to be significantly inhibited, whereas tecarfarin metabolism was not altered in the setting of significant renal insufficiency. The safety of repeated dosing of tecarfarin in CKD patients was not evaluated in that study. However, if the pharmacokinetic findings of this single-dose study are present with repeated dosing, tecarfarin may have more predictable levels of anticoagulation than warfarin in severe CKD patients.

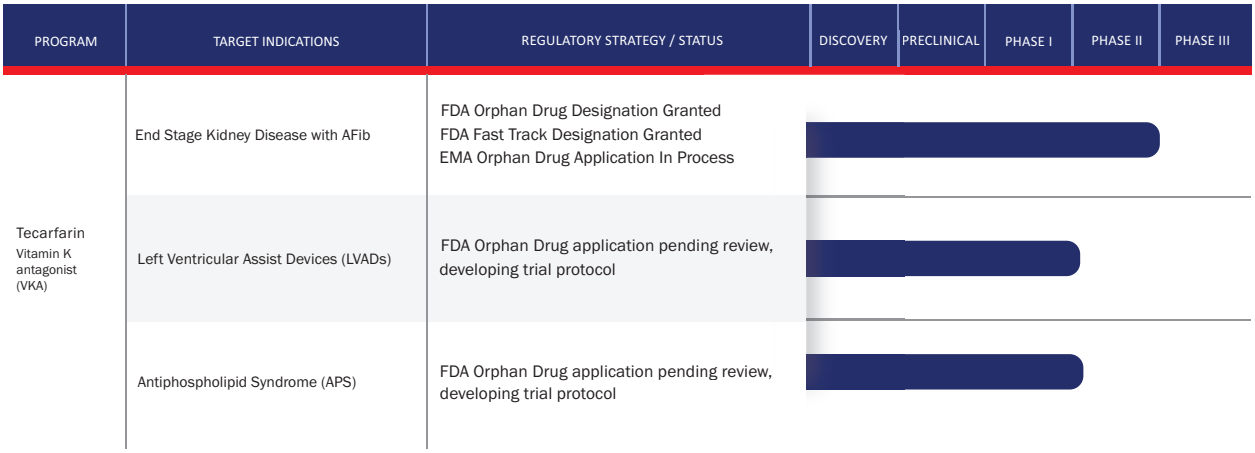
Our Strategy

Our goal is to build a biopharmaceutical company with a foundation of product candidates that significantly advance patient care in rare cardiovascular conditions. Key elements of our strategy are as follows:

- Complete the clinical development of and seek FDA approval for tecarfarin for patients with unmet needs in anticoagulation therapy. We intend to initiate a pivotal Phase 3 clinical trial in 2025, subject to funding from additional financings. We believe, based upon the latest feedback that the prior owner of tecarfarin had with the FDA in 2019, a single pivotal trial, if successful, will be sufficient for NDA filing. ACTOR AF: Anti-Coagulation with Tecarfarin on Outcomes in Renal disease and Atrial Fibrillation is designed as a Phase 3, 492-patient, Randomized, Double-Blind, Placebo-Controlled Outcomes Study of Tecarfarin vs. Placebo in Subjects with End-Stage Kidney Disease and Atrial Fibrillation not Currently Treated with Chronic Oral Anticoagulation. If we are able to complete the Phase 3 clinical trial and we are able to obtain FDA approval of our NDA, we believe tecarfarin can be the first approved treatment for patients with ESKD and AFib who are currently without an approved treatment.
- If we obtain FDA approval of our NDA for our first indication, we intend to seek to expand the label for tecarfarin through a supplemental NDA. We intend to explore the full potential of tecarfarin in additional indications, including the treatment of patients with LVADs and APS who require chronic anticoagulation.

- An LVAD is an implantable pump attached to the heart, connecting the apex of the left ventricle to the ascending aorta. LVADs are intended to treat patients suffering from advanced heart failure.
- APS is an autoimmune disorder characterized by an increased tendency to form abnormal blood clots, which can form in nearly any blood vessel in the body, and which can also cause miscarriages in women.

- If we obtain ODD for use in patients with LVADs, and receive acceptable feedback from the FDA regarding our trial protocol, and subject to funding from additional financings and/or partnerships, we may choose to advance tecarfarin in patients with LVADs as our first indication.
- We intend to partner and/or in-license and/or acquire clinical-stage cardiovascular products to augment our current pipeline, which consists of one investigational product.
- Create a commercial infrastructure for our product candidates. If tecarfarin is approved by the FDA, we intend to expand our commercial infrastructure and hire and train a focused and dedicated specialty salesforce which we believe can efficiently cover the top prescribing physicians and approximately 3,000 anticoagulation clinics in the U.S., which presently monitor patients on warfarin.



Retrometabolic Drug Design Process

We utilize a retrometabolic drug design process to design product candidates that follow a metabolic pathway that we believe will confer significant clinical advantages over existing drugs metabolized by the CYP450 pathway. "Drug metabolism" refers to the process by which a drug is inactivated by the body and rendered easier to eliminate or to be cleared by the body. Most approved drugs are metabolized in the liver through the CYP450 pathway by the enzymes known as CYP2C9 and CYP3A4. The CYP450 metabolic pathway has limited capacity, and patients taking multiple medications that interact with CYP2C9, or those with impaired kidney function, can experience an overload in the pathway, creating a bottleneck causing insufficient clearance, which results in a toxic build-up of one or more drugs. In some instances, patients taking multiple medications that interact with CYP2C9 may also experience that a drug is eliminated too quickly from the body, reducing the efficacy of the drug. Patient-specific genetic differences can also hinder drug clearance in the CYP450 pathway. Our product candidates were designed so that they follow a metabolic pathway distinct from or in addition to the CYP450 pathway, eliminating or minimizing the CYP450 metabolism by the liver, and are instead or additionally eliminated by large capacity and non-saturable tissue esterase pathways that exist throughout the body rather than just in the liver. We believe that the use of these alternative pathways can minimize the impact of drug-to-drug interactions, impaired kidney function and genetic variability, on the metabolism of our drugs, thereby ultimately minimizing clearance-related safety issues.

By designing drugs that break down to the ideal metabolite, and accordingly, are not cleared through the CYP450 pathway, we create product candidates that we believe would reduce many of the safety risks and complications that patients experience with drugs that are cleared through the CYP450 pathway. As a result, we believe there may be better compliance with a tecarfarin treatment regimen, if approved by FDA, which may also result in increased efficacy for the patients taking our drug product candidates.

Our Investigational Product Candidate

Tecarfarin for Use in Patients with LVADs

We have also applied for an orphan drug designation (ODD) for the prevention of thrombosis and thromboembolism in patients with left ventricular assist devices (LVADs). There are approximately 15,000 patients in the U.S. with LVADs, and therefore, this meets the prevalence requirement of fewer than 200,000 patients.

Implantable left ventricular assist device (LVAD) therapy is used to improve quality of life, alleviate symptoms, and extend survival rates in patients with advanced heart failure, irrespective of eligibility for cardiac transplant. Patients with LVADs require chronic anticoagulation to reduce the risk of thromboembolic complications, and they commonly experience bleeding events. Recent data reveals that the current standard of care anticoagulant, warfarin, yields suboptimal levels of anticoagulation, leading to excess bleeding complications.

LVAD patients require life-long anticoagulant therapy to reduce the risk of pump thrombosis. Anticoagulation management in patients with LVADs continues to be a challenge. Patients and their clinicians are faced with the daily challenge of needing adequate anticoagulation versus the bleeding risks that are associated with anticoagulation. Warfarin is the recommended oral anticoagulant for all currently available LVAD devices, however, warfarin is known to be a difficult medication to manage due to its narrow therapeutic window, and its many interactions. Recent data also highlights the need for a next generation VKA anticoagulant. 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 continued aspirin, along with warfarin. 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 predominant findings showed that the average time in the therapeutic range was only 56% with warfarin, far below the target of 70%, and that, despite the superior design of the HM3 device, poor quality anticoagulation was associated with excess thrombotic and bleeding events.

Tecarfarin for Use in Patients with ESKD and AFib

Thrombosis is the formation or presence of a blood clot (a thrombus) within a blood vessel that blocks normal blood flow. A formed thrombus can detach from the vessel or heart atrium wall, resulting in a thromboembolism that causes a blockage of the blood flow to vital organs, such as the brain, heart and lungs. According to the CDC, each year, approximately 800,000 people in the U.S. experience a new or recurrent stroke, of which approximately 87% are ischemic strokes, which are caused by either a thrombotic event or embolism, in which blood flow to the brain is blocked. In addition, the CDC estimates that as many as 900,000 people in the U.S. could be affected by venous thromboembolism (blood clotting in the veins) or a pulmonary embolism (blood clotting in the lungs) each year.

Types of Anticoagulants

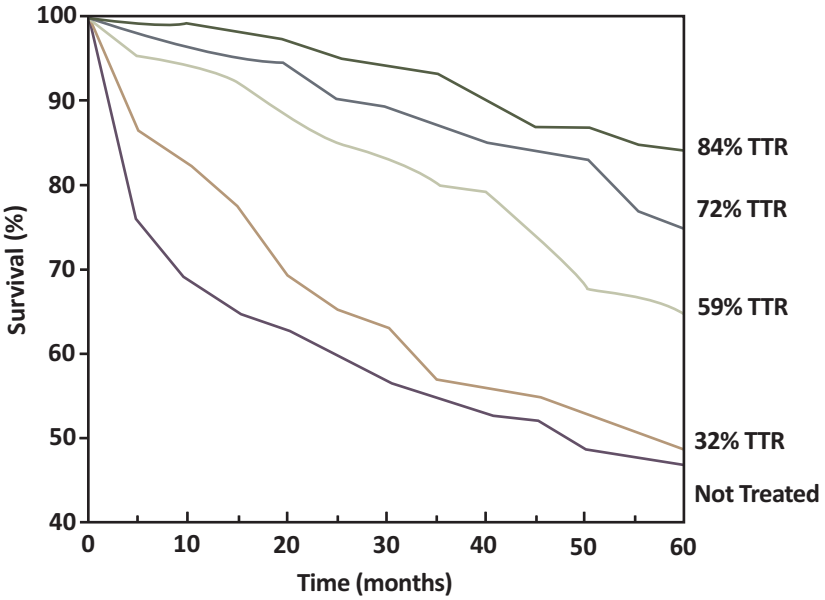
The prevailing treatment for patients at risk of thrombosis is an oral anticoagulant of which there are two common types: vitamin K antagonists, or VKAs, and direct oral anticoagulants, or DOACs.

Vitamin K Antagonists: Warfarin

Vitamin K antagonists, or VKAs, are substances that block the production of vitamin K-dependent blood clotting factors such that the blood is "thinned," preventing clots. VKAs are used as anticoagulants in the treatment of thrombosis. For patients treated with a VKA, the international normalized ratio, or INR, a system established by the World Health Organization and the International Committee on Thrombosis and Hemostasis, is a commonly available, inexpensive measure of the body's coagulation status. Each VKA patient's dose must be individualized, based on a target range for his or her INR test. The percentage of time that a patient's INR is maintained within his or her target range is known as the time in therapeutic range, or TTR. TTR is a well-established FDA metric used to evaluate anticoagulation control (safety and efficacy) of a VKA based on prothrombin time and the INR. When used as a therapy, VKAs are titrated to a patient's individual INR range and that patient is expected to visit a clinic for regular INR monitoring. A higher TTR reflects better anticoagulation control and is related to improved clinical outcomes, including rates of death, bleeding, myocardial infarction, stroke and systemic embolism, and a TTR measure of ≥ 70% is generally accepted as the goal for stable anticoagulation with a VKA. When patients are above their individual INR range, they are at higher

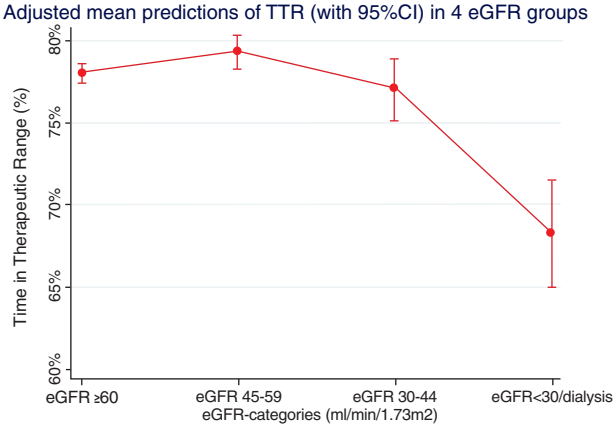
risk for bleeding, due to reduced clotting ability, while patients are below their target INR range are at higher risk for thrombotic events. Potential benefits of monitoring INR include ascertaining patient compliance with their drug treatment regimen, the ability to detect when dose adjustments are needed and maintaining safety and efficacy of the drug treatment. TTR is predictive of adverse events, including mortality, stroke and myocardial infarction.

As depicted in the chart below, higher TTR is generally correlated with higher survival rates.



Source: Currie et al. Heart 2006 (92) 196-200

Higher TTR levels are also associated with better kidney functioning, as measured by estimated glomerular filtration rate (eGFR), as reported by the Journal of the American Heart Association in 2017.



VKAs are reversible, meaning that in cases of over-anticoagulation, vitamin K or fresh frozen plasma, or a combination, can be administered to bring patients back down into their INR range.

Warfarin is currently one VKA treatment option for thrombosis in the U.S. and has been in use since the 1950s. However, as reported by the National Center for Biotechnology Information, there are many adverse events associated with warfarin, including bleeding, skin necrosis and hair loss, and warfarin has been reported as number three on the list of drugs implicated in adverse effects causing hospital admission due to its many drug-to-drug interactions. Due to these side effects and the increasing use of DOACs, the use of warfarin has decreased during the last decade.

Limitations of Warfarin Treatment

Warfarin has significant safety risks stemming from its metabolic process, including its elimination pathway. Other drawbacks of warfarin are widely recognized such as narrow therapeutic range, slow onset and offset of action causing difficulty to manage during peri-invasive procedures, and multiple drug and food interactions.

Warfarin's efficacy and safety profile are affected by its metabolism and elimination characteristics and various interactions with other drugs. Warfarin is metabolized through the CYP450 pathway, primarily by the CYP2C9 enzyme, and approximately 15% of clinically used drugs are metabolized by the same enzyme, including certain anticoagulants, antiplatelets and non-steroidal anti-inflammatory drugs, or NSAIDS. Patients taking warfarin and on CYP2C9 interacting drugs may experience either or both of, warfarin being eliminated by the body too quickly, thereby decreasing its anticoagulation effect, or warfarin being eliminated by the body too slowly, resulting in excessive and dangerous thinning of the blood. In both of these situations, increased monitoring is required and dose adjustments are often necessary. Patients who take both warfarin and these CYP2C9 interacting drugs also have an increased risk of being outside their individual INR target range and experiencing lower or higher TTR. For these patients, their CYP2C9 interacting drugs must be used with caution, or at times, their use must cease.

Warfarin's efficacy and safety profile are also affected by genetic mutations that lead to a lower activity of the CYP2C9 enzyme, the primary enzyme used to eliminate warfarin from the body. Clinical studies have shown that these persons require lower dosages of warfarin and are at an increased risk of anticoagulation.

Currently, warfarin is commonly used in patients with non-valvular AFib and in patients with valvular heart diseases (VHD) with AFib. However, as reported by an article published by the Egyptian Heart Journal on March 28, 2022, an analysis of 6,454 patients with AFib taking warfarin showed that almost 50% of the time the INR was outside the target range of 2 – 3, leading to a higher risk of bleeding and thrombotic complications. The major adverse effect associated with warfarin is bleeding. Major and fatal bleeding events occur at rates of 7.2 and 1.3 per 100 patient-years, respectively, according to a meta-analysis of 33 studies.

INR should be more frequently monitored in patients with impaired kidney function. Patients with impaired kidney function have a decreased ability to metabolize drugs through the CYP450 pathway, and accordingly have an increased risk of being outside their individual INR target range and experiencing lower TTR. Further, according to an article published by Frontiers in Medicine in January 2021, warfarin was associated with an increase in the risk of major bleeding without reduction in stroke/thromboembolism or mortality in patients with end-stage CKD requiring dialysis.

As a result of some or all of the above, and other factors, trials have shown that patients treated with warfarin often experience TTRs lower than 70%, the generally accepted TTR threshold representing stable anticoagulation. In a 2019 study conducted to evaluate the TTR of 300 patients on long-term warfarin for non-valvular AFib, as reported by an article published in Health and Quality of Life Outcomes on October 20, 2020, 75.5% of patients had a poor TTR with a mean of only 39.5%, with the mean TTR of all patients in the study being 47%. In another study of 406 AFib patients conducted in Lithuania to evaluate the quality of warfarin as anticoagulation therapy, more than half (57.3%) of INR values were outside of the target range and the median TTR was only 40%, with only 20% of patients having a TTR greater than or equal to 65%.

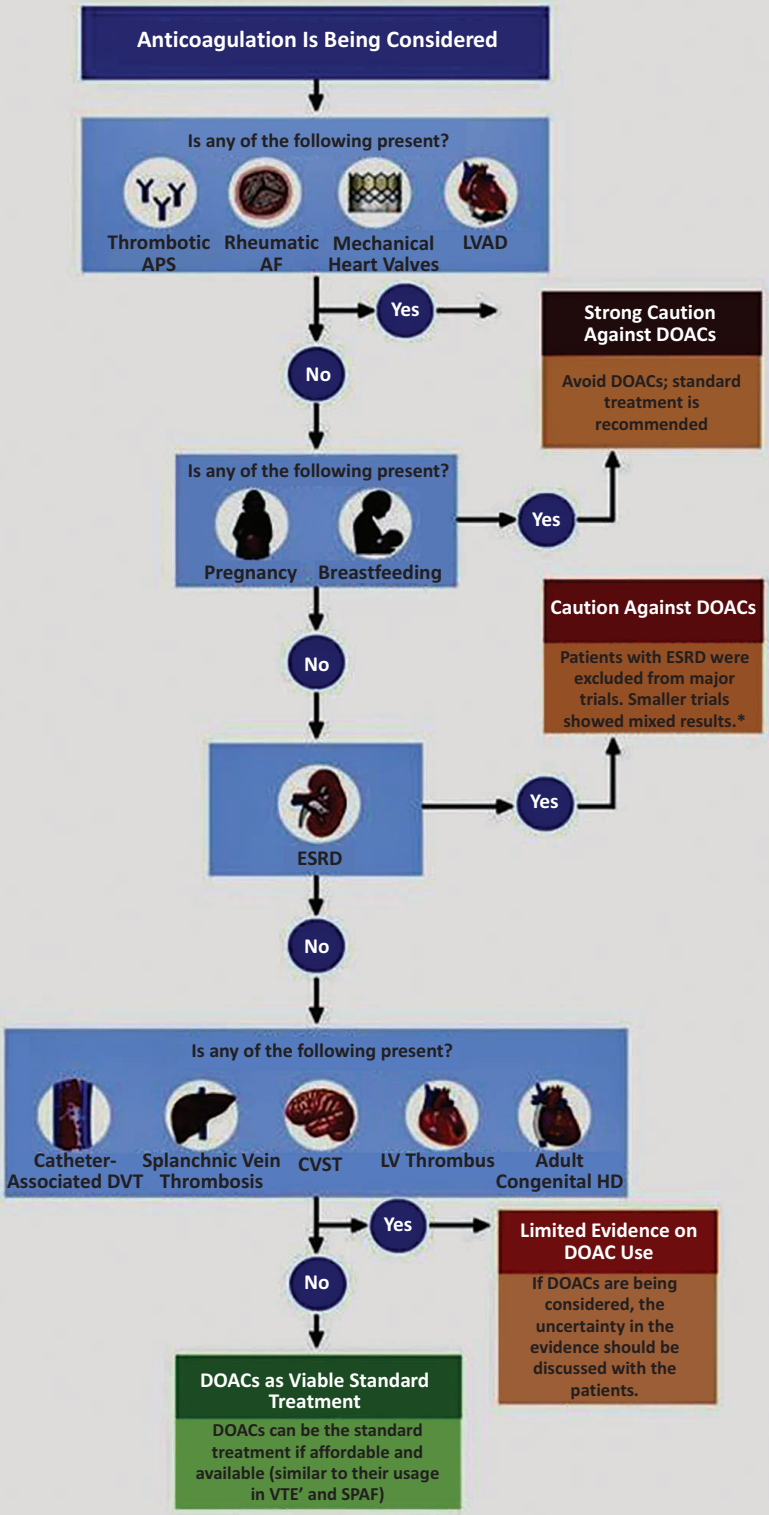
Direct Acting Oral Anticoagulants (DOACs)

DOACs, are a form of treatment that inhibits certain blood clotting factors. While VKAs block the synthesis of vitamin K-dependent blood clotting factors, NOACs block the activity of these clotting factors. There are two classes of DOACs, oral direct thrombin inhibitors and oral direct factor Xa inhibitors. Currently, there are only four DOACs approved by the FDA for use outside of a hospital setting: apixaban (the generic name for Eliquis), dabigatran (the generic name for Pradaxa), rivaroxaban (the generic name for Xarelto) and edoxaban (the generic name for Savaysa). 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.

Limitations of DOAC Treatment for Patients with LVADs, ESKD and AFib, and thrombotic APS

DOACs have been approved in the U.S. for the treatment of specific oral anticoagulation indications; however, there are anticoagulation indications for which DOACs are warned against use or are not recommended for use, including for anticoagulation treatment in patients with mechanical heart valves. DOACs do not have the same broad label indication as warfarin and are only indicated for some thrombosis indications.

CENTRAL ILLUSTRATION: Important Considerations for Direct Oral Anticoagulant Use



Bejjani A, et al. J Am Coll Cardiol. 2024;83(3):444-465.

Our Proposed Solution: Tecarfarin for Treatment of ESKD and AFib, Patients with LVADs, and thrombotic APS

Tecarfarin, our lead investigational product candidate, is a VKA, once-daily OAC. Tecarfarin was specifically designed using a retrometabolic drug design which targets a different metabolic pathway than the most commonly prescribed drugs for the treatment of thrombosis and AFib. Like warfarin, tecarfarin will also require INR monitoring. Due to its retrometabolic design, tecarfarin is eliminated by large capacity and non-saturable tissue esterase pathways that exist throughout the body, rather than just in the liver. This is a metabolic pathway that is distinct from the CYP450 pathway and infrequently used by other medications, which could potentially reduce the risk for drug-to-drug interactions. Moreover, unlike warfarin, we do not believe tecarfarin's metabolism is affected by CYP2C9 genetic variant alleles or by kidney function.

Given the metabolic process and related safety issues with warfarin and the limited treatment indications for which DOACs are approved, we believe there is a significant thrombosis patient population in need of an alternative anticoagulation treatment. The lack of stable and predictable anticoagulation control is particularly problematic in large underserved patient subpopulations with risk factors such as:

- Patients treated with CYP2C9 interacting drugs;
- Patients with severely impaired kidney function;
- Patients with genetic variant alleles for CYP2C9;
- Patients with LVADs;
- Patients with mechanical heart valve implants; and
- Patients treated with thrombotic APS

Tecarfarin Clinical Program

Tecarfarin has been evaluated in eleven clinical trials: eight Phase 1 trials, two Phase 2 trials and one Phase 2/3 trial evaluating the efficacy and safety of tecarfarin. We are currently planning to commence a pivotal Phase 3 trial in 2025. A readout of the two-year animal carcinogenicity study is expected to be completed in first half of 2025. We will also conduct any further trials as may be required by the FDA.

A summary of the clinical trials conducted to date with tecarfarin is shown below.

Study Number	Study Description	Study Population	Number Exposed	Date started	Date completed	Sponsor
ZK-TEK-201905	**Multiple-dose tolerance and PK-PD study of tecarfarin**	**Healthy Chinese Volunteers**	**40**	**2020**	**January 2021**	**Zhaoke Pharmaceutical (Guangzhou) Co., Ltd**
LP-HK-001	**Phase 1, Sequential Cohort, Single-dose escalation study**	**Healthy Chinese Volunteers**	**40**	**June 2018**	**July 2019**	**Lee's Pharmaceutical (Hong Kong) Limited**
CLN-512	**Phase 1 pharmacokinetic study in chronic kidney disease subjects**	**Chronic kidney disease subjects; healthy volunteers**	**23**	**November 2015**	**May 2016**	**Armetheon, Inc.**
CLN-505	**Phase 2/3 randomized, blinded head-to-head anticoagulation in broad indications (EMBRACE-AC)**	**Patients (all indications)**	**609**	**June 2008**	**December 2009**	**ARYx Therapeutics, Inc.**
CLN-509	**Pilot Phase 2 study for trial methodology to be used in CLN-505**	**Patients (all indications)**	**50**	**January 2008**	**August 2008**	**ARYx Therapeutics, Inc.**
CLN-504	**Phase 2a open-label anticoagulation in AFib**	**Patients Requiring Oral Anticoagulation**	**66**	**December 2006**	**October 2007**	**ARYx Therapeutics, Inc.**

Study Number	Study Description	Study Population	Number Exposed	Date started	Date completed	Sponsor
CLN-508	**Phase 1 DDI study with amiodarone**	**Healthy volunteers**	**19**	**July 2007**	**September 2007**	**ARYx Therapeutics, Inc.**
CLN-507	**Phase 1 DDI study with fluconazole**	**Healthy volunteers**	**20**	**June 2007**	**August 2007**	**ARYx Therapeutics, Inc.**
CLN-503	**Phase 1 Dose titration to target**	**Healthy volunteers**	**28**	**October 2006**	**January 2007**	**ARYx Therapeutics, Inc.**
CLN-502	**Phase 1 Effect on INR in multiple dose response**	**Healthy volunteers**	**42**	**November 2005**	**July 2006**	**ARYx Therapeutics, Inc.**
CLN-501 & CLN-501.X	**Phase 1 Safety and human pharmacokinetics**	**Healthy volunteers**	**66**	**August 2005**	**April 2006**	**ARYx Therapeutics, Inc.**

Phase 2 Trials

CLN-504: Trial CLN-504 was an open-label study in which 66 patients with AFib were treated with tecarfarin for a period of six weeks, with the option of continuing treatment for an additional six weeks. The trial, which was conducted by our predecessor company that owned the rights to tecarfarin, was primarily designed to determine an optimal dosing regimen and monitoring schedule and to describe the efficacy and explore the quality of anticoagulation as measured by TTR for INR. Before the trial, warfarin-treated patients had a mean TTR of 59.4%. After the initial three weeks of dose titration, the tecarfarin-treated patients were within the target INR range 71.4% of the time ($p<0.001$). The most commonly reported treatment-related adverse events, or TEAEs, were mild hemorrhagic complications of anticoagulation, such as bruising and nosebleed.

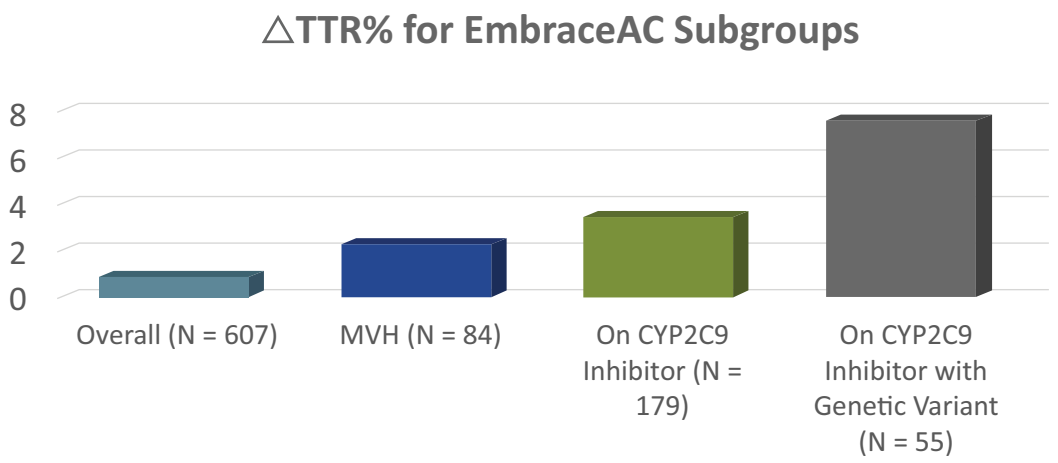
There were two deaths after trial drug treatment was completed: one patient died due to idiopathic pulmonary fibrosis and pneumonia two weeks following his last dose of tecarfarin, and one patient died due to bronchial carcinoma two weeks following his last dose of tecarfarin. These deaths were not attributed to tecarfarin.

CLN-509: The CLN-509 trial was a pilot Phase 2 study to assess clinical trial methodology to be used in CLN-505, in patients having a variety of clinical indications requiring chronic oral anticoagulation, as measured by INR. Fifty patients, including patients with AFib, some of whom were already taking warfarin and some of whom had not, received daily doses of tecarfarin ranging from 1 mg to 60 mg to maintain their INR value (the INR varied based upon the patient's condition). The objectives of evaluating safety and INR control in patients with a variety of clinical indications for chronic oral anticoagulation and assessing the feasibility of tecarfarin treatment in multiple dose strengths were met. INR control was shown for patients with atrial fibrillation, venous thromboembolic disease, prosthetic heart valves, and cardiomyopathy. There were no off-target adverse events due to tecarfarin and there were no clinically important safety signals in other measures of safety. The results of this trial resulted in the development of the clinical trial methodology for the Phase 2/3 trial (EMBRACE-AC).

CLN-505 (EMBRACE-AC): The Phase 2/3 CLN-505 trial, referred to as the EMBRACE-AC trial, was a multi-center, randomized, stratified, double-blind, parallel group, active control trial for a minimum period of six months and up to one year designed to compare the quality of anticoagulation of tecarfarin and warfarin as determined by TTR. Dosing of study drugs was managed by a centralized dose control center. In total, 609 patients were enrolled and of those, 607 patients completed the trial and of these, 304 patients received warfarin and 303 patients received tecarfarin. The EMBRACE-AC trial did not achieve statistical significance on its primary endpoint and the results of the primary analysis showed that tecarfarin was not superior to warfarin as measured by TTR. However, the TTR observed in patients taking tecarfarin (72.3%) was numerically similar to patients taking warfarin (71.5%) (difference of 0.8%; $p=0.51$).

As part of its original design, the EMBRACE-AC trial included analyses of INR measurements while patients were temporarily off their trial drug due to other medical reasons. Subsequently a post-hoc analysis was conducted in which we excluded INR values collected during these periods and showed that the percentage of TTR was higher on tecarfarin (68.8%) than on warfarin (66.4%) (difference of 2.3%; $p<0.04$).

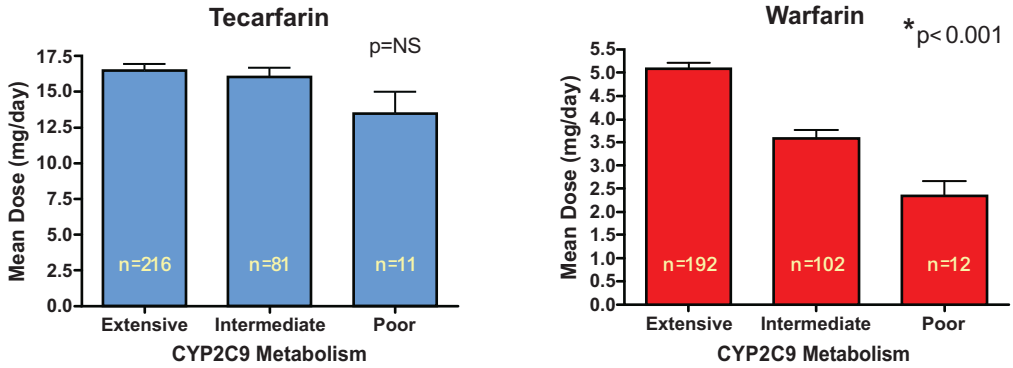
Post-hoc analyses were conducted in other patient subgroups in our EMBRACE-AC trial. The following chart depicts the findings of the analysis of the study and the degree to which TTR% on tecarfarin was higher than on warfarin:



- In the 179 patients taking CYP2C9 interacting drugs, the TTR of patients taking tecarfarin was similar to that of patients taking warfarin (72.2% and 69.9%, respectively; p=0.15).
- In the 55 patients taking CYP2C9 interacting drugs who also had a CYP2C9 genetic variant allele, the TTR of patients taking tecarfarin was similar to that of patients taking warfarin (76.5% and 69.5%, respectively; p=0.09).
- In the 84 patients with mechanical heart valve implants, the TTR of patients taking tecarfarin was similar to that of patients taking warfarin (68.4% and 66.3%, respectively; p=0.51).

The potential benefit of tecarfarin over warfarin as measured by TTR was not demonstrated in EMBRACE-AC. However, the TTR observed in patients taking tecarfarin in the trial, and in the subpopulations described above, were numerically similar to the TTR observed in the patients taking warfarin, and the TTR observed in patients taking tecarfarin demonstrated stable anticoagulation. The TTR in patients treated with warfarin exceeded previously reported TTR rates observed in patients taking warfarin, which are typically in the 50% to 65% range, which we believe was due to the use of dose control centers in the administration of the trial. When dose control centers are used in the administration of warfarin, large teams of medical professionals are able to closely monitor patients and mitigate many of the drug-to-drug and genetic variant-related limitations of the drug that are not easily managed in real world settings.

EMBRACE-AC also provided information for dosing and dose adjustments for tecarfarin. The average daily doses required of both tecarfarin and warfarin was analyzed in patients who had poor, intermediate or extensive metabolism capacity of the CYP2C9 enzyme. Patients with poor metabolism capacity of the CYP2C9 enzyme who were treated with warfarin required a significantly lower average daily dose compared to those patients with extensive CY2C9 enzyme metabolism capacity. In contrast, as depicted below, the required dosage of tecarfarin did not vary significantly based on the patient's CYP2C9 activity level.



Tecarfarin appeared to be well tolerated with only 1.6% of the blinded tecarfarin subjects suffering from major bleeding and no thrombotic events. When thrombotic and major bleeding events during the blinded period were combined, a numerical imbalance favoring tecarfarin over warfarin was seen (warfarin 11 subjects, 3.6%; tecarfarin 5 subjects, 1.6%). The safety data from EMBRACE-AC showed comparable rates of adverse events 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.

The trial had some limitations. The TTR with warfarin achieved in Embrace-AC was much higher than that typically seen in clinical trials and as compared to "real-world practice," exceeding 71% on an interpolated basis in both treatment arms. The most likely reason stemmed from the dosing of study drugs which was managed by a centralized dose control center, which had access to genotyping.

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.

Phase 1 Trials

CLN-501: Trials CLN-501 and CLN-501.X evaluated the safety tolerability of tecarfarin in a total of 64 healthy volunteers. The studies were sufficiently similar in their requirements and study populations to be combined and analyzed together. The primary differences between the studies were the study drug formulation (CLN-501 used a solution formulation while study 501.X used tablets) and the range of single doses studied. In CLN-501, cohorts of 6 eligible subjects were randomly assigned to receive tecarfarin at one of eight ascending dose levels between 0.2 and 10.0 mg or placebo. In CLN-501.X, similar cohorts received tecarfarin at one of three ascending dose levels (20.0, 30.0, or 40.0 mg) or placebo. The studies demonstrated that there were no apparent differences between pharmacokinetics parameters after tecarfarin was administered at single doses from 0.2 to 10.0 mg as an oral solution or at single doses from 20.0 to 40.0 mg as an oral solid tablet formulation and that tecarfarin was well-tolerated.

CLN-502: Trial CLN-502 evaluated tecarfarin pharmacokinetics, dose range, and duration of dosing that would attain a stead steady state INR of 1.7 to 2.0 and would give stead-state plasma concentrations of tecarfarin. Forty-two healthy volunteer subjects were randomized and received either 1, 3, 6, 10, 20, 30, or 40 mg of tecarfarin or placebo (the 3 and 6 mg cohorts were discontinued after one week due to lack of pharmacodynamic effect). The study successfully determined the active dose of tecarfarin and provided the pharmacokinetic and pharmacodynamic basis for subsequent multidose trials. Doses of 20 mg and above brought subjects into the target INR range of 1.7 to 2.0, with the 40 mg dose bringing all subjects into the target range within one week of dosing. The trial demonstrated that tecarfarin was well-tolerated at all doses studied as assessed by adverse events, vital signs, electrocardiography, and laboratory testing, and that a loading dose of 40 mg could be appropriate for initiating anticoagulation in Phase II trials.

CLN-503: Trial CLN-503 evaluated the safety and tolerability of tecarfarin versus warfarin when administered alone and in combination with amiodarone as measured by INR in 28 healthy subjects. During the first phase, subjects were administered tecarfarin or warfarin for 10 days, with doses titrated daily to achieve a target INR range of 1.5 to 2.0. Subjects who remained within the target INR range without requiring a dose change continued to the next phase with amiodarone, with all subjects receiving 200 mg amiodarone twice daily in addition to tecarfarin or warfarin. The primary objectives of the trial were completely met. Both tecarfarin and warfarin were well-tolerated, both alone and in the presence of amiodarone. There were no safety signals as ascertained by adverse event reports, clinical laboratory

testing, vital sign measurement, and by electrocardiography. The quality of anticoagulation was good for both cohorts and a target INR was reached and maintained during the 3-day maintenance period. The results of the trial suggested the use of the same INR therapeutic range for tecarfarin as is recommended for warfarin.

CLN-507: Trial CLN-507 evaluated the effects of co-administration of fluconazole, a drug that blocks the activity of the CYP450 enzyme, with either 50 mg tecarfarin or 17.5 mg warfarin in 20 healthy volunteers. The trial demonstrated that co-administration of fluconazole did not affect the metabolism or elimination of tecarfarin. In contrast, the co-administration of fluconazole prolonged the half-life of warfarin.

CLN-512: Trial CLN-512 evaluated the effects of severe chronic kidney dysfunction on the metabolism and elimination of tecarfarin and warfarin. Thirteen patients with severe kidney dysfunction (stage 4 chronic kidney disease, or CKD) and 10 healthy volunteers (matched for age, weight, gender and CYP2C9 genotype) were administered 30 mg tecarfarin and 10 mg warfarin in a randomized crossover design. The trial demonstrated that tecarfarin's elimination from the body was not affected by severe kidney dysfunction: the half-life and the amount of drug in the body were similar in people with CKD and healthy patients. In contrast, the plasma concentration and half-life of warfarin was increased in patients with CKD, with warfarin's exposure increasing 44% in these patients. These effects were exaggerated in patients with CYP2C9 genetic variant alleles and in those who required concomitant CYP2C9 interacting drugs. At the conclusion of the trial, the safety of repeated dosing of tecarfarin in CKD patients remained unknown. However, overall, the results of this study suggest that no adjustment in the dose of tecarfarin is needed for patients with CKD.

CLN-508: Trial CLN-508 evaluated the effects of co-administration of 400 mg amiodarone with either 50 mg tecarfarin or 17.5 mg warfarin in 19 healthy volunteers, nine on tecarfarin and 10 on warfarin. Amiodarone, a drug used to treat irregular heartbeat, is a moderately potent inhibitor of CYP2C9 metabolism and is frequently used as a treatment for AFib in combination with warfarin. The effects of amiodarone on the pharmacokinetics of warfarin and tecarfarin showed that the exposure was increased to about the same extent for both drugs. The exposure of R-warfarin increased by 27% and the exposure for S-warfarin increased by 38%. The exposure of tecarfarin increased by approximately 31%. These changes in exposure did not result in any changes in INR in either the tecarfarin or the warfarin cohorts and demonstrated that tecarfarin behaved similarly to warfarin when administered in combination with amiodarone.

An Open-label, Phase 1, Sequential Cohort, Single-Dose Escalation Study to Assess the Safety and Tolerability of Tecarfarin (ATI-5923) in Healthy Chinese Volunteers

Study Protocol: LP-HK-001 completed in July 2019

This was an open-label, phase 1, sequential cohort, single-dose escalation study conducted in China to assess the safety and tolerability of tecarfarin (ATI-5923) in healthy Chinese volunteers. The study site enrolled up to a total of 40 subjects. Ten (10) healthy Chinese subjects received tecarfarin (ATI-5923) at each dose level (i.e., 10 mg, 20 mg, 30 mg and 40 mg).

The safety assessment results of this study were consistent with the results of CLN-501 study, and there was no safety risk after single dose administration of 10mg~40mg tecarfarin. AEs with higher incidence rate included headache and dizziness, and such AEs were graded as mild in severity. Tecarfarin showed a promising safety and tolerability profile in Chinese subjects.

Based on the results in this open-labelled, single-dose escalation, phase 1 study of tecarfarin, the following conclusions were made:

Single dose administration of tecarfarin in dose level ranging from 10 mg to 40 mg had no clinically significant effect on coagulation function. However, a slightly increasing trend in INR and PT values were observed with dose escalation. A slightly decreasing trend in coagulation factors II, VII and X were observed with dose escalation. Tecarfarin showed a promising safety and tolerability profile in Chinese subjects. The results of this study warrant further multiple-dose pharmacokinetic studies in the Chinese population. We do not believe we can extrapolate this data to other populations, including the United States, but other trials were performed in the U.S.

A Multiple-Dose, Safety and Tolerability PK/PD Study of Tecarfarin in Healthy Chinese Volunteers

Study Protocol: ZK-TEK-201905 completed in January 2021

This was a multiple-dose phase 1 pharmacokinetic-pharmacodynamic study conducted in China to assess the safety and tolerability of tecarfarin in healthy Chinese volunteers. The study site enrolled up to a total of 40 subjects. Ten (10) healthy Chinese subjects received tecarfarin once-daily on fasting every morning for 14 days at each dose level (i.e., 10 mg, 20 mg, 30 mg and 40 mg).

Tecarfarin was well tolerated in Chinese volunteers without serious adverse events in both single ascending dose and multiple ascending dose ("MAD") studies. There was only one treatment related adverse event (hematochezia) that resulted in early withdrawal in the MAD 40mg cohort. Exposure levels of tecarfarin were generally dose proportional.

Summary of Tecarfarin Clinical Trials

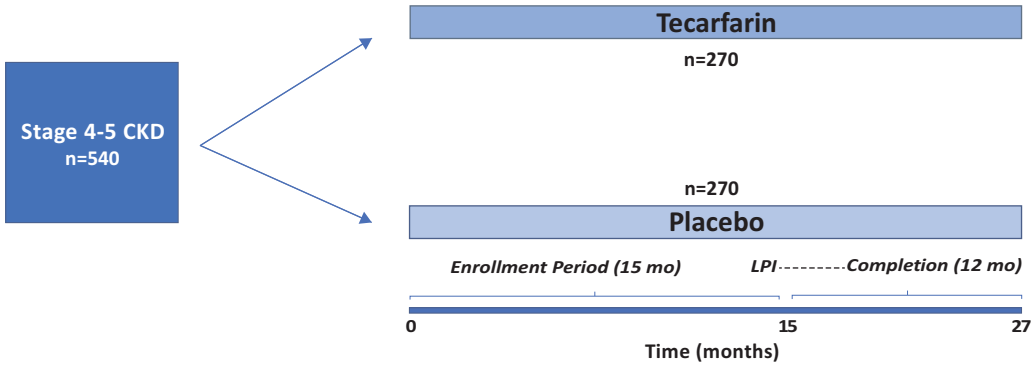
Clinical and preclinical trials of tecarfarin have demonstrated lack of drug-to-drug interactions with tecarfarin, predictable clearance that is independent of CYP450 blood clotting factors and any genetic variation in these factors, and the lack of impact of kidney function on clearance of tecarfarin. In the largest and longest of the clinical trials, EMBRACE-AC, tecarfarin and warfarin were found to have similar major and overall bleeding risks. In EMBRACE-AC, warfarin-treated patients had five thrombotic events, while there were no such events among tecarfarin-treated patients. When thrombotic and major bleeding events were combined, a trend favoring tecarfarin over warfarin was seen (five tecarfarin patients (1.6%) compared to 11 warfarin patients (3.6%)). We will conduct further studies and intend to submit this data to FDA in the NDA.

Upcoming Pivotal Phase 3 Trial: CLN-515 (ACTOR AF)

In 2019, the United States Food and Drug Administration (the "FDA"), provided input on the Phase 3 trial design for tecarfarin, which was submitted by Espero, the previous owner of tecarfarin. We intend to submit our Phase 3 trial design to the FDA using the same protocol that was submitted by Espero. Assuming the FDA accepts our Phase 3 trial design and we have sufficient funding, we intend to commence the Phase 3 pivotal trial in 2025. Our cash and the proceeds from our initial public offering and the private placement offering that we consummated in July 2023 will only fund our operations for a limited time. The proceeds from our financings to date are insufficient to allow us to fully fund our planned pivotal Phase 3 clinical trial. We will need to raise additional capital for the initiation of enrollment of patients and completion of the planned pivotal Phase 3 trial.

However, there can be no assurance that we will raise sufficient funds to support the planned Phase3 trial or that the trial design will be accepted by the FDA. We are pursuing regulatory approval of tecarfarin as an individual treatment, although we might evaluate, in consultation with the FDA, other potential uses in the future. Our Phase 3 trial is expected to be a randomized, double-blind, placebo-controlled study of tecarfarin in subjects with ESKD and AFib not currently treated with chronic oral anticoagulation. The study will assess the safety and efficacy of evaluate the efficacy and safety of tecarfarin (target INR 2.0-3.0) in subjects with ESKD (stage 5 — eGFR < 15 mL/min/1.73 mm2) and AFib. Subjects must have chronic paroxysmal, persistent or permanent AFib documented. All subjects will undergo genetic testing for VKORC1 prior to randomization, which will also be used for stratification at the time of randomization. Subjects will be randomly assigned to receive either blinded tecarfarin or placebo in a 1:1 ratio. Approximately 540 subjects (270 per arm) will be enrolled in the study.

An enrollment period of 15 months is anticipated. A 10% dropout rate (48 subjects) is anticipated resulting in 492 evaluable subjects. All subjects enrolled in the study will remain on study drug until the last subject enrolled completes a minimum of 12 months of therapy or until the required number of adjudicated major adverse cardiovascular events (death, ischemic stroke, pulmonary embolus, and/or myocardial infarction) have been obtained, whichever is later. The primary efficacy assessment is time to first major adverse cardiovascular event, or MACE. There will be approximately 125 study sites in the United States and Canada, with other trial sites to be determined. Based upon internal statistical projections, assuming the Phase 3 clinical trial is powered at 80%, the study is expected to demonstrate a treatment effect of 25%.



Sub-License

Lee's Pharmaceutical Holdings Limited License

In September 2015, China Cardiovascular Focus Ltd., a wholly owned subsidiary of Lee's Pharmaceutical Holdings Limited, or LPH, entered into an agreement (the "LPH License") with Armetheon, Inc. for the license, development and commercialization of our tecarfarin compound in China, Hong Kong, Macau, Taiwan and Thailand (the "Territory"). In October 2017, Armetheon, Inc. merged with Espero BioPharma, Inc. ("Espero"). The assets owned by Espero were assigned to HESP LLC in a court-approved assignment for the benefit of creditors. On April 1, 2022 we acquired from HESP LLC, pursuant to an asset purchase agreement, the assets related to tecarfarin, including the LPH License. Under the terms of the LPH License, LPH provided a non-refundable up-front payment of $1 million and agreed, during the term of the agreement, not to develop, manufacture or commercialize a competitive product in the Territory. Conversely, we agreed not to develop, manufacture or commercialize a competitive product in the Territory. If all potential development, regulatory and commercial milestones under the LPH License are met, we are entitled to receive payments of approximately $52.0 million. In addition, we are also entitled to receive royalties between 9% to 15% of the net sales of tecarfarin in certain specified markets. The LPH License expires on a country-by-country basis within the Territory, upon the latest of the expiration of the last intellectual property covering the tecarfarin compound in such country of the Territory, or the twelfth anniversary of the first commercial sale of tecarfarin in such country of the Territory.

Manufacturing

We do not have a manufacturing infrastructure and do not intend to develop one. We intend to contract with third parties for the production and packaging of our products and product candidates. With respect to tecarfarin, we have executed contracts with third-party contract pharmaceutical manufacturers for the development of validated processes and the supply of active pharmaceutical ingredient and clinical trial material in accordance with good manufacturing practices. Such contract manufacturers have the capability to scale up for commercial production of tecarfarin. However, we have not entered into any long-term supply agreements or commercialization partnership with these vendors. Certain material suppliers and manufacturing sites for our products and product candidates are in locations outside of the U.S.

While the materials and substances used in our product candidate 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 tecarfarin on commercially reasonable terms.

Sales and Marketing

If any of our product candidates are approved by the FDA or other regulatory authorities, we intend to commercialize our products by leveraging our existing commercial infrastructure and 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.

Market Opportunity

Based on a 2024 market and pricing study commissioned by us in the LVAD and ESKD with AFib patient populations, we estimate that the annual U.S. market revenue potential for tecarfarin is in excess of $2 billion at estimated orphan drug pricing, assuming that we receive FDA approval and successfully commercialize tecarfarin in accordance with projections.

Competition

There have been several randomized trials to definitively assess the treatment effects of apixaban compared with VKAs in the population dependent on dialysis. The RENAL-AF (Trial to Evaluate Anticoagulation Therapy in Hemodialysis Patients With Atrial Fibrillation) was terminated early in 2019 by its sponsor. In addition, the AXADIA study (Compare Apixaban and Vitamin-K Antagonists in Patients With Atrial Fibrillation and End-Stage Kidney Disease), which is currently recruiting patients, will randomize patients to apixaban 2.5 mg twice daily versus phenprocoumon. The randomization of study drug and blinded event adjudication in these trials will help to minimize bias and confounding, and will better elucidate the risks and benefits of standard versus low-dose apixaban. Neither of these trials are adequately powered to address the important questions relating to intracerebral hemorrhage.

The development and commercialization of new drugs is highly competitive. We face competition with respect to developing our current product candidate, 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. We are seeking to develop tecarfarin as a marketable VKA, once-daily OAC for chronic anticoagulation. If we succeed in developing the lead indication or additional indications, we will face substantial competition. Existing anticoagulant treatments for thrombosis include warfarin and DOACs such as Pradaxa (dabigatran), Xarelto (rivaroxaban), Eliquis (apixaban) and Savaysa (edoxaban) for specific indications. Warfarin is generic and manufactured by multiple generic pharmaceutical companies. The entry of the first generic DOACs, starting with Boehringer Ingelheim's loss of U.S., Japanese and Canadian patent protection for Pradaxa (dabigatran) in November 2018 and Eliquis and Xarelto by 2026, could increase competition and reduce the total dollars spent on the treatment of thrombosis, as a result of lower generic drug pricing. The next generation of anticoagulants in development, factor XI inhibitors, are currently in Phase 2 and 3 studies. In a statement posted to its website, drugmaker Bayer said the termination of OCEANIC-AF "is based on the recommendation of the study's Independent Data Monitoring Committee (IDMC) as part of ongoing surveillance which showed an inferior efficacy of asundexian versus the control arm. At the American Heart Association (AHA) 2023 Scientific Sessions, another novel factor XI inhibitor (Anthos Therapeutics), abelacimab, also showed promise for significantly reducing bleeding compared with rivaroxaban in AFib patients at moderate-to-high risk of stroke. The agent curbed bleeding so much in the phase II AZALEA-TIMI 71 trial that it was stopped prematurely and an extension trial was begun for the control arm. However, the impact of abelacimab on stroke remains unclear. In 2022, Merck received fast-track designation for its investigational anticoagulant therapy MK-2060 for the reduction in risk of major thrombotic cardiovascular events in patients with end-stage kidney disease (ESKD).

Many of these named products are marketed by some of the largest and most successful pharmaceutical companies worldwide. 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.

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, technology, reputation, customer service capabilities and access to market partners and customers. 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 these organizations has a long operating history, extensive resources, strong brand recognition and large customer base. 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 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.

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 biological 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 two issued U.S. patents directed to tecarfarin, and a pending provisional application. The expiration date of the issued patents is April 8, 2024 for both our composition of matter patent and our method of treatment patent, not including any possible patent term extension. Foreign patents corresponding to the tecarfarin patents expire in 2025. In the absence of (i) future ODD marketing exclusivity granted by the FDA, (ii) future market and data exclusivity granted by regulatory agencies and (iii) additional patent filings covering new inventions, upon expiration of our issued patents, we would not be able to adequately protect our 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.

However, 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 EU 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 candidates receive 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 tecarfarin is approved by the FDA, we expect to receive five years of data exclusivity, often referred to as new chemical entity exclusivity, for our tecarfarin new drug application ("NDA"), so long as FDA has not approved a drug containing the same active moiety as tecarfarin. It is possible that the FDA may disagree with our position and not approve tecarfarin or grant new chemical exclusivity to our NDA for tecarfarin. Assuming the FDA approves tecarfarin 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 tecarfarin, 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 investigational new drug application, or IND, 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, or GCPs, 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 GCPs 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 current good manufacturing practice requirements. The FDA will not approve the product unless compliance with current good manufacturing practices, or GMPs, 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, or 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, or 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 new drug applications 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 an 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.

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.

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 current good manufacturing practices, 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 current good manufacturing practice 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.

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, or 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 Affordable Care Act, or 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 the 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 8, 2024, we had four employees, all of which are full-time, and engage approximately fifteen 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 dated October 15, 2022 with Veranda III Partners, Ltd. (the "Lease Agreement"). The Lease Agreement has an initial term of 24 months commencing on November 1, 2022. The monthly rent is $2,167. 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;
- 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.

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

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

We are a recently formed company that was formed in January 2022 and have had limited operations to date. We have to manufacture product, complete clinical trials and receive regulatory approval of new drug applications, or 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 candidate, tecarfarin;
- 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 candidate, tecarfarin;

- 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 candidate, tecarfarin, 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 and our Chief Executive Officer has been involved with the development of tecarfarin for five years, as a company we have yet to prove that we can successfully run a clinical trial. 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 is unproven and our business model is continually evolving. 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 tecarfarin. 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 candidate and if approved, the market acceptance of our product offering and our capacity to develop, introduce and sell our product to our targeted markets. 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 undertake the pivotal clinical trial for our product candidate;
- 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 tecarfarin, for preparation and submission of a supplemental NDA for such alterations, if required by the FDA, and in connection with the launch of tecarfarin, if approved. Further, as we pursue FDA approval for tecarfarin, we expect that our research and development expenses will continue to increase significantly as we advance our pivotal Phase 3 clinical trial.

Our cash and the proceeds of our initial public offering and the private placement offering that we consummated in July 2023 will only fund our operations for a limited time, and we will need to raise additional capital to fund our planned pivotal Phase 3 clinical trial and to support our development and commercialization efforts for our product candidate, tecarfarin.

If we do not succeed in raising additional funds on acceptable terms, we will be unable to commence our planned Phase 3 pivotal clinical trial or obtain approval of our product candidate from the FDA and other regulatory authorities. 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, which includes the net proceeds from our initial public offering and the private placement offering that we consummated in July 2023, will be sufficient in the aggregate to meet our anticipated cash requirements for at least the next twelve months. We will, however, require additional financing 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 pivotal Phase 3 trial. Our liquidity may be negatively impacted as a result of a 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 Phase 3 clinical trial to obtain regulatory approval for tecarfarin in the United States;
- the costs of manufacturing our clinical product and establish 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.

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 raise sufficient additional capital on acceptable terms, or at all. We anticipate that the additional funding we require will be funded through the incurrence of other indebtedness, additional equity financings or a combination of these potential sources of liquidity. We may seek additional capital 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 additional 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 business is dependent upon the success of our investigational product candidate, tecarfarin, which requires additional clinical testing before we can seek regulatory approval and potentially launch commercial sales. We do not own any other product candidates or have any other products in clinical development.

Our business and future success depends upon our ability to obtain regulatory approval of and then successfully commercialize our product candidate, tecarfarin. Tecarfarin is in late clinical stage development. Our main focus and the investment of a significant portion of our efforts and financial resources is expected to be in the development of our only product candidate, tecarfarin, for which we are currently planning a Phase 3 clinical trial. We believe that the proceeds from our initial public offering and the private placement offering that we consummated in July 2023 will not provide us with sufficient funds to initiate or complete this pivotal Phase 3 clinical trial. Even though we are pursuing a registration pathway based on specific FDA input and guidance, 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 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 tecarfarin, which may never occur. We currently generate no revenues from our product candidate, and we may never be able to develop or commercialize a marketable drug.

All of our current data for our product candidate 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.

We possess toxicology, pharmacokinetic, and other preclinical data and clinical data on tecarfarin from studies and trials conducted several years ago by third parties. As of now, tecarfarin has been tested in eleven clinical trials and is now in preparation to enter a pivotal Phase 3 trial. There is no guarantee that Phase 1 or Phase 2 results can or will be replicated by the pivotal Phase 3 study. 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 using tecarfarin have had different trial designs, doses, parameters and endpoints than the planned Phase 3 clinical trial that is expected to serve as a basis for approval of tecarfarin. We have not received FDA input on our Phase 3 protocol and there can be no assurance that the planned protocol will be accepted by the FDA. We plan to use a fixed dose in future clinical trials that we believe provides good coverage given the dose ranges tested clinically; however, it is possible that the dose selected will not be the optimal dose and so drug effects may be limited or not be demonstrated sufficiently in clinical testing.

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

We did not acquire tecarfarin until April of 2022, and do not have first-hand knowledge of how the Phase 1 and Phase 2 clinical trials were completed. 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 Phase 3 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 demonstrate superiority to warfarin 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:

- although we have FDA minutes documenting Espero's correspondence with the FDA regarding tecarfarin, the FDA minutes are from 2019, are not binding on FDA, and our expectations regarding such plans may be out of date and not be in line with current market dynamics and the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the 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;
- we may not be able to successfully manufacture drug supplies for our clinical trial;
- the results of our clinical trial may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency, or 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 tecarfarin, and we may not be able to commercialize our product candidate 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 candidate 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. In 2020 and 2021, the FDA approved only three new molecular entities to treat cardiovascular/vascular diseases. 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 tecarfarin or any future product candidates will be harmed.

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 we have received Fast Track designation for tecarfarin for the prevention of systemic thromboembolism of cardiac origin in patients with ESKD and AFib, 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.

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

Even if we receive regulatory approval of tecarfarin or any future product candidates, we will be subject to ongoing regulatory obligations, such as post market surveillance and current good manufacturing practice ("GMP") 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 current GMPs and current good clinical practices ("GCPs") 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 FDA's and other regulatory authorities' policies 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 tecarfarin 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 tecarfarin 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 product candidates including tecarfarin, 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 Investigational New Drug, or 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 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. A resurgence of COVID-19 or another 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, tecarfarin may not have labeling that allows us to successfully commercialize it.

The commercial success of tecarfarin and any of our future 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 tecarfarin for fewer or more limited indications than we request or may approve tecarfarin 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 our product candidate 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 tecarfarin. Product revenues from our product candidate, tecarfarin, 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 tecarfarin, the timing or scope of any approval may prohibit or reduce our ability to commercialize tecarfarin 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 tecarfarin 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 tecarfarin. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals, such as risk management plans and Risk Evaluation and Mitigation Strategies, or 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 tecarfarin. 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 tecarfarin.

Our potential future product candidate, tecarfarin, 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 potential future product candidates, including tecarfarin, 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 accuracy of the international normalized ratio, or INR, testing and whether such testing can be conducted at home or in a medical facility such as a doctor's office. A prothrombin time, or PT, is a test used to help detect and diagnose a bleeding disorder or excessive clotting disorder; the INR is calculated from a PT result and is used to monitor how well an anticoagulant medication such as tecarfarin is working to prevent thrombosis;
- 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, or 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.

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.

Although we have been granted orphan drug designation for tecarfarin, this does not mean FDA will approve the NDA. Even if we obtain FDA approval, we may not be able to obtain or maintain orphan drug exclusivity for tecarfarin. We may not be the first to obtain marketing approval of tecarfarin designation for the orphan-designated indication 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 drug 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 drug designation have been granted.

After approval of tecarfarin, tecarfarin 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 tecarfarin, the FDA and other regulatory authorities may impose significant restrictions on its 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 candidate, 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 current Good Manufacturing Practices requirements, or cGMPs, and current Good Clinical Practices requirements, or GCPs, 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, or 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 tecarfarin, 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 tecarfarin and intend to rely upon third parties to produce and distribute our product candidate.

We have executed contracts with third-party contract pharmaceutical manufacturers for the development of validated processes and the supply of active pharmaceutical ingredients and clinical trial material in accordance with good manufacturing practices. Such contract manufacturers have the capability to scale up for commercial production of tecarfarin. However, we have not entered into any long-term supply agreements or commercialization partnership with these vendors. Certain material suppliers and manufacturing sites for our products and product candidates are in locations outside of the U.S. While the materials and substances used in our product candidate 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 tecarfarin on commercially reasonable terms.

We currently do not have an agreement with any third-party manufacturers for the production of tecarfarin and there can be no assurance that we will be able to enter into an agreement on acceptable terms. If an agreement is not entered into, we may experience longer manufacturing lead times for any purchase orders we place with a manufacturer under purchase orders. We intend to rely on third-party manufacturers to produce tecarfarin for our clinical studies who are

expected to purchase materials from third-party vendors and transport the materials necessary to produce tecarfarin, such as the required reagents and containers. 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 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. We are seeking to develop tecarfarin as an oral and reversible anticoagulant (blood thinner), to prevent heart attacks, strokes, and deaths due to blood clots in patients with certain rare medical conditions. If we succeed in developing tecarfarin, we shall 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.

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. 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. We may not be able to successfully compete with these existing products. 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.

Serious adverse events have occurred in the clinical trials of our product candidate. For example, major hemorrhages occurred in 1.6% of the blinded tecarfarin patients randomized in the EMBRACE-AC trial. We expect that additional patients will experience serious adverse events in our future clinical trials and during marketing if our products are approved. Design features of ACTOR AF, such as using a smaller number of patients and using MACE clinical outcomes as an endpoint, may produce results that show an imbalance in adverse events between treatment groups, when no such imbalance truly exists, or may not permit an assessment of the risk of rare events (due to the overall reduced size of the safety database), either of which could lead the FDA to require additional studies to demonstrate the safety of tecarfarin.

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 commercialize tecarfarin 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 tecarfarin, restrict or regulate post-approval activities and affect our ability to profitably sell tecarfarin. 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 tecarfarin, 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, or 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 the Centers for Medicare & Medicaid Services, or 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 2010 Affordable Care Act, 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 tecarfarin 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.

The 2010 Affordable Care Act is intended to broaden access to health Insurance and reduce or constrain the growth of healthcare spending. Further, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also increased the amount of the rebates drug manufacturers must pay to state Medicaid programs, required that Medicaid rebates be paid on managed Medicaid utilization, and increased the additional rebate on "line extensions" (such as extended-release formulations) of solid oral dosage forms of branded products. The law also contains substantial provisions affecting fraud and abuse compliance and transparency, which may require us to modify our business practices with healthcare practitioners, and incur substantial costs to ensure compliance.

Many members of the Republican Party have consistently opposed the Affordable Care Act since it was signed. Efforts to repeal the Act have been attempted numerous times and some portions of the Act have been amended in 2017 and 2018. It is unclear whether further amendments or repeal will be effectuated and what the effect on the healthcare sector will be. In addition to potential changes to the Affordable Care Act, there are indications that the Medicaid and Medicare programs may be restructured, which could lead to revisions in coverage and reimbursement of prescription drugs. While we are unable to predict what legislation, if any, may potentially be enacted, to the extent that future changes affect how our product candidates could be paid for and/or reimbursed by the government and private payers, our business could be adversely affected.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 included, among other things, provisions that have led to 2% across-the-board reductions in Medicare payment amounts. Several states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

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 Affordable Care Act, 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 Affordable Care Act 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, or 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, or 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 tecarfarin 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 tecarfarin 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 tecarfarin or any future product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of tecarfarin or any future product candidates.

We intend to seek approval to market tecarfarin 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 tecarfarin 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 Affordable Care Act, 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.

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 tecarfarin, 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 GCPs 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 GCPs, 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 have limited 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 tecarfarin. 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 tecarfarin, 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 tecarfarin 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 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 tecarfarin in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize tecarfarin 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 tecarfarin 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, such as the outbreak of COVID-19. If there is a resurgence of COVID-19 or if we experience another 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 the resurgence of COVID-19 or another global health crisis, including:

- unwillingness of potential study participants to enroll in our pivotal Phase 3 clinical trial and/or visit healthcare facilities;
- postponement of enrollment in our pivotal Phase 3 clinical trial
- postponement of the initiation of our pivotal Phase 3 clinical trial;
- 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 pivotal Phase 3 clinical trial, 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 pivotal Phase 3 clinical trial;
- delays in clinical sites receiving the supplies and materials needed to conduct our pivotal Phase 3 clinical trial;
- 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 pivotal Phase 3 clinical trial is conducted, which may result in unexpected costs, or to discontinue the clinical trial 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 or other activities related to COVID-19.

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, or 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 tecarfarin 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 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 tecarfarin 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 tecarfarin 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 tecarfarin and any of our future product candidates. We will face further risk if we commercialize tecarfarin or 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, including tecarfarin;
- 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 tecarfarin 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 tecarfarin, we intend to expand our insurance coverage to include the sale of tecarfarin, 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 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.

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.

Declining general economic or business conditions 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.

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, COVID-19 or other 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.

Global climate change and related regulations could negatively affect our business.

The effects of climate change, such as extreme weather conditions, create financial risks to our business. For example, the demand for our products may be affected by unseasonable weather conditions. The effects of climate change could also disrupt our operations by impacting the availability and cost of materials needed for manufacturing and could increase insurance and other operating costs. We could also face indirect financial risks passed through the supply chain and disruptions that could result in increased prices for our products and the resources needed to produce them.

Climate change is continuing to receive ever-increasing attention worldwide. Many scientists, legislators and others attribute climate change to increased levels of greenhouse gases, including carbon dioxide, which could lead to additional legislative and regulatory efforts to limit greenhouse gas emissions. For example, new federal or state restrictions on emissions of carbon dioxide that may be imposed on vehicles and automobile fuels could adversely affect demand for vehicles, annual miles driven or the products we sell or lead to changes in automotive technology. Compliance with any new or more stringent laws or regulations, or stricter interpretations of existing laws, could require increased capital expenditures to improve our product portfolio to meet such new laws, regulations and standards. While we have been committed to continuous improvements to our product portfolio to meet and exceed anticipated regulatory standard levels, there can be no assurance that our commitments will be successful, that our products will be accepted by the market, that proposed regulation or deregulation will not have a negative competitive impact or that economic returns will reflect our investments in new product development.

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 is 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 U.S. Patent and Trademark Office, or 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 tecarfarin product. 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, make and market products using our tecarfarin technology.

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, or 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" 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.

Our issued patents expire in 2024 and 2025 and therefore we will lose protection from such patents in the next several years.

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 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 will lose effective patent protection in the United States, as well as key countries outside of the United States, in the next several years. *See supra* Intellectual Property Section. With respect to tecarfarin, we have two issued U.S. patents directed to tecarfarin. The expiration dates of the U.S. patents are 2024 for both a composition of matter patent and a method of treatment patent and our foreign patents expire in 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, 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. Pursuant to the Rule, we have 180 calendar days (until March 4, 2024), to regain compliance with the Nasdaq Listing Rules (the "Compliance Period"). Compliance is generally achieved by meeting the price requirement for a minimum of 10 consecutive business days. However, Nasdaq may, in its discretion, require a company to satisfy the applicable price-based requirement for a period in excess of 10 consecutive business days, but generally no more than 20 consecutive business days, before determining that a company has demonstrated an ability to maintain long-term compliance. For the period January 19, 2024 through February 7, 2024, representing 14 consecutive business days, our Common Stock traded above $1.00 per share. However, we never received notification from Nasdaq that we regained compliance. On February 16, 2024, we requested an additional 180 calendar days to comply with the Rule. On March 5, 2024, we received written notification from Nasdaq granting our request for a 180-day extension or until September 3, 2024 to regain compliance with the Rule. Compliance is generally achieved by meeting the minimum bid price of $1.00 per share (the "Price Requirement") for a minimum of 10 consecutive business days. However, the Staff may, in its discretion, require a Company to satisfy the applicable Price Requirement for a period in excess of 10 consecutive business days, but generally no more than 20 consecutive business days, before determining that the Company has demonstrated an ability to maintain long-term compliance. In the event we fail to regain compliance with the Rule and Nasdaq provides notice that our Common Stock is subject to delisting, we will have the right to a hearing before Nasdaq's Hearing Panel. We do not expect Nasdaq to respond to our request until after the Compliance Period has expired.

If Nasdaq delists our securities from trading on its exchange at some future date, 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. Since our securities began trading on Nasdaq, the closing price of our Common Stock has fluctuated between a high of $4.12 on January 20, 2023 and a low of $0.41 on November 13, 2023. 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;
- 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.

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, directors, and principal stockholders 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, directors and principal stockholders who beneficially own more than 5% or more of our outstanding Common Stock, in the aggregate, beneficially own shares representing approximately 57.21% of our outstanding capital stock. Quang Pham, our Chief Executive Officer, beneficially owns 39.51% 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. Initially, the aggregate number of shares of our Common Stock that might be issued pursuant to stock awards under our 2022 Successor Equity Incentive Plan was 2,000,000 shares, of

which 269,551 remain available for grant as of the date hereof. 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 the Sarbanes-Oxley Act of 2002, or SOX, and the Dodd-Frank Wall Street Reform and Consumer Protection Act, or 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. Beginning with this Annual Report, 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 the Sarbanes-Oxley Act 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. We currently have 16,008,469 shares of Common Stock outstanding, options exercisable to purchase 2,195,000 shares of Common Stock, and 4,674,786 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, 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.

Because we will not declare cash dividends on our Common Stock in the foreseeable future, stockholders must rely on appreciation of the value of our Common Stock for any return on their investment.

We have never declared or paid cash dividends on our Common Stock. We currently anticipate that we will retain any future earnings from the development, operation and expansion of our business and will not declare or pay any cash dividends in the foreseeable future. As a result, only appreciation of the price of our Common Stock, if any, will provide a return to investors in this offering. See "Dividend Policy" in Part II, Item 5 of this Annual Report.

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 dated October 15, 2022 with Veranda III Partners, Ltd. (the "Lease Agreement"). The Lease Agreement has an initial term of 24 months commencing on November 1, 2022. The monthly rent is $2,170. 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 7, 2024 was $0.64 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 7, 2024, we had 28 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, upon effectiveness of the Registration Statement 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, 2023 with respect to shares of our common stock that may be issued under our existing equity compensation plans, which as of December 31, 2023 was only the Initial Plan.

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	1,175,000	$ 0.86	685,000
Equity compensation plans not approved by security holders	—	—	—
Total	1,175,000	$ 0.86	685,000

2022 Successor Equity Incentive Plan

See "Equity Incentive Plans — 2022 Successor Equity Incentive Plan" in Part III, Item 11 for a description of the Cadrenal Therapeutics, Inc. 2022 Successor Equity Incentive Plan.

Recent Sales of Unregistered Securities

We have not issued unregistered securities to any person during the year ended December 31, 2023 that were not previously disclosed in our filings with the SEC.

Use of Proceeds

On January 24, 2023, we consummated our initial public offering of 1,400,000 shares of our common stock at a public offering price of $5.00 per share, generating gross proceeds of $7.0 million which resulted in net proceeds to us of approximately $5.4 million, after deducting underwriting discounts and commissions of $490,000, underwriter non-accountable expenses of $70,000, and offering-related transaction costs of approximately $1.0 million. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. Our shares of common stock commenced trading on the Nasdaq on January 20, 2023 under the symbol "CVKD." The offering has terminated.

In connection with our initial public offering, on January 19, 2023, we entered into an underwriting agreement (the "Underwriting Agreement") with Boustead Securities, LLC, as representative of the underwriters (the "Representative"), a form of which was previously filed as an exhibit to our registration statement on Form S-1, as amended (File No. 333-267562), which was declared effective by the SEC on January 19, 2023 (the "Registration Statement"). Pursuant to the Underwriting Agreement, we agreed to issue to the underwriters a five-year warrant (the "Representative's Warrant") to purchase an aggregate of 84,000 shares of our common stock, which is equal to six percent (6%) of the shares of common stock sold in the initial public offering. Such Representative's Warrant has an exercise price of $6.00, which is equal to 120% of the public offering price of the common stock in the initial public offering.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on January 23, 2023 pursuant to Rule 424(b)(4), of $3 million of proceeds to be used for CMC preparation, research and development, and other trial preparation expenses necessary for initiation of our planned Phase 3 pivotal trial and $2.4 million of proceeds to be used for working capital, including payments made to officers in accordance with the terms of their employment agreements and payment to Phamace, LLC, a consulting firm of which Quang Pham, our Chief Executive Officer, is the sole member, as described in Part III, Item 13 "Certain Relationships and Related Transactions, and Director Independence."

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, 2023 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.

Company Overview

We are developing tecarfarin, a late-stage novel oral and reversible anticoagulant (blood thinner), to prevent heart attacks, strokes, and deaths due to blood clots in patients with certain rare medical conditions. Tecarfarin has orphan drug and Fast Track designations for the prevention of systemic thromboembolism (blood clots) of cardiac origin in patients with ESKD and AFib. We are also pursuing additional regulatory strategies for unmet needs in anticoagulation

therapy for patients with LVADs and those with thrombotic APS. These patients have historically been treated with warfarin, which has been shown to be challenging and unreliable. The direct oral anticoagulants, which are an alternative to warfarin for certain indications, are contraindicated for LVAD patients and have been associated with an increased risk for recurrent thrombosis in patients with APS.

Tecarfarin is specifically designed to target a different metabolism pathway than the most commonly prescribed drugs used in the treatment of thrombosis and AFib. Tecarfarin has been evaluated in eleven (11) human clinical trials conducted by its previous owners and other third parties in over 1,003 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 having completed it, only 1.6% of the blinded tecarfarin subjects suffered from major bleeding and there were no thrombotic events. Five patients died during the trial, but only one death due to intracerebral hemorrhage was considered to be possibly related to the tecarfarin.

Tecarfarin was developed by researchers using a small molecule "retrometabolic" drug design process which targets a different metabolic pathway than the most commonly prescribed drugs for the treatment of thrombosis and AFib. "Drug metabolism" refers to the process by which a drug is inactivated by the body and rendered easier to eliminate or to be cleared by the body. Most approved drugs, including warfarin, the only FDA-approved Vitamin K antagonists, or VKAs, which is a prescribed drug for the treatment of thrombosis, are metabolized in the liver through a pathway known as the Cytochrome CYP450 system, or CYP450, by the enzymes known as CYP2C9 and CYP3A4. By using a different metabolic pathway, tecarfarin eliminates or minimizes the CYP450 metabolism in the liver. 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 a toxic build-up of one or more drugs. In some instances, patients taking multiple medications metabolized by the same CYP450 pathway may experience decreased efficacy of one or more of the medications due to rapid metabolism or increased drug effect and/or toxicity due to enzyme induction. Patient-specific genetic differences can also hinder drug clearance in the CYP450 pathway. Our product candidate tecarfarin was designed to follow a metabolic pathway distinct from the CYP450 pathway and is metabolized by both CYP450 and non-CYP450 pathways. We believe this may allow elimination by large capacity and non-saturable tissue esterase pathways that exist throughout the body rather than just in the liver.

Tecarfarin is an orphan designated, vitamin K antagonist, oral, once-daily and reversible anticoagulant in the same drug class as warfarin designed for use in patients requiring chronic VKA anticoagulation, to prevent pathologic thrombus/thromboembolism in certain medical conditions that are not well served by currently available VKAs and in which DOACS are contraindicated or not effective.

The prevailing treatment for thrombosis is with an oral anticoagulant, either a VKA, like warfarin, or non-vitamin K oral anticoagulant ("DOAC"). VKAs block the production of vitamin K-dependent blood clotting factors, such that the blood is "thinned," preventing clots, while DOACs directly block the activity of certain of these clotting factors. Tecarfarin, like warfarin, is a VKA.

Initial Public Offering

On January 24, 2023, we consummated our initial public offering (the "IPO") of 1,400,000 shares of our common stock at a public offering price of $5.00 per share, generating gross proceeds of $7,000,000. Our shares of common stock commenced trading on the Nasdaq on January 20, 2023 under the symbol "CVKD."

Private Placement

On July 12, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor (the "Investor") pursuant to which we sold to the Investor in a private placement priced at-the-market (the "Private Placement") consistent with the rules of the Nasdaq), (i) an aggregate of 1,300,000 shares of common stock, (ii) in lieu of additional share of common stock, pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 2,985,715 shares of common stock, and (iii) accompanying common warrants (the "Common Warrants") to purchase up to an aggregate of 4,285,715 shares of common stock. The combined purchase price of each share and accompanying Common Warrants was $1.75. The combined purchase price of each Pre-Funded Warrant and accompanying Common Warrants was $1.7499.

The Private Placement closed on July 14, 2023. We received aggregate gross proceeds from the Private Placement of approximately $7.5 million before deducting the placement agent commissions and estimated offering expenses payable by us. We intend to use the net proceeds from the Private Placement for working capital purposes. H.C. Wainwright & Co., LLC ("H.C.W.") acted as the placement agent in the Private Placement, and as part of its compensation, we issued to designees of H.C.W. Placement Agent Warrants to purchase up to 278,571 shares of common stock.

Results of Operations

The following table summarizes our results of operations for the fiscal year ended December 31, 2023 and for the period January 25, 2022 (inception) to December 31, 2022.

	Year Ended December 31, 2023	January 25, 2022 (inception) through December 31, 2022
Operating expenses:		
General and administrative expenses	$ 3,549,514	$ 2,307,503
Research and development expenses	4,081,349	392,859
Depreciation expense	1,980	1,266
Total operating expenses	7,632,843	2,701,628
Loss from operations	(7,632,843)	(2,701,628)
Other (income) expense:		
Interest and dividend income	(249,092)	(21)
Interest expense	3,534	40,213
Interest expense, amortization of debt discount	13,567	66,913
Change in fair value of derivative liabilities	216,095	3,905,596
Loss on extinguishment of debt	740,139	—
Total other (income) expense	724,243	4,012,701
Net loss and comprehensive loss	$ (8,357,086)	$ (6,714,329)

General and administrative expenses

General and administrative expenses were $3,549,514 for the year ended December 31, 2023 compared to $2,307,503 for the period January 25, 2022 (inception) to December 31, 2022. The $1,242,011 or 54% increase can be attributed to a $654,768 increase in personnel-related expenses, a $276,046 increase in insurance expenses, a $132,650 increase in consulting fees, a $161,035 increase in professional fees, and a $468,262 increase in other expenses as the Company expanded operations and incurred additional expenses associated with being a publicly-traded company. These increases were partially offset by a $450,750 decrease in stock-based compensation due to the timing of vesting.

Research and development expenses

Research and development expenses were $4,081,349 for the year ended December 31, 2023 compared to $392,859 for the period January 25, 2022 (inception) to December 31, 2022. The $3,688,490 increase can be primarily attributed to the issuance of 600,000 shares of common stock (valued at $3.0 million) in January 2023 to HESP LLC, pursuant to the terms of an Amendment to the Asset Purchase Agreement. The remainder of the increase can be primarily attributed to additional personnel-related expenses and stock-based compensation, as the Company did not hire a full-time Chief Medical Officer until January 2023.

Interest and dividend income

Interest and dividend income was $249,092 for the year ended December 31, 2023. This represents the interest and dividend income earned from our investments in money market funds from the proceeds of our IPO and July 2023 PIPE financing.

Change in fair value of derivative liabilities

We determined that the redemption features in the convertible notes that we issued in March 2022, June 2022, July 2022, August 2022 and September 2022 in the aggregate principal amount of $1,125,000 contained rights and obligations for conversion contingent upon a potential future financing event or a change in control. Thus, the embedded put options were bifurcated from the face value of the convertible notes and accounted for as derivative liabilities to be remeasured at the end of each reporting period with the change in the fair value included in other expense, in the accompanying statement of operations and comprehensive loss.

Concurrent with the closing of the IPO in January 2023, the note holders converted the debt into common stock, accordingly, the derivative financial liabilities were de-recognized and reclassified to stockholders' equity (deficit) on January 24, 2023.

The derivative liabilities were considered a level 3 fair value financial instrument and were remeasured up to January 24, 2023 which was the date of derecognition. We recorded a non-cash charge of $216,095 in January 2023. This charge represented the increase in the fair value of the derivative liabilities since the previous measurement date of December 31, 2022.

Loss on extinguishment of debt

We recorded a $740,139 loss on the extinguishment of debt during the year ended December 31, 2023. This loss represents the unamortized debt discount associated with the convertible notes and the November promissory notes, which were settled concurrent with the IPO.

Liquidity and Capital Resources

Since inception, we have incurred losses and negative cash flows from operations. To date, we have funded our operations from the proceeds of the sale of convertible notes, and the nonconvertible notes and warrants issued in November 2022, as well as our IPO completed in January 2023 and our Private Placement consummated in July 2023. We had a net loss of $8,357,086 for the year ended December 31, 2023 which included $4,682,454 of non-cash expenses. Cash used in operating activities for the year ended December 31, 2023 totaled $3,530,323. As of December 31, 2023, we had cash and cash equivalents of approximately $8.4 million and no debt. Our current cash and cash equivalents balance as of March 8, 2024 of approximately $6.9 million, is sufficient to fund our operations for at least the next twelve months; however, we expect to require additional funding to complete our planned Phase 3 clinical trial and submit our NDA. In order to fund the commencement and completion of our Phase 3 clinical trial, we intend to raise additional funds through equity and debt financings as well as potential partnering relationships. However, there can be no assurance that we will be able to complete any additional financings or partnering relationships on terms acceptable to us or at all. If we are unable to raise additional funding to meet our working capital needs in the future, we will be forced to delay or reduce the scope of our research programs and/or limit or cease our operations.

Cash Flows

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

	Year Ended December 31, 2023	January 25, 2022 (inception) through December 31, 2022
Cash used in operating activities	$ (3,530,323)	$ (1,204,770)
Cash used in investing activities	(3,254)	(2,279)
Cash provided by financing activities	11,903,491	1,239,635
Net increase in cash	8,369,914	32,586
Cash and cash equivalents, beginning of period	32,586	—
Cash and cash equivalents, end of period	$ 8,402,500	$ 32,586

Operating activities

During the year ended December 31, 2023, cash used in operating activities was $3,530,323. Net loss adjusted for the non-cash items as detailed on the statement of cash flows, used $3,674,632 in cash, and the changes in operating assets and liabilities, as detailed on the statement of cash flows, provided $144,309 in cash primarily from a $672,295 decrease in deferred equity offering costs, partially offset by a decrease in accrued liabilities of $225,645 and a decrease in accounts payable of $237,578.

During the period January 25, 2022 (inception) to December 31, 2022, cash used in operating activities was $1,204,770. Net loss adjusted for the non-cash items as detailed on the statement of cash flows, used $1,812,505 in cash, and the changes in operating assets and liabilities, as detailed on the statement of cash flows, provided $607,735 in cash primarily from a $404,897 increase in accounts payable and an $863,622 increase in accrued liabilities partially offset by a $672,295 increase in deferred equity offering costs.

Financing activities

During the year ended December 31, 2023, net cash provided by financing activities totaled $11,903,491 as we completed our IPO in January 2023, generating net proceeds of $5,408,575, and we completed a private placement financing in July 2023, generating net proceeds of $6,494,916. We also received $250,000 from the exercise of warrants that we issued in November 2022, which proceeds were used to repay the notes that were issued in November 2022.

During the period January 25, 2022 (inception) to December 31, 2022, net cash provided by financing activities was $1,239,635, primarily consisting of the $1,011,964 of net proceeds from the issuance of convertible notes and $219,721 of net proceeds from the issuance of a non-convertible promissory note and warrants.

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, or 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 common stock prior to our IPO, 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, that 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.

Acquisitions

We evaluate 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 we have 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 meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated 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. We also evaluate 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 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) we must reasonably expect that we will use the asset acquired in the alternative manner and anticipate economic benefit from that alternative use, and (b) our use of the asset acquired is not contingent on further development of the asset subsequent to the acquisition date (that is, the asset can be used in the 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.

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 FDA or other regulatory agencies for marketing; has not reached technical feasibility; or otherwise has no foreseeable alternative future use. Nonrefundable 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.

Derivative Financial Instruments

We evaluate all of our agreements to determine if such instruments have derivatives or contain features that qualify as embedded derivatives. We account for certain redemption features that are associated with convertible notes as liabilities at fair value and adjust the instruments to their fair value at the end of each reporting period. Derivative financial liabilities are initially recorded at fair value, with gains and losses arising from changes in the fair value recognized in other income (expense) in the accompanying statements of operations and comprehensive loss for each reporting period while such instruments are outstanding. The embedded derivative liability is valued using a probability-weighted expected return model. If we repay the note holders or if, during the next round of financing, the note holders convert the debt into equity, the derivative financial liability will be de-recognized on that date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

Stock-Based Compensation

We measure our stock-based awards granted to employees, consultants and directors based on the estimated 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 period 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
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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
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, 2023 and 2022, and the related statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for the year ended December 31, 2023 and for the period from January 25, 2022 (inception) through December 31, 2022, 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, 2023 and 2022, and the results of its operations and its cash flows for the year ended December 31, 2023 and for the period from January 25, 2022 (inception) through December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on 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 8, 2024
PCAOB ID No. 100

CADRENAL THERAPEUTICS, INC.
BALANCE SHEETS

	December 31, 2023	December 31, 2022
Assets:		
Current assets:		
Cash and cash equivalents	$ 8,402,500	$ 32,586
Prepaid expenses	89,673	22,715
Deferred offering costs	—	672,295
Total current assets	8,492,173	727,596
Property, plant and equipment, net	2,287	1,013
Right of use assets	20,998	43,578
Other assets	3,792	5,987
Total assets	$ 8,519,250	$ 778,174
Liabilities and Stockholders' Equity (Deficit):		
Current liabilities:		
Accounts payable	$ 167,319	$ 404,897
Accrued liabilities	638,206	863,564
Operating lease liability	21,350	22,288
Promissory note payable, net of debt discount	—	43,728
Total current liabilities	826,875	1,334,477
Convertible note payable, net of debt discount – related parties	—	442,960
Convertible note payable, net of debt discount	—	110,380
Derivative liabilities	—	4,379,944
Accrued interest	—	40,213
Operating lease liability, noncurrent	—	21,350
Total liabilities	826,875	6,329,324
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 75,000,000 shares authorized, 13,022,754 shares issued and outstanding as of December 31, 2023; 8,193,875 shares issued and outstanding as of December 31, 2022	13,022	8,194
Additional paid-in capital	22,750,768	1,154,985
Accumulated deficit	(15,071,415)	(6,714,329)
Total stockholders' equity (deficit)	7,692,375	(5,551,150)
Total liabilities and stockholders' equity (deficit)	$ 8,519,250	$ 778,174

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

CADRENAL THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31, 2023	January 25, 2022 (inception) through December 31, 2022
Operating expenses:		
General and administrative expenses	$ 3,549,514	$ 2,307,503
Research and development expenses	4,081,349	392,859
Depreciation expense	1,980	1,266
Total operating expenses	7,632,843	2,701,628
Loss from operations	(7,632,843)	(2,701,628)
Other (income) expense:		
Interest and dividend income	(249,092)	(21)
Interest expense	3,534	40,213
Interest expense, amortization of debt discount	13,567	66,913
Change in fair value of derivative liabilities	216,095	3,905,596
Loss on extinguishment of debt	740,139	—
Total other (income) expense	724,243	4,012,701
Net loss and comprehensive loss	$ (8,357,086)	$ (6,714,329)
Net loss per common share, basic and diluted	$ (0.62)	$ (0.85)
Weighted average number of common shares used in computing net loss per common share, basic and diluted	13,491,980	7,890,507

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

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

For the year ended December 31, 2023

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance, December 31, 2022	8,193,875	$ 8,194	$ 1,154,985	$ (6,714,329)	$ (5,551,150)
Issuance of common shares in initial public offering, net of offering costs	1,400,000	1,400	5,407,175	—	5,408,575
Issuance of common shares to settle convertible debt	1,140,700	1,140	1,139,560	—	1,140,700
De-recognition of derivative liabilities	—	—	4,596,039	—	4,596,039
Issuance of common shares, pre-funded warrants and warrants in private placement, net of fees	1,300,000	1,300	6,493,616	—	6,494,916
Issuance of common shares from exercise of warrants	250,000	250	249,750	—	250,000
Issuance of common shares to settle asset purchase obligation	600,000	600	2,999,400	—	3,000,000
Issuance of restricted common shares for consulting services	77,340	77	108,199	—	108,276
Equity-based compensation – options, restricted stock and RSUs	60,839	61	602,044	—	602,105
Net loss	—	—	—	(8,357,086)	(8,357,086)
Balance, December 31, 2023	13,022,754	$ 13,022	$ 22,750,768	$ (15,071,415)	$ 7,692,375

For the period from January 25, 2022 (inception) through December 31, 2022

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance, January 25, 2022	—	$ —	$ —	$ —	$ —
Issuance of founder shares	7,950,000	7,950	—	—	7,950
Equity-based compensation – options, restricted stock and RSUs	243,875	244	927,805	—	928,049
Issuance of placement agent warrants	—	—	51,621	—	51,621
Issuance of investor warrants	—	—	175,559	—	175,559
Net loss	—	—	—	(6,714,329)	(6,714,329)
Balance, December 31, 2022	8,193,875	$ 8,194	$ 1,154,985	$ (6,714,329)	$ (5,551,150)

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

CADRENAL THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2023	January 25, 2022 (inception) through December 31, 2022
Cash flows from operating activities:		
Net loss	$ (8,357,086)	$ (6,714,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,980	1,266
Equity-based compensation	710,381	928,049
Amortization of debt discount	13,567	66,913
Change in fair value of derivative liabilities	216,095	3,905,596
Loss on extinguishment of debt	740,139	—
Non-cash lease expense	292	—
Issuance of shares to settle asset purchase agreement	3,000,000	—
Changes in operating assets and liabilities:		
Prepaid expenses	(66,958)	(22,715)
Deferred offering costs	672,295	(672,295)
Other assets	2,195	(5,987)
Accounts payable	(237,578)	404,897
Accrued liabilities	(225,645)	863,622
Accrued interest	—	40,213
Net cash used in operating activities	(3,530,323)	(1,204,770)
Cash flows used in investing activities:		
Purchase of property and equipment	(3,254)	(2,279)
Net cash used in investing activities	(3,254)	(2,279)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, net of debt issuance costs	—	1,011,964
Proceeds from issuance of convertible notes, net of debt issuance costs	—	219,721
Proceeds from issuance of founder shares	—	7,950
Proceeds from issuance of common shares, pre-funded warrants and warrants in private placement, net of fees	6,494,916	—
Proceeds from exercise of warrants	250,000	—
Repayment of promissory notes	(250,000)	—
Proceeds from sale of common stock in initial public offering, net of offering costs	5,408,575	—
Net cash provided by financing activities	11,903,491	1,239,635
Net change in cash	8,369,914	32,586
Cash and cash equivalents – beginning of the period	32,586	—
Cash and cash equivalents – end of the period	$ 8,402,500	$ 32,586
Suplemental disclosure of non-cash investing activity:		
Non-cash right of use assets and operating lease liabilities	$ —	$ 47,090
Supplemental disclosure of non-cash financing activity:		
Issuance of common shares to settle convertible debt	$ 1,140,700	$ —
De-recognition of derivative liabilities	$ 4,596,039	$ —
Non-cash debt issuance costs – placement agent warrants	$ —	$ 51,621
Fair value of financial instruments at issuance	$ —	$ 474,349
Issuance of investor warrants	$ —	$ 175,559

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 (inception) in the State of Delaware and is headquartered in Ponte Vedra, Florida. Cadrenal is developing tecarfarin for unmet needs in anticoagulation therapy. Tecarfarin is a late-stage novel oral and reversible anticoagulant (blood thinner) to prevent heart attacks, strokes, and deaths due to blood clots in patients with rare cardiovascular conditions. Tecarfarin has orphan drug and fast-track designations 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). The Company is also pursuing additional regulatory strategies for unmet needs in anticoagulation therapy for patients with left ventricular assist devices (LVADs) and those with thrombotic antiphospholipid syndrome (APS). The direct-acting oral anticoagulants (DOACs), which are an alternative to warfarin for certain indications, are contraindicated for LVAD patients and have been associated with an increased risk for recurrent thrombosis in patients with APS.

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 date of inception was January 25, 2022, and the fiscal year-end is December 31.

Liquidity

The accompanying financial statements have been prepared assuming 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 inception, the Company has incurred operating losses, and negative cash flows from operations. For the year ended December 31, 2023, the Company had a net loss of $8,357,086, which included $4,682,454 of non-cash expenses. Cash used in operations for the year ended December 31, 2023 totaled $3,530,323. As of December 31, 2023, the Company had cash and cash equivalents of $8,402,500, net working capital of $7,665,298, and an accumulated deficit of $15,071,415.

The Company's cash and cash equivalents balance of approximately $6.9 million as of March 8, 2024 is expected to be sufficient to fund its operations for at least the next twelve months from the date of the filing of its Annual Report on Form 10-K, however, the Company will require additional funding to complete its planned Phase 3 clinical trial and submit its NDA.

Management intends to raise additional funds through partnering and 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. 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.

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 are applicable to public companies. The relief afforded under the JOBS Act includes an extended transition period for the implementation of 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.

Note 1. Description of Business and Summary of Significant Accounting Policies (cont.)

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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 financial instruments, the fair value of common stock prior to our IPO, 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 and, at times, balances may exceed federally insured limits. All interest-bearing and non-interest-bearing cash balances are insured up to $250,000 per depositor 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 a number of 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.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined it operates in a single operating segment and has one reportable segment.

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.

Derivative Financial Instruments

The Company evaluates all of its agreements to determine if such instruments have derivatives or contain features that qualify as embedded derivatives. The Company accounts for certain redemption features that are associated with convertible notes as liabilities at fair value and adjusts the instruments to their fair value at the end of each reporting period. Derivative financial liabilities are initially recorded at fair value, with gains and losses arising from changes in the fair value recognized in other (income) expense in the accompanying statements of operations and comprehensive loss for each reporting period while such instruments are outstanding. The embedded derivative liabilities are valued using a probability-weighted expected return model. If the Company repays the noteholders or if, during the next round of financing, the noteholders convert the debt into equity, the derivative financial liabilities will be de-recognized and reclassified to stockholders' equity (deficit) on that date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

Note 1. Description of Business and Summary of Significant Accounting Policies (cont.)

Concurrent with the closing of the initial public offering in January 2023 (the "IPO"), the note holders converted the debt into common stock, accordingly, the derivative financial liabilities were de-recognized and reclassified to stockholders' equity (deficit) on January 24, 2023.

Stock-Based Compensation

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

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. The Company completed its initial public offering on January 24, 2023, and the offering costs were recorded against the proceeds of the offering. As of December 31, 2023, there were no deferred offering costs.

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 meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated 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

Note 1. Description of Business and Summary of Significant Accounting Policies (cont.)

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 and are expensed as incurred as a component of general and administrative expenses.

Note 2. Recent Accounting Guidance

Recently Issued Accounting Pronouncements Not Yet Adopted

Accounting standards that have been issued by the Financial Accounting Standards Board ("FASB") or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

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.

The Company classified its embedded derivative liability as a Level 3 financial instrument and measured and reported its embedded derivatives at fair value. Concurrent with the closing of the initial public offering in January 2023, the note holders converted the debt into common stock, accordingly, the derivative financial liabilities were de-recognized and reclassified to stockholders' equity (deficit) on January 24, 2023.

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, 2023			
	Level 1	Level 2	Level 3	Fair Value
Financial Assets:				
Money market funds	$ 8,287,843	$ —	$ —	$ 8,287,843
Total financial liabilities	$ 8,287,843	$ —	$ —	$ 8,287,843
Financial Liabilities:				
Derivative liabilities	$ —	$ —	$ —	$ —
Total financial liabilities	$ —	$ —	$ —	$ —

	December 31, 2022			
	Level 1	Level 2	Level 3	Fair Value
Financial Assets:				
Money market funds	$ —	$ —	$ —	$ —
Total financial liabilities	$ —	$ —	$ —	$ —
Financial Liabilities:				
Derivative liabilities	$ —	$ —	$ 4,379,944	$ 4,379,944
Total financial liabilities	$ —	$ —	$ 4,379,944	$ 4,379,944

Note 3. Fair Value Measurements (cont.)

The following table summarizes the changes in the fair value of the derivative liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3)

	Derivative Liabilities
Balance at December 31, 2022	$ 4,379,944
Change in fair value	216,095
De-recognition of derivative liabilities	(4,596,039)
Balance at December 31, 2023	$ —

	Derivative Liabilities
Balance at January 25, 2022	$ —
Fair value of financial instruments at issuance	474,348
Change in fair value	3,905,596
Balance at December 31, 2022	$ 4,379,944

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, 2023	December 31, 2022
Accrued consulting fees	$ 4,000	$ 165,192
Accrued compensation	596,131	605,290
Other	38,075	93,082
Total accrued liabilities	$ 638,206	$ 863,564

Note 5. Asset Purchase Agreement

On April 1, 2022, the Company completed an asset purchase agreement with HESP LLC, the assignee of tecarfarin and related assets (the "Asset Purchase Agreement"). Pursuant to the terms of the Asset Purchase Agreement, the Company acquired all of the assets of HESP LLC, including all intellectual property and other rights related to tecarfarin, the tecarfarin IND 77041, all rights under the license, development and commercialization agreement dated as of September 16, 2015 by and between Armetheon, Inc. ("Armetheon") (which was later assigned by Armetheon to Espero BioPharma, Inc. ("Espero"), and China Cardiovascular Focus Ltd, an affiliate of Lee's Pharmaceutical Holdings Limited ("Lee's Pharmaceutical"), relating to tecarfarin and related trademarks. In consideration of the purchase of the assets, the Company paid HESP LLC $100,000 on the closing date and paid an additional $100,000 on June 1, 2022. As additional consideration, the Asset Purchase Agreement initially provided for a cash payment by the Company to HESP LLC upon achievement of the following development milestone payments, which cash payment was later amended to be a payment in shares of the Company's common stock upon consummation of its IPO:

Development Milestones	Milestone Payments
Completion of enrollment of Lee's Pharmaceutical Phase 3 clinical trial	$ 250,000
First MAA submitted in the People's Republic of China	$ 350,000
First Commercial Sale to a Third Party	$ 1,200,000

Note 5. Asset Purchase Agreement (cont.)

Financing Milestones

As additional consideration, the Company agreed to pay the following amounts, up to $2,000,000, upon each financing milestone as follows (i) 35% of any proceeds received from any licensing or partnering revenue; and (ii) IPO proceeds. The aggregate payments under the development milestone payments and financing milestone payments shall not exceed $2,000,000.

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 tecarfarin 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 including the direct transaction costs of $20,095, 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	20,095
Total	$ 220,095

All costs the Company incurred in connection with this Asset Purchase Agreement 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 of the acquisition transaction. Due to the nature of the regulatory, sales and financing-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 the milestone events occur.

On August 18, 2022, the Company entered into an Amendment to Asset Purchase Agreement, whereby in lieu of the $1,800,000 cash payment that would have been due to HESP LLC pursuant to the Asset Purchase Agreement as a result of an initial public offering, HESP LLC agreed to accept shares of the Company's common stock, such number of shares to be calculated based upon a 40% discount to the price of the Company's common stock sold in the initial public offering.

On January 19, 2023, the Company issued 600,000 shares of common stock to HESP LLC, pursuant to the terms of an Amendment to the Asset Purchase Agreement, dated August 18, 2022, between the Company and HESP LLC. The Company recognized the stock payment of $3.0 million as research and development expense on January 19, 2023. This payment settled all obligations under the Amendment to the Asset Purchase Agreement.

Note 6. Debt

Debt outstanding is presented on the balance sheets as follows:

	December 31, 2023	December 31, 2022
Convertible notes payable – related parties	$ —	$ 550,000
Debt issuance costs	—	(107,040)
	—	442,960
Convertible note payable	—	575,000
Debt issuance costs	—	(464,620)
	—	110,380
Promissory note payable	—	250,000
Debt issuance costs	—	(206,272)
	—	43,728
Total debt, net	$ —	$ 597,068

Note 6. Debt (cont.)

March 2022 Convertible Note

In March 2022, the Company entered into a convertible promissory note agreement (the "March 2022 Note") and received cash proceeds of $500,000. The March 2022 Note bore interest at a rate equal to simple interest of 5.0% per annum computed on the basis of the 360-day year of twelve (12) 30-day months. The March 2022 Note was due and payable on March 1, 2025, unless earlier converted or repaid.

Pursuant to the March 2022 Note, the principal and accrued but unpaid interest was to be automatically converted into equity securities sold in the Next Equity Financing of the Company comprising a single transaction or a series of related transactions in which total proceeds of at least $3.0 million is raised. The principal and unpaid and accrued interest of the March 2022 Note at the date of conversion was to be converted into shares at a conversion price equal to 80% of the price per share paid by investors purchasing such shares in the Next Equity Financing. If the Company consummated a Change of Control (as defined in the March 2022 Note) prior to repayment in full of the March 2022 Note, immediately prior to the Change of Control, the outstanding principal and any unpaid and accrued interest would be automatically converted into common equity of the Company (or directly into proceeds paid to the holders of common equity in connection with the Change of Control) at a price per share that is 80% of the price per share of common equity paid at the Change of Control.

The Company evaluated whether the March 2022 Note contained embedded features that met the definition of derivatives under FASB ASC 815, Derivatives and Hedging. The Company determined that these redemption features contained rights and obligations for conversion contingent upon a potential future financing event or a change in control. Thus, the embedded put options were bifurcated from the face value of the March 2022 Note and accounted for as a derivative liability to be remeasured at the end of each reporting period with the change in the fair value included in other expense, in the accompanying statement of operations and comprehensive loss. The fair value of the put option derivative liability at issuance was $104,883, with the offsetting amount being recorded as a debt discount. Debt issuance costs totaled $1,460. The debt discount and debt issuance costs were being amortized to interest expense using the effective interest method over the expected term of the March 2022 Note. The effective interest rate of the March 2022 Note was 12.1% compared to a stated interest rate of 5.0%.

June 2022 Convertible Note

In June 2022, the Company entered into a convertible promissory note agreement (the "June 2022 Note") and received cash proceeds of $50,000. The June 2022 Note bore interest at a rate equal to simple interest of 6.0% per annum computed on the basis of the 360-day year of twelve (12) 30-day months. The June 2022 Note was due and payable on June 13, 2025, unless earlier converted or repaid.

Pursuant to the June 2022 Note, the principal and accrued but unpaid interest was to be automatically converted into equity securities sold in the Next Equity Financing of the Company comprising a single transaction or a series of related transactions in which total proceeds of at least $3.0 million is raised. The principal and unpaid and accrued interest of the June 2022 Note at the date of conversion was to be converted into shares at a conversion price equal to 60% of the price per share paid by investors purchasing such shares in the Next Equity Financing. If the Company consummated a Change of Control (as defined in the June 2022 Note) prior to repayment in full of the June 2022 Note, immediately prior to the Change of Control, the outstanding principal and any unpaid and accrued interest would automatically convert into common equity of the Company (or directly into proceeds paid to the holders of common equity in connection with the Change of Control) at a price per share that is 60% of the price per share of common equity paid at the Change of Control.

The Company evaluated whether the June 2022 Note contained embedded features that meet the definition of derivatives under FASB ASC 815, Derivatives and Hedging. The Company determined that these redemption features contained rights and obligations for conversion contingent upon a potential future financing event or a change in control. Thus, the embedded put options were bifurcated from the face value of the June 2022 Note and accounted for as a derivative liability to be remeasured at the end of each reporting period with the change in the fair value included in other expenses, in the accompanying statement of operations and comprehensive loss. The fair value

Note 6. Debt (cont.)

of the put option derivative liability at issuance was $29,532, with the offsetting amount being recorded as a debt discount. The debt discount was amortized to interest expense using the effective interest method over the expected term of the June 2022 Note. The effective interest rate of the June 2022 Note was 25.7% compared to a stated interest rate of 6.0%.

Boustead Private Placement Notes

In July 2022, the Company issued convertible promissory notes in the aggregate amount of $450,000 (the "July 2022 Notes"), in August 2022, the Company issued a convertible promissory note in the amount of $50,000 (the "August 2022 Note") and in September 2022, the Company issued convertible promissory notes in the aggregate amount of $75,000 (the "September 2022 Notes" and together with the July 2022 Note and the August 2022 Note, the "Private Placement Notes"). The July 2022 Notes, the August 2022 Note and the September 2022 Notes bore interest at 6% and mature on September 13, 2025 ("Maturity Date").

The principal amount due under the July 2022 Notes, the August 2022 Note and the September 2022 Notes (and any accrued but unpaid interest under the July 2022 Notes, the August 2022 Note and the September 2022 Notes) was to be automatically converted, on or before the Maturity Date, into Next Equity Securities in the Next Equity Financing. The July 2022 Notes, the August 2022 Note and September 2022 Notes were convertible into shares of common stock at a conversion price equal to the quotient obtained by dividing (i) the entire principal amount of the July 2022 Notes, the August 2022 Note and the September 2022 Notes, plus (if applicable) any accrued but unpaid interest under the July 2022 Notes, the August 2022 Note and the September 2022 Notes by (ii) sixty percent (60%) of the price per share of the Next Equity Securities sold in the Next Equity Financing. In the event of a Change of Control (as defined in the Private Placement Notes) which occurred prior to repayment in full of the July 2022 Notes, the August 2022 Note or the September 2022 Notes, immediately prior to the Change of Control, the outstanding principal and any accrued but unpaid interest on the July 2022 Notes, the August 2022 Note and the September 2022 Notes was to convert directly into our common equity (or directly into proceeds paid to the holders of our common equity in connection with the Change of Control) at a price per share that is 60% of the price per share of common equity paid at the Change of Control. Boustead Securities, LLC ("Boustead") acted as the placement agent for the private placement and received as part of its compensation and five-year warrants to purchase shares of the Company's common stock at a price equal to the conversion price of the Private Placement Notes in an amount equal to 6% of the shares of common stock underlying the Private Placement Notes. The Company has determined that the warrants issued to the placement agent receive equity treatment. The warrants were recorded at fair value at issuance and recorded as debt issuance costs associated with the Boustead Private Placement Notes.

The Company had determined the redemption features in the Private Placement Notes contained rights and obligations for conversion contingent upon a potential future financing event or a change in control, and that such features were required to be bifurcated from the host debt instrument and accounted for as a derivative liability to be remeasured at the end of each reporting period.

The Company evaluated whether the July Notes, August Note, and September 2022 Notes contained embedded features that meet the definition of derivatives under FASB ASC 815, Derivatives and Hedging. The Company determined that these redemption features contained rights and obligations for conversion contingent upon a potential future financing event or a change in control. Thus, the embedded put options were bifurcated from the face value of the July, August and September Notes and accounted for as derivative liabilities to be remeasured at the end of each reporting period with the change in the fair value included in other expenses, in the accompanying statements of operations and comprehensive loss. The fair value of the put option derivative liabilities at issuance was $339,934, with the offsetting amount being recorded as a debt discount. The debt discount was being amortized to interest expense using the effective interest method over the expected term of the July, August and September 2022 Notes. The effective interest rates of the July, August and September 2022 Notes were 36.3%, 26.1%, and 28.8%, respectively, compared to a stated interest rate of 6.0%.

Note 6. Debt (cont.)

Non-Convertible Promissory Note

On November 30, 2022, the Company closed a $250,000 note offering (the "November Private Placement") pursuant to which the Company sold to two accredited investors units consisting of (i) notes in the aggregate principal amount of $250,000, which bore interest at the rate of 10%, repayable at the earlier of the time of the completion of the IPO or November 30, 2023 (the "November Notes") and (ii) warrants to purchase up to an aggregate of 250,000 shares of common stock exercisable at $1.00 per common share, which were exercisable at any time and were automatically exercised into shares of the Company's common stock upon the consummation of the IPO (the "November Warrants"). At the time the November Notes and November Warrants were sold, it was intended that the principal amount of the November Notes would be repaid upon the consummation of the IPO out of the proceeds of the November Warrants exercise.

The issuance of the November Warrants triggered an adjustment to the conversion price of the Private Placement Notes (the July 2022 Notes, August 2022 Note and September 2022 Notes) to $1.00 per share, pursuant to down-round protection included in those notes. As a result of the adjustment of the conversion price of the Private Placement Notes, the five-year warrants issued to Boustead in connection with the Private Placement, were amended to provide for the purchase of an aggregate of 11,500 shares of the Company's common stock at an exercise price equal to 60% of the initial public offering price per share.

The Company also issued 15,000 warrants to Boustead for the placement of the November financing. The November placement agent warrants have an exercise price of $1.00 per common share.

In December 2022, the Company entered into amendments to the March 2022 Note and the June 2022 Note to adjust the conversion price of the March 2022 Note and the June 2022 Note to $1.00 per common share. The March 2022 Note and June 2022 Note originally had a conversion price equal to 80% and 60%, respectively, of the IPO price. While this amendment was not required, as the March 2022 Note and June 2022 did not have down-round protection like the Private Placement Notes, the amendment was entered into to provide the investors in the March and June Notes with the same conversion price as the Private Placement Notes.

The Company incurred debt issuance costs attributed to the November Notes, which were recorded as a debt discount.

January 2023 Settlement of Debt

On January 24, 2023, concurrent with the consummation of the IPO, the Company issued 1,140,700 shares of common stock upon conversion of the convertible promissory notes. All convertible notes and related accrued interest were settled in full on January 24, 2023.

On January 24, 2023, the Company issued 250,000 shares of common stock upon the exercise of the November Warrants. The $250,000 of proceeds of the warrant exercise were used to concurrently pay off the $250,000 November Notes. All of the November Notes were settled in full on January 24, 2023.

Upon pay-off and settlement of the convertible promissory notes and November Notes, the Company had $740,139 of unamortized debt discount costs remaining on the balance sheet. During January 2023, the Company recorded a $740,139 loss on the extinguishment of debt for the unamortized debt issuance costs.

Note 7. Related Party Transactions

On January 25, 2022, the Company into an agreement with Phamace, LLC, a consulting firm of which Quang Pham, the Company's Chief Executive Officer, is the sole member, for an initial term of January 25, 2022 through February 28, 2022. Pursuant to the agreement, the Company shall pay the sum of $115,000 to Phamace, LLC for advisory and administrative services rendered relating to preparing the Company to launch as an operating company, which was due and payable on September 30, 2022. The Company settled this obligation in January 2023.

Note 7. Related Party Transactions (cont.)

On January 25, 2022, the Company issued 7,500,000 shares of common stock, pursuant to a subscription agreement, to Quang Pham, the Company's Chief Executive Officer, of which 3,000,000 were subsequently transferred to a related trust, of which Mr. Pham's child is a beneficiary and Mr. Pham is the trustee with sole voting and disposition power with respect to the shares owned by the trust, 1,100,000 were subsequently transferred to friends, family and a trust of which Mr. Pham's child is a beneficiary, but of which Mr. Pham has no voting or disposition power, and 125,000 were transferred to non-profit organizations. Mr. Pham paid a total of $7,500 for such founders shares.

On March 1, 2022, the Company issued a convertible promissory note in the amount of $500,000 to John Murphy, a member of the Company's board of directors, which bore interest at 5% and matures on March 1, 2025. The note, as amended in December 2022, converted into 514,792 shares of the Company's common Stock at a conversion price equal to $1.00 upon consummation of the initial public offering. See Note 6 for further discussion.

On May 17, 2022, the Company issued 450,000 shares of restricted common stock, pursuant to a restricted stock purchase agreement, to Matthew Szot its Chief Financial Officer, which shares shall vest quarterly over a period of two years, subject to certain adjustments, as provided in the Restricted Stock Purchase Agreement dated May 17, 2022.

On August 22, 2022, the Company issued a convertible promissory note in the amount of $50,000 to Glynn Wilson, a member of the Company's board of directors, which bears interest at 6% and matures on September 13, 2025. The note was converted into 50,000 shares of the Company's common Stock at a conversion price equal to $1.00 upon consummation of the initial public offering. See Note 6 for further discussion.

Note 8. Leases, Commitments, and Contingencies

Leases

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

In accordance with ASC 842, Leases, the Company determines if 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. 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, but payments are recognized as expenses on a straight-line basis over the lease term. The Company has elected not to recognize leases with terms of 12 months or less.

A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. The Company combines the lease and non-lease components of fixed costs in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Note 8. Leases, Commitments, and Contingencies (cont.)

Finance and operating lease assets and 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 payments are expensed using the straight-line method as an operating expense over the lease term.

The Company's operating lease ROU assets and liabilities as of December 31, 2023 and 2022 are as follows:

	December 31, 2023	December 31, 2022
Assets		
Right of use assets	$ 20,998	$ 43,578
Liabilities		
Current		
Operating lease liabilities	$ 21,350	$ 22,288
Noncurrent		
Operating lease liabilities	—	21,350
Total operating lease liabilities	$ 21,350	$ 43,638

Operating lease expenses were $26,555 and $4,394 for the years ended December 31, 2023 and 2022, respectively. Cash paid for amounts included in the measurement of operating lease liabilities included in operating cash flows was $26,003 for the year ended December 31, 2023 and $4,334 for the year ended December 31, 2022. The remaining operating lease term was 10 months, and the operating lease discount rate was 12% as of December 31, 2023.

Future annual lease payments under non-cancellable operating leases as of December 31, 2023 were as follows:

2024	$ 22,319
Total lease payments	22,319
Less: Imputed interest	969
Total operating lease liabilities	$ 21,350

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 9. Stockholders' Equity and Warrants

Common Stock

Pursuant to the Certificate of Incorporation filed on January 25, 2022, the Company was authorized to issue a total of 10,000,000 shares of common stock with a par value of $0.001 per share. On December 5, 2022, the Company filed an Amended and Restated Certificate of Incorporation to increase the authorized capital stock of the Company to 82,500,000 shares, consisting of 75,000,000 shares of common stock, par value $0.001 per share, and 7,500,000 shares of preferred stock, par value $0.001 per share, which was approved by the Company's Board of Directors, as well as a majority of the Company's shareholders, on December 5, 2022.

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.

On January 24, 2023, the Company consummated its IPO of 1,400,000 shares of its common stock at a public offering price of $5.00 per share, generating gross proceeds of $7,000,000 and net proceeds of $5,408,575. The Company's shares of common stock commenced trading on the Nasdaq Capital Market on January 20, 2023, under the symbol "CVKD."

In connection with the IPO, on January 19, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Boustead, as representative of the underwriters (the "Representative"). Pursuant to the Underwriting Agreement, the Company agreed to issue to the underwriters a five-year warrant (the "Representative's Warrant") to purchase an aggregate of 84,000 shares of the Company's common stock, which is equal to six percent (6%) of the shares of common stock sold in the IPO. Such Representative's Warrant has an exercise price of $6.00, which is equal to 120% of the public offering price of the common stock in the IPO.

On July 12, 2023, the Company entered into a securities purchase agreement with an institutional investor (the "Investor Selling Stockholder") pursuant to which the Company sold to the Investor Selling Stockholder in a private placement (the "Private Placement") (i) an aggregate of 1,300,000 shares of Common Stock (the "Shares"), (ii) in lieu of additional Shares, the Pre-Funded Warrants to purchase up to an aggregate of 2,985,715 shares of Common Stock, and (iii) accompanying Common Warrants to purchase up to an aggregate of 4,285,715 shares of Common Stock (the "Common Warrants"). The combined purchase price of each Share and accompanying Common Warrants was $1.75. The combined purchase price of each Pre-Funded Warrant and accompanying Common Warrants was $1.7499.

The Private Placement closed on July 14, 2023. The Company received aggregate gross proceeds from the Private Placement of approximately $7.5 million before deducting the placement agent commissions and offering expenses payable by the Company. H.C. Wainwright & Co., LLC ("H.C.W.") acted as the placement agent in the Private Placement and as part of its compensation the Company issued to designees of H.C.W. Placement Agent Warrants to purchase up to 278,571 shares of Common Stock at an exercise price of $2.1875.

Each Pre-Funded Warrant has an exercise price equal to $0.0001 per share. The Pre-Funded Warrants are exercisable at any time after their original issuance and will not expire until exercised in full. Each Common Warrant has an exercise price equal to $1.75 per share. The Common Warrants are exercisable at any time after their original issuance and will expire on January 16, 2029. The exercise price and number of shares of Common Stock issuable upon exercise of the Common Warrant and Pre-Funded Warrant are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events.

The Pre-Funded Warrants and the Common Warrants issued in the Private Placement 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. They also provide that a holder of Pre-Funded Warrants or Common Warrants, as applicable, will not have the right to exercise any portion of its Pre-Funded Warrants or Common Warrants if such holder, together with its affiliates, and any other party whose holdings would be aggregated with those of the holder for purposes of Section 13(d) or Section 16 of the Exchange Act would beneficially own in excess of 9.99% for the Pre-Funded Warrants and 4.99% for the Common Warrants of the number of shares of Common Stock outstanding immediately

Note 9. Stockholders' Equity and Warrants (cont.)

after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that the holder may increase or decrease the Beneficial Ownership Limitation by giving notice to the Company, with any such increase not taking effect until the sixty-first day after such notice is delivered to the Company but not to any percentage in excess of 9.99%. The Common Warrants may be exercised on a cashless basis if a registration statement registering the shares of Common Stock underlying the Common Warrants is not effective. The Pre-Funded Warrants may be exercised on a cashless basis.

Warrant Summary

The following table summarizes the total warrants outstanding at December 31, 2023:

	Issue Date	Exercise Price Per Share	Expiration Date	Outstanding as of December 31, 2022	New Issuance	Exercised	Outstanding as of December 31, 2023
Placement agent warrants	July – Sept 2022	$ 3.00	July – Sept 2027	11,500	—	—	11,500
Placement agent warrants	Nov 2022	$ 1.00	Nov 2027	15,000	—	—	15,000
Investor warrants	Nov 2022	$ 1.00	Earlier of IPO or Nov 2027	250,000	—	(250,000)	—
Representative warrants	Jan 2023	$ 6.00	Jan 2028	—	84,000	—	84,000
Pre-funded investor warrants	July 2023	$ 0.0001	Once exercised	—	2,985,715	—	2,985,715
Common warrants	July 2023	$ 1.75	Jan 2029	—	4,285,715	—	4,285,715
Placement agent warrants	July 2023	$ 2.1875	Jan 2029	—	278,571	—	278,571
				276,500	7,634,001	(250,000)	7,660,501

Note 10. 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 Plans in connection with awards was 2,000,000 shares, of which 685,000 remained available for issuance as of December 31, 2023. 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. All available shares may be utilized toward the grant of any type of award under the 2022 Plan.

Note 10. Equity-Based Compensation (cont.)

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

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

	Year Ended December 31, 2023	January 25, 2022 (inception) to December 31, 2022
Risk-free interest rate	4.51%	2.98% – 4.10%
Dividend yield	—	—
Expected term (years)	5.33	5.27 – 5.81
Volatility	70.7%	62.4% – 62.5%

Activity under the Plans for the period from December 31, 2022 to December 31, 2023 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, 2022	1,100,000	$ 0.84	9.57	$ 4,578,000
Granted	75,000	1.20	9.56	—
Exercised	—	—	—	—
Canceled/forfeited/expired	—	—	—	—
Outstanding at December 31, 2023	1,175,000	$ 0.86	8.64	$ 105,000
Options vested and exercisable at December 31, 2023	584,724	$ 0.77	8.56	$ 10,808
Options vested and expected to vest as of December 31, 2023	1,175,000	$ 0.86	8.64	$ 105,000

The weighted average grant date fair value of options granted to date was $1.09. At December 31, 2023, the Company had $676,479 of unrecognized stock-based compensation expense related to stock options which will be recognized over the weighted average remaining requisite service period of 1.4 years. The Company settles employee stock option exercises with newly issued shares of common stock.

On January 24, 2023, the Company granted 50,000 shares of the Company's common stock to the Company's Chief Financial Officer. The shares were fully vested on the date of grant.

On March 30, 2023, the Company issued 10,839 shares of its common stock to a consultant for services rendered.

On March 31, 2023, the Company issued 77,340 shares of its common stock for services to be performed from April through September 2023.

Note 10. Equity-Based Compensation (cont.)

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

	Year Ended December 31, 2023	January 25, 2022 (Inception) to December 31, 2022
General and administrative	$ 340,499	$ 791,247
Research and development	369,882	136,802
Total stock-based compensation	$ 710,381	$ 928,049

Note 11. Net Loss Per Share

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

	Year Ended December 31, 2023	January 25, 2022 (Inception) to December 31, 2022
Numerator:		
Net loss	$ (8,357,086)	$ (6,714,329)
Denominator:		
Weighted average common shares outstanding	13,491,980	7,890,507
Net loss per share, basic and diluted	$ (0.62)	$ (0.85)

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 convertible notes, 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,	
	2023	2022
Anti-dilutive common stock equivalents:		
Stock options to purchase common stock	1,175,000	1,100,000
Warrants to purchase common stock	7,660,501	276,500
Total anti-dilutive common stock equivalents	8,835,501	1,376,500

Note 12. Income Taxes

The Company's loss before provision (benefit) for income taxes for the year ended December 31, 2023 and for the period from January 25, 2022 (inception) to December 31, 2022 was generated in the following jurisdictions:

	Year Ended December 31, 2023	January 25, 2022 (Inception) to December 31, 2022
Domestic	$ (8,357,086)	$ (6,714,329)
Foreign	—	—
Loss before income taxes	$ (8,357,086)	$ (6,714,329)

Note 12. Income Taxes (cont.)

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 year ended December 31, 2023 and for the period from January 25, 2022 (inception) to December 31, 2022:

	Year Ended December 31, 2023	January 25, 2022 (Inception) to December 31, 2022
Current		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current provision	—	—
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred provision	—	—
Provision for income taxes	$ —	$ —

A reconciliation of income tax expense to the amount computed by applying the statutory federal income tax rate to the loss from operations is summarized for the year ended December 31, 2023 and for the period from January 25, 2022 (inception) to December 31, 2022, as follows:

	Year Ended December 31, 2023	January 25, 2022 (Inception) to December 31, 2022
Tax benefit at statutory tax rate	$ (1,754,988)	$ (1,410,009)
State benefit, net of federal benefit	(136,314)	(263,978)
Permanent differences	27,006	8,910
Equity-based compensation	3,150	125,248
Deferred rate change	17,642	—
Derivatives	141,457	1,003,603
Other	47	—
Increase in valuation allowance	1,702,000	536,226
	$ —	$ —

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, 2023 and 2022 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 $1,702,000 for the year ended December 31, 2023 was primarily due to an increase in the Company's net operating losses and capitalized research costs occurring during the current year.

Note 12. Income Taxes (cont.)

The components of deferred tax assets and liabilities consisted approximately of the following at December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating loss carryforwards	$ 1,099,000	$ 298,000
Equity-based compensation	138,000	44,000
Capitalized research costs	807,000	55,000
Lease liabilities	5,000	—
Accruals and other temporary differences	137,000	135,000
Total deferred tax assets	2,186,000	532,000
Convertible debt	—	(53,000)
Right of use assets	(5,000)	—
Valuation allowance for deferred tax assets	(2,181,000)	(479,000)
Net deferred tax asset	$ —	$ —

As of December 31, 2023, the Company has net operating loss carryforwards of approximately $4.7 million and $2.7 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. As of December 31, 2022, the Company has net operating loss carryforwards of approximately $1.2 million and $1.2 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 $4.7 million and $1.2 million as of December 31, 2023 and 2022, 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, 2023, 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, 2023, 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 13. Subsequent Events

The Company has evaluated events that occurred through March 8, 2024, the date that the financial statements were issued, and determined that there have been no events that have occurred that would require adjustments to our disclosures in the financial statements except for the transactions described below.

On January 22, 2024, the Company received a notice to exercise 1,444,715 Pre-Funded Warrants for proceeds of $144. On February 5, 2024, the Company received a notice to exercise 1,267,000 Pre-Funded Warrants for proceeds of $127. On February 26, 2024, the Company received a notice to exercise 274,000 Pre-Funded Warrants for proceeds of $27. As a result of the respective Pre-Funded Warrant exercises, the Company issued 2,985,715 shares of common stock. As of February 26, 2024, there are no Pre-Funded Warrants outstanding.

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, 2023. 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, 2023, 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 the Sarbanes-Oxley Act, 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 U.S. 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 U.S. 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, 2023. 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, 2023.

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, 2023, 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.

None.

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 8, 2024. There are no family relationships among any of our directors or executive officers.

Name	Age	Position
Executive Officers and Directors		
Quang Pham	59	Chairman and Chief Executive Officer
Matthew Szot	49	Chief Financial Officer
Douglas Losordo	65	Chief Medical Officer
Jeffrey Cole	56	Chief Operating Officer
Non-Employee Directors		
Robert Lisicki	56	Director
John R. Murphy	73	Director
Glynn Wilson	76	Director
Steven Zelenkofske	64	Director

Quang Pham, Chairman and Chief Executive Officer

Quang Pham has served as our Chief Executive Officer since he formed the Company. He previously served as Chief Executive Officer, Chairman of the Board of Directors and founder of Espero BioPharma, Inc. ("Espero"), the previous sponsor of the tecarfarin IND, 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. He then served as a consultant to HESP LLC, the assignee of Espero, from July 2020 until December 2021. From February 2012 to August 2015, Mr. Pham was a partner with D+R LATHIAN, LLC, a life sciences multichannel marketing agency. Prior to joining D+R LATHIAN, he founded and served as Chairman and Chief Executive Officer of Lathian Systems, Inc., a digital and database marketing company serving the pharmaceutical industry from 2000 until 2003 and from 2008 until 2012 when the company was acquired by D&R Communications, LLC in February 2012. He has a Bachelor of Arts in Economics from UCLA, and served as a U.S. Marine Corps Officer. 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 six-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 and Compensation Committees of INVO Bioscience, Inc., a Nasdaq-listed commercial-stage fertility company. He also serves on the Board of Directors and serves as Chairman of the Audit Committee 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 mergers and acquisitions, corporate strategy, equity and

debt financings, corporate governance, SEC reporting and compliance, and developing and implementing financial and operational workflows and process improvements. He also has extensive experience in international operations, joint ventures, and technology license agreements.

Douglas Losordo, M.D., Chief Medical Officer

Douglas Losordo has served as our Chief Medical Officer since August 8, 2022. Dr. Losordo has worked in the biotech industry developing cell-based therapies for over twenty years. Since February 2021, he has served on the Board of Directors of Longeveron Inc., a clinical-stage biotechnology company developing cellular therapies for aging-related and life-threatening conditions. Dr. Losordo also served as Global Head Clinical Development and Operations of American Regent, Inc., a clinical development pharmaceutical company from June 2021 until August 2022. Prior thereto he served as Chief Medical Officer of KBP Biosciences Co., Ltd., a biotechnology research and development company, from November 2020 until June 2021 and as Executive Vice President, Global Head of Research and Development, Chief Medical Officer of Caladrius Biosciences, a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse chronic disease, from August 2013 until November 2020. Dr. Losordo has extensive knowledge of clinical, regulatory, manufacturing, supply chain and commercial factors unique to cellular therapy technologies as a result of his prior industry experience. Dr. Losordo also previously served as a Professor of Medicine at NYU Langone Medical Center and Northwestern University's Feinberg School of Medicine. He received his MD from the University of Vermont College of Medicine, and his B.A. in Zoology from the University of Vermont.

Jeffrey Cole, Chief Operating Officer

Jeffrey Cole has served as our Chief Operating Officer since February 8, 2024 and has served as a consultant to the Company since November 2023. Mr. Cole brings over 25 years of experience in global pharmaceutical manufacturing and commercial operations, finance, and corporate development.. 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. From March 2015 to July 2020, he served as President, Chief Financial Officer, Board Director and co-founder of Espero BioPharma, Inc. From August 2010 to February 2015, he served as President and co-founder of Marcas USA, 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), a NYSE-listed company, 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 and also served as Principal in the Financial Management Consulting practice at PricewaterhouseCoopers. Mr. Cole holds an MBA with honors from the University of Michigan and a BS in accounting from the University of Southern California.

Robert Lisicki

Mr. Lisicki, has served on our Board of Directors since July 23, 2023. He currently serves as an independent consultant and advisor to both public and private pharmaceutical and biotechnology companies. Since January 8, 2024 has served as the President and COO of Zura Bio, a clinical stage auto-immune company. Since October of 2023, Mr. Lisicki has served as an Independent Director of Adiso Therapeutics, a privately held clinical-stage auto-immune company. From October 2022 until March 2023, he served as the Chief Executive Officer and board member of InCarda Therapeutics, Inc., a privately held clinical-stage biopharmaceutical company focused on cardiovascular diseases. Previously, he served as Executive Vice President and Chief Commercial Officer of Arena Pharmaceuticals ("Arena") from November 2018 until March 2022, when Arena was acquired by Pfizer, Inc. Prior to joining Arena, Mr. Lisicki served as General Manager, Vice President Cardio-Metabolic and Inflammation at Regeneron Pharmaceuticals, Inc. from June 2018 to November 2018, leading the Company's U.S.-based cardiovascular and inflammation business, and Senior Vice President of Sales and Marketing and Chief Customer Officer at Daiichi Sankyo, Inc. from August 2014 until February 2018, with responsibility for the company's U.S.-based cardiovascular and oncology therapeutics. Mr. Lisicki also held several management positions at Amgen Inc. between 2005 and 2014, including Vice President and General Manager, responsible for a 700+ person sales force in the U.S. His U.S. leadership experiences included such market shaping products Enbrel and Prolia. During his tenure he also covered several ex-U.S. regions, and

worked as an International Franchise Lead running the development and international strategies and business plans across Amgen's portfolio including Nephrology, Cardiology, Bone and Oncology. Mr. Lisicki held various sales and marketing positions at Johnson & Johnson Corporation. Mr. Lisicki brings over 25 years of experience in biopharmaceutical management, sales and marketing to the Company. Mr. Lisicki holds a Bachelor of Science degree in Finance and Business Administration from the State University of New York at Albany. Mr. Lisicki is qualified to serve on our Board of Directors due to his public company experience and his biopharmaceutical management, sales, and marketing experience.

John R. Murphy

John R. Murphy has served on our Board of Directors since January 19, 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.

Dr. Glynn Wilson has served on our Board of Directors since January 19, 2023. He has served on the Board of Directors of Jupiter Wellness, Inc. ("Jupiter") since November 2018, serving as Chairman since October 2019. Dr. Wilson also serves 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.

Dr. Steven Zelenkofske has served on our Board of Directors since January 19, 2023. Dr. Zelenkofske has served on the Board of Directors of Dinaqor AG since May 2020. He is currently serving as President of SLZ Consulting, LLC. He has served as Chief Medical Officer of SwanBio Therapeutics since June 1, 2020 until September 2022. Dr. Zelenkofske is also an advisor to Veralox Therapeutics, Inc., as Chair of the Scientific Advisory Board, a position he has held since March 2020. 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-Aventis, 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.

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 during 2024 for the Class II directors, 2025 for the Class III directors and 2026 for the Class I directors. Our directors are divided among the three classes as follows:

- the Class I directors are Quang Pham and Glynn Wilson and their terms will expire at the annual meeting of stockholders to be held in 2026;
- the Class II directors are Robert Lisicki and John Murphy and their terms will expire at the annual meeting of stockholders to be held in 2024; and
- the Class III director is Steven Zelenkofske and his term will expire at the annual meeting of stockholders to be held in 2025.

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.

Principal Investigator

Sean Pokorney, M.D.

Sean Pokorney has been designated as our Principal Investigator. Dr. Pokorney is a cardiologist, electrophysiologist and researcher specializing in patients with ESKD and AFib. He is an Assistant Professor of Medicine at Duke University and is a member of the Duke Clinical Research Institute. We entered into a Scientific Advisory Board and Consulting Agreement with Dr. Pokorney ("Pokorney Agreement"), dated June 15, 2022, which provides that he shall be granted stock options, pursuant to the Cadrenal Therapeutics, Inc. 2022 Equity Incentive Plan, to purchase 100,000 shares of our Common Stock at an exercise price per share equal to the fair market value per share of the

Company's Common Stock on the date of the grant, which stock options will vest over a three-year vesting schedule. The Pokorney Agreement further provides that we shall pay Dr. Pokorney at the rate of $650 per hour for services that exceed the scope of work of general members of the Scientific Advisory Board.

Scientific Advisory Board (SAB)

We intend that our Scientific Advisory Board will work with our management team in planning, developing and executing further scientific, clinical, and research and development initiatives and strategies. Our scientific advisory board is comprised of the following individuals, who have significant experience in the field of cardiovascular medicine:

Christopher Granger, MD

- Professor of Medicine in the Division of Cardiology at Duke University
- Director of Cardiac Care Unit for Duke University Medical Center
- Member, Duke Clinical Research Institute (DCRI)

C. Michael Gibson, MS, MD

- CEO of not-for profit Baim/PERFUSE Research Institutes
- Harvard University Professor
- Cardiologist at Beth Israel Deaconess Medical Center of Boston
- Founder and Chairman WikiDoc.org

Richard Whitlock, MD, PhD

- Cardiac Surgeon and Associate Professor at Population Health Research Institute, McMaster University Medical Center
- Investigator, Population Health Research Institute

A. Michael Lincoff, MD

- Vice Chairman, Department of Cardiovascular Medicine, Cleveland Clinic
- Director of Clinical Research, Lerner Research Institute

Wolfgang C. Winkelmayer, MD, MPH, ScD

- Chief, Section of Nephrology and Professor of Medicine, Baylor College of Medicine
- Director, Selzman Institute for Kidney Health at Baylor College of Medicine

Elaine Hylek, MD, MPH

- Professor of Medicine at the Boston University School of Medicine
- Director, Thrombosis and Anticoagulation Service at Boston Medical Center
- Researcher focused on anticoagulation and stroke prevention in AFib

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 or her background, employment and

affiliations, including family relationships, our Board of Directors has determined that Robert Lisicki, John R. Murphy, Dr. Steven Zelenkofske, and Dr. Glynn Wilson 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*. Members will serve on these committees until their resignation or until otherwise determined by our Board of Directors. 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.

The following table shows the directors who are currently members or Chairman of each of the Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee.

Board Members	Audit Committee	Compensation Committee	Nominating and Governance Committee
Quang Pham	—	—	—
Robert Lisicki	—	Member	Member
John Murphy	Chair	Member	—
Glynn Wilson	Member	—	Chair
Steven Zelenkofske	Member	Chair	Member

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 will:

- select and hire the independent registered public accounting firm to audit our financial statements;
- help to ensure the independence and performance of the independent registered public accounting firm;
- approve audit and non-audit services and fees;
- review financial statements and discuss 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;
- prepare the audit committee report that the SEC requires to be included in our annual proxy statement;
- review reports and communications from the independent registered public accounting firm;
- review the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- review our policies on risk assessment and risk management;

- review and approve related party transactions; and
- establish and oversee 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, Robert Lisicki, 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, or the Code. Our compensation committee oversees our compensation policies, plans and benefits programs. The compensation committee will also:

- oversee our overall compensation philosophy and compensation policies, plans and benefit programs;
- review and recommend to our board of directors for approval compensation for our executive officers and directors;
- 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
- administer our equity compensation plans.

Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee consists of Dr. Glynn Wilson, Robert Lisicki 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 corporate governance and nominating committee will:

- identify, evaluate and make 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;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- evaluate the performance of our board of directors and of individual directors.

Candidates for director should have certain minimum qualifications, including the ability to understand basic financial statements, being over 21 years of age, having relevant business experience (taking into account the business experience of the other directors), and having high moral character. The Nominating and Corporate Governance Committee retains the right to modify these minimum qualifications from time to time.

In evaluating an incumbent director whose term of office is set to expire, the Nominating and Corporate Governance Committee reviews such director's overall service to the Company during such director's term, including the number of meetings attended, level of participation, quality of performance, and any transactions with the Company engaged in by such director during his term.

When selecting a new director nominee, the Nominating and Corporate Governance Committee first determines whether the nominee must be independent for Nasdaq purposes or whether the candidate must qualify as an "audit committee financial expert." The Nominating and Corporate Governance Committee then uses its network of contacts

to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm to assist in the identification of qualified director candidates. The Nominating and Corporate Governance Committee also will consider nominees recommended by our stockholders. The Nominating and Corporate Governance Committee does not distinguish between nominees recommended by our stockholders and those recommended by other parties. The Nominating and Corporate Governance Committee evaluates the suitability of potential nominees, taking into account the current board composition, including expertise, diversity and the balance of inside and independent directors. The Nominating and Corporate Governance Committee does not have a set policy or process for considering diversity in identifying nominees, but endeavors to establish a diversity of background and experience in a number of areas of core competency, including business judgment, management, accounting, finance, knowledge of our industry, strategic vision, research and development and other areas relevant to our business. In considering any person recommended by one of our stockholders, the Nominating and Corporate Governance Committee will look for the same qualifications that it looks for in any other person that it is considering for a position on the Board of Directors.

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 Ethics") that is applicable to all of our employees, officers and directors. The full text of our Code of Ethics is available on our website at *www.cadrenal.com*. If we amend or grant any waiver of a provision of our Code of Ethics that applies to our directors or executive officers, we will publicly disclose such amendment or waiver on our website and as required by applicable law. The information on the website is not and should not be considered part of this Annual Report and is not incorporated by reference in this Annual Report.

Insider Trading Policy

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 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 is annexed to this Annual Report as an exhibit and the full text of the Trading Policy is available on our website at *www.cadrenal.com*.

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. See the section titled "Description of Securities — Limitations on Liability and Indemnification of Officers and Directors" for additional information.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2023, which consist of our principal executive officer and the next most highly compensated executive officers, are:

- Quang Pham, Chairman and Chief Executive Officer
- Matthew Szot, Chief Financial Officer
- Douglas Losordo, 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, 2023 and period from January 25, 2022 (inception) through December 31, 2022.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Stock Award ($)[2]	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Quang Pham	2023	$ 662,500	$ 292,950	—	$ —	$ —	$ 11,550[3]	$ 967,000
Chief Executive Officer[6]	2022	$ 350,000	$ 337,500	—	$ —	$ —	$ 128,723[3]	$ 816,223
Matthew Szot	2023	$ 377,180	$ 184,053	$ 250,000	$ —	$ —	$ 33,657[4]	$ 844,890
Chief Financial Officer[7]	2022	—	$ 187,500	—	$ —	$ —	$ 172,105[4]	$ 359,605
Douglas Losordo	2023	$ 401,026	$ 119,128	—	$ —	$ —	$ 8,536[5]	$ 528,690
Chief Medical Officer[8]	2022	—	—	—	$ 625,200	$ —	$ 23,360[5]	$ 648,560

(1) Bonuses for 2023 were accrued as of December 31, 2023, but such bonuses were paid in February 2024. Bonuses for 2022 were accrued as of December 31, 2022, but such bonuses were paid in February 2023.

(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 10 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 in 2023 included $11,550 of 401K employer match contributions. All other compensation for Mr. Pham in 2022 included $115,000 of accrued consulting fees due to Phamace, LLC, a consulting firm of which Quang Pham, our Chief Executive Officer, is the sole member. Other compensation also included $13,723 for the cost of his monthly premiums for health insurance.

(4) All other compensation for Mr. Szot in 2023 included $12,888 of 401K employer match contributions and $20,769 of consulting fees prior to the Company's IPO. All other compensation for Mr. Szot in 2022 represents Mr. Szot's monthly consulting fee of $22,500 from May 17, 2022 through December 31, 2022 plus $2,836 of premiums for health insurance.

(5) All other compensation for Dr. Losordo in 2023 included $8,536 of 401K employer match contributions. All other compensation for 2022 represents Dr. Losordo's consulting fees from August 8, 2022 through December 31, 2022.

(6) Mr. Pham became our Chief Executive Officer on January 25, 2022 (inception).

(7) Mr. Szot became our Chief Financial Officer on May 17, 2022.

(8) Dr. Losordo became our Chief Medical Officer on August 8, 2022.

Agreements with Our Named Executive Officers

Quang Pham Employment Agreement

We entered into an employment agreement with Quang 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. 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, and was increased to $435,750 on January 1, 2024. 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.

Douglas Losordo Employment Agreement

Upon completion of the initial public offering, we entered into an employment agreement with Douglas Losordo, effective January 24, 2023. Under the employment agreement, Dr. Losordo continues to serve as our Chief Medical Officer. He initially received an annual base salary of $425,000, which was increased to $435,625 effective January 1, 2024, with an annual targeted cash bonus of 40% of his base salary.

Pursuant to Dr. Losordo's employment agreement, we need to provide 90 days' written notice to terminate his employment without Cause, as such term is defined in the employment agreement. If Dr. Losordo 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 6 months, (ii) a lump sum payment equal to 50% of 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 6 months following his termination date, if applicable conditions are met.

Dr. Losordo 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. Losordo 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, Dr. Losordo's employment is terminated without Cause or Dr. Losordo 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 (iv) payment of his full COBRA premiums for 12 months following his termination date, if applicable conditions are met.

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

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, 2023:

	Option Awards					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock not yet Vested (#)	Market Value of Shares or Units not yet Vested ($)
Douglas Losordo.	08/18/2022[1]	125,000	175,000	0.64	08/17/2032	—	—

(1) These options vest quarterly over a period of three years commencing October 1, 2022.

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. The material terms of the 2022 Plan are summarized below.

Administration

The 2022 Plan vests broad powers in a committee to administer and interpret the 2022 Plan. Our board of directors has initially designated the compensation committee to administer the 2022 Plan. Except when limited by the terms of the 2022 Plan, the compensation committee has the authority to, among other things: select the persons to be granted awards; determine the type, size and term of awards; establish performance objectives and conditions for earning awards; determine whether such performance objectives and conditions have been met; and accelerate the vesting or exercisability of an award. In its discretion, the compensation committee may delegate all or part of its authority and duties with respect to granting awards to one or more of our officers, subject to certain limitations and provided applicable law so permits.

Our board of directors may amend, alter or discontinue the 2022 Plan and the compensation committee is able to amend any outstanding award at any time; provided, however, that no such amendment or termination may adversely affect awards then outstanding without the holder's permission. In addition, any amendments seeking to increase the total number of shares reserved for issuance under the 2022 Plan or modifying the classes of participants eligible to receive awards under the 2022 Plan requires ratification by our stockholders in accordance with applicable law. Additionally, as described more fully below, neither the compensation committee nor the board of directors is permitted to reprice outstanding options or stock appreciation rights without shareholder consent.

Eligibility

Any of our employees, directors, and consultants, or those of our affiliates, are eligible to participate in the 2022 Plan and may be selected by the compensation committee to receive an award.

Vesting

The compensation committee determines the vesting conditions for awards. These conditions may include the continued employment or service of the participant, the attainment of specific individual or corporate performance goals, or other factors as determined in the compensation committee's discretion (collectively, "Vesting Conditions").

Shares of Stock Available for Issuance

Subject to certain adjustments, as of the date of this Annual Report, the maximum number of shares of common stock that were originally available to be issued under the 2022 Plan in connection with awards was 1,910,000 shares, consisting of (i) the 760,000 shares of common stock that were reserved and available for issuance pursuant to the grant of new awards under our Initial Plan as of January 19, 2023, and (ii) the 1,150,000 shares that were subject to outstanding stock options or other awards granted under our Initial Plan or the 2022 Plan as of January 19, 2023 that terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. In addition, 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 shares available under the 2022 Plan increased by 694,550 shares to a maximum of 2,604,550 shares. As of the date of this Annual Report, there are 269,551 shares available for future issuance under the 2022 Plan. All available shares may be utilized toward the grant of any type of

award under the 2022 Plan. The 2022 Plan imposes a $100,000 limitation on the total grant date fair value with respect to which incentive stock options are exercisable for the first time by an individual optionee during any single calendar year.

In the event of any merger, consolidation, sale or disposition of all or substantially all our assets, sale or disposition of at least 50% of our outstanding securities, or other similar corporate transaction that affects our common stock, the board of directors or compensation committee shall make adjustments to the number and kind of shares authorized by the 2022 Plan and covered under outstanding 2022 Plan awards as it determines appropriate and equitable.

Shares subject to 2022 Plan awards that expire without being fully exercised or that are otherwise forfeited, cancelled or terminated may again be made available for issuance under the 2022 Plan. In addition, shares withheld in settlement of a tax withholding obligation, or in satisfaction of the exercise price payable upon exercise of an option, will again become available for issuance under the 2022 Plan.

Types of Awards

The following types of awards may be granted to participants under the 2022 Plan: (i) incentive stock options, or ISOs; (ii) nonqualified stock options, or NQOs and together with ISOs, options, (iii) stock appreciation rights, (iv) restricted stock, or (v) restricted stock units.

Stock Options. An option entitles the holder to purchase from us a stated number of shares of common stock. An ISO may only be granted to an employee of ours or our eligible affiliates. The compensation committee will specify the number of shares of common stock subject to each option and the exercise price for such option, provided that the exercise price may not be less than the fair market value of a share of common stock on the date the option is granted. Notwithstanding the foregoing, if ISOs are granted to any 10% stockholder, the exercise price shall not be less than 110% of the fair market value of common stock on the date the option is granted.

Generally, options may be exercised in whole or in part through a cash payment. The compensation committee may, in its sole discretion, permit payment of the exercise price of an option pursuant to a "cashless exercise," in the form of previously owned shares of common stock based on the fair market value of the shares on the date the option is exercised, or through means of "net settlement," which involves the cancellation of a portion of the option to cover the cost of exercising the balance of the option or by such other means as it deems acceptable.

All options shall be or become exercisable in accordance with the terms of the applicable award agreement. The maximum term of an option shall be determined by the compensation committee on the date of grant but shall not exceed 10 years (5 years in the case of ISOs granted to any 10% stockholder). In the case of ISOs, the aggregate fair market value (determined as of the date of grant) of common stock with respect to which such ISOs become exercisable for the first time during any calendar year cannot exceed $100,000. ISOs granted in excess of this limitation will be treated as non-qualified stock options.

Stock Appreciation Rights. A stock appreciation right represents the right to receive, upon exercise, any appreciation in a share of common stock over a particular time period. The base price of a stock appreciation right shall not be less than the fair market value of a share of common stock on the date the stock appreciation right is granted. This award is intended to mirror the benefit the participant would have received if the compensation committee had granted the participant an option. The maximum term of a stock appreciation right shall be determined by the compensation committee on the date of grant but shall not exceed 10 years. Distributions with respect to stock appreciation rights may be made in cash, shares of common stock, or a combination of both, at the board of director's discretion.

Unless otherwise provided in an award agreement or determined by the compensation committee, if a participant terminates employment with us (or our affiliates) for any reason other than cause, the participant may exercise his or her unexercised options and stock appreciation rights, to the extent they were exercisable on the termination date, within the following period of time, provided however that in no event may any award be exercised after termination of its maximum term: (i) three months following the date of such termination if such termination is a termination without cause (other than any termination due to the participant's disability or death); (ii) 12 months following the date of such termination if such termination is due to the participant's disability; (iii) 18 months following the date of such termination if such termination is due to the participant's death; or (iv) 18 months following the date of the participant's death if such death occurs following the date of such termination but during the period such Award is otherwise exercisable. If the participant terminates employment with us (or our affiliates) for cause, all unexercised

options and stock appreciation rights (whether vested or unvested) shall terminate and be forfeited on the termination date. Unless otherwise provided by the compensation committee, any options and stock appreciation rights that are not exercisable at the time of termination of employment shall terminate and be forfeited on the termination date.

Restricted Stock. A restricted stock award is a grant of shares of common stock, which are subject to forfeiture restrictions during a restriction period. The compensation committee will determine the price, if any, to be paid by the participant for each share of common stock subject to a restricted stock award. The restricted stock may be subject to Vesting Conditions. If the specified Vesting Conditions are not attained, the participant will forfeit the portion of the restricted stock award with respect to which those conditions are not attained, and the underlying common stock will be forfeited to us. At the end of the restriction period, if the Vesting Conditions have been satisfied, the restrictions imposed will lapse with respect to the applicable number of shares. Unless otherwise provided in an award agreement or determined by the compensation committee, upon termination a participant will forfeit all restricted stock that then remains subject to forfeiture restrictions.

Restricted Stock Units. Restricted stock units are granted in reference to a specified number of shares of common stock and entitle the holder to receive, on the achievement of applicable Vesting Conditions, shares of common stock. Unless otherwise provided in an award agreement or determined by the compensation committee, upon termination a participant will forfeit all restricted stock units that then remain subject to forfeiture.

Change of Control

In the event of a change of control, unless otherwise provided in a grant agreement, employment agreement or other agreement between the Company and the participant, and unless otherwise determined by an affirmative vote of a majority of the board of directors prior to the occurrence of such change of control: (i) the vesting and settlement of all outstanding awards to non-employee directors will be automatically accelerated and the shares immediately issued to the participant (or the Board may direct the payment of a cash settlement equal to the fair market value of the shares that would otherwise be issued to the participant); (ii) the settlement of vested awards to employees and consultants will automatically be accelerated and the shares immediately issued to the participant; and (iii) unvested awards to employees and consultants shall be terminated and forfeited unless the acquiring entity assumes, continues or substitutes any such awards. Notwithstanding the foregoing, to the extent permitted and in compliance with the requirements of Section 409A of the Code, the Board may in its discretion determine to elect to accelerate the vesting and settlement of the unvested awards to employees and consultants upon a Change of Control, or direct the payment of a cash settlement equal to the fair market value of the shares that would otherwise be issued to the participant).

Repricing

Neither our board of directors nor the compensation committee may reduce the exercise price in effect for outstanding options under the 2022 Plan without obtaining the consent of any participant whose award would be materially impaired by such action.

Miscellaneous

Generally, awards granted under the 2022 Plan shall be nontransferable except by will or by the laws of descent and distribution. No participant shall have any rights as a stockholder with respect to shares covered by options or restricted stock units, unless and until such awards are settled in shares of common stock. Our obligation to issue shares or to otherwise make payments in respect of 2022 Plan awards will be conditioned on our ability to do so in compliance with all applicable laws and exchange listing requirements. The awards will be subject to our recoupment and stock ownership policies, as may be in effect from time to time. The 2022 Plan expires 10 years after it becomes effective.

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.

Administration

The Initial Plan vested broad powers in a committee to administer and interpret the Initial Plan. Our board of directors was initially designated to administer the Initial Plan. Except when limited by the terms of the Initial Plan, our board of directors has the authority to, among other things, accelerate the vesting or exercisability of an award.

Our board of directors may amend any outstanding award at any time; provided, however, that no such amendment or termination may adversely affect awards then outstanding without the holder's permission. Additionally, as described more fully below, neither the board of directors nor any committee designated to administer the Initial Plan, or the Administrator, is permitted to reprice outstanding options or stock appreciation rights without shareholder consent.

Vesting

The Administrator determines the vesting conditions for awards. These conditions may include the continued employment or service of the participant, the attainment of specific individual or corporate performance goals, or other factors as determined in the Administrator's discretion (collectively, "Vesting Conditions").

Shares Subject to the Initial Plan

All outstanding awards under the Initial Plan remain outstanding but no further grants will be made under the Initial Plan.

In the event of any merger, consolidation, reorganization, recapitalization, stock split, reverse stock split, split up, spin-off, combination of shares, exchange of shares, stock dividend, dividend in kind, or other like change in capital structure (other than ordinary cash dividends), or other similar corporate event or transaction that affects our common stock, the Administrator shall make adjustments to the number and kind of shares covered under outstanding Initial Plan awards as it determines appropriate and equitable.

Shares subject to Initial Plan awards that expire without being fully exercised or that are otherwise forfeited, canceled, or terminated may be made available for issuance under the 2022 Plan. In addition, shares withheld in settlement of a tax withholding obligation, or in satisfaction of the exercise price payable upon exercise of an option, will become available for issuance under the 2022 Plan.

Change of Control

In the event of a change of control, unless otherwise provided in a grant agreement, employment agreement or other agreement between the Company and the participant, and unless otherwise determined by an affirmative vote of a majority of the board of directors prior to the occurrence of such change of control: (i) all outstanding stock options and stock appreciation rights which have been outstanding for at least six months shall become exercisable in full, whether or not otherwise exercisable at such time, and any such stock option and stock appreciation right shall remain exercisable in full thereafter until it expires pursuant to its terms; and (ii) all restrictions and deferral limitations contained in restricted stock and restricted stock unit awards granted under the Initial Plan shall lapse and the shares of stock subject to such awards shall be distributed to the participant within thirty (30) days of the change of control to the extent permitted under Section 409A of the Code.

Repricing

The Administrator cannot, without obtaining prior approval of our stockholders, reduce the exercise price in effect for outstanding options under the Initial Plan.

Miscellaneous

Generally, awards granted under the Initial Plan shall be nontransferable except by will or by the laws of descent and distribution. No participant shall have any rights as a stockholder with respect to shares covered by options or restricted stock units, unless and until such awards are settled in shares of common stock. The Company's obligation to issue shares or to otherwise make payments in respect of Initial Plan awards will be conditioned on the Company's ability to do so in compliance with all applicable laws and exchange listing requirements. The awards will be subject to our recoupment and stock ownership policies, as may be in effect from time to time.

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 may 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 annexed to this Annual Report as an exhibit.

Director Compensation

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, 2023, all of whom were director nominees at the time of grant, in anticipation of director services to be provided:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1][2]	Option Awards ($)[1][2]	Total ($)
John R. Murphy	$ 50,000	$ —	—	$ 50,000
Steven Zelenkofske, D.O.	$ 35,000	$ —	—	$ 35,000
Glynn Wilson, Ph.D.	$ 35,000	$ —	—	$ 35,000
Robert Liscicki	$ 17,500	$ —	$ 57,000	74,500

(1) 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 10 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.

For the fiscal year ended December 31, 2023, our directors received annual cash compensation in the amount of $35,000 and the Chair of the Audit Committee received an additional annual cash compensation of $15,000 per year. Beginning the fiscal year ended December 31, 2024, the additional annual cash compensation for the Chair of the Audit Committee will be increased to $25,000 per year and the Chair of the Compensation Committee and Nominating and Corporate Governance Committee will each receive additional annual cash compensation of $10,000 per year. From time to time, we may grant additional stock options to certain of our non-employee directors as compensation for their services as directors.

(2) 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, 2023
John R. Murphy	100,000
Steven Zelenkofske, D.O.	50,000
Glynn Wilson, Ph.D.	50,000
Robert Lisicki	75,000

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 7, 2024, 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 director; and
- all of our current executive officers and directors as a group

As of March 7, 2024, we had 16,008,469 shares of common stock outstanding, held by approximately 28 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 16,008,469 shares of our common stock outstanding as of March 7, 2024. 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 7, 2024, 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 Pham	6,325,000[1]	39.51%
Matthew Szot	500,000[2]	3.12%
Douglas Losordo	175,000[3]	1.08%
John Murphy	706,460[4]	4.39%
Steven Zelenkofske	102,501[5]	*
Glynn Wilson	98,334[6]	*
Robert Lisicki	16,667[7]	*
All executive officers and directors as a group (7 persons)	7,973,963	48.47%
5% Stockholders other than executive officers and directors		
The PVBQ Living Trust	3,000,000[1]	18.74%
Armistice Capital Master Fund Ltd	1,399,384[8]	8.74%

* Represents beneficial ownership of less than one percent.

(1) Includes (i) 3,325,000 shares of Common Stock owned by Quang Pham; and (ii) 3,000,000 shares of Common Stock owned by The PVBQ Living Trust. 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. Does not include 150,000 shares of Common Stock issuable upon the exercise of options held by Mr. Pham that are not exercisable within the 60-day period following March 7, 2024.

(2) Consists of 450,000 shares of restricted Common Stock, which shares shall vest quarterly over a period of two (2) years, subject to certain adjustments, and 50,000 shares of Common Stock. Does not include 250,000 shares of Common Stock issuable upon the exercise of options held by Mr. Szot that are not exercisable within the 60-day period following March 7, 2024.

(3) Includes 175,000 shares of Common Stock issuable upon the exercise of options held by Dr. Losordo that are exercisable within the 60-day period following March 7, 2024. Does not include 275,000 shares of Common Stock issuable upon the exercise of options held by Dr. Losordo that are not exercisable within the 60-day period following March 7, 2024.

(4) Includes: (i) 614,792 shares of Common Stock; and (ii) 91,668 shares of Common Stock issuable upon the exercise of options held by Mr. Murphy that are exercisable within the 60-day period following March 7, 2024. Does not include 108,332 shares of Common Stock issuable upon the exercise of options held by Mr. Murphy that are not exercisable within the 60-day period following March 7, 2024.

(5) Includes: (i) 40,000 shares of Common Stock; and (ii) 62,501 shares of Common Stock issuable upon the exercise of options held by Dr. Zelenkofske that are exercisable within the 60-day period following March 7, 2024. Does not include 87,499 shares of Common Stock issuable upon the exercise of options held by Dr. Zelenkofske that are not exercisable within the 60-day period following March 7, 2024.

(6) Includes 50,000 shares of Common Stock. And (ii) 48,334 shares of Common Stock issuable upon the exercise of options held Dr. Wilson that are exercisable within the 60-day period following March 7, 2024 Does not include 71,666 shares of Common Stock issuable upon the exercise of options held by Dr. Wilson that are not exercisable within the 60-day period following March 7, 2024.

(7) Represents 16,667 shares of Common Stock issuable upon the exercise of options held by Mr. Lisicki. Does not include 108,333 shares of Common Stock issuable upon the exercise of options held by Mr. Lisicki that are not exercisable within the 60-day period following March 7, 2024.

(8) Information for Armistice Capital Master Fund Ltd. (the "Master Fund") is based upon a Schedule 13G filed with the SEC on February 14, 2024 by Armistice Capital, LLC and Steven Boyd. Does not include 4,285,715 shares of Common Stock issuable upon exercise of Common Warrants. All of the foregoing securities are directly held by the Master Fund, a Cayman Islands exempted company, and may be deemed to be indirectly beneficially owned by (i) Armistice Capital, LLC ("Armistice"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Armistice and Steven Boyd disclaim beneficial ownership of the reported securities except to the extent of their respective pecuniary interest therein. Under the terms of the Common Warrants, Armistice may not exercise the Common Warrants to the extent such exercise would cause Armistice, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of such warrants which have not been exercised. The address for Armistice is 510 Madison Avenue, New York, New York 10022.

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.

Each of the related party transactions described below was negotiated on an arm's length basis. We believe that the terms of such agreements are as favorable as those we could have obtained from parties not related to us. The following are summaries of certain provisions of our related party agreements and are qualified in their entirety by reference to all of the provisions of such agreements. Because these descriptions are only summaries of the applicable agreements, they do not necessarily contain all of the information that you may find useful. We therefore urge you to review the agreements in their entirety. Copies of the forms of the agreements have been filed as exhibits to the Registration Statement and are available electronically on the website of the SEC at *www.sec.gov*.

In addition to 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," the following is a description of each transaction since January 25, 2022 or any currently proposed 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."

On January 25, 2022, we entered into an agreement with Phamace, LLC, a consulting firm of which Quang Pham, our Chief Executive Officer, is the sole member, for an initial term of January 25, 2022 through February 28, 2022 to provide advisory and administrative services relating to preparing the Company to launch as an operating company. Pursuant to the agreement, the Company shall pay the sum of $115,000 to Phamace, LLC for services rendered, which was paid in January 2023.

On January 25, 2022, we issued 7,500,000 shares of common stock, pursuant to a subscription agreement, to Quang Pham, our Chief Executive Officer. Mr. Pham paid a total of $7,500 for such founders shares.

On March 1, 2022, we issued a convertible promissory note in the amount of $500,000 to John Murphy, a director, which bears interest at 5% and matures on March 1, 2025. The note, as amended in December 2022, converted into 514,792 shares of Common Stock at a conversion price equal to $1.00 upon consummation of the initial public offering.

On May 17, 2022, we issued 450,000 shares of restricted common stock, pursuant to a restricted stock purchase agreement, to Matthew Szot, our Chief Financial Officer, which shares shall vest quarterly over a period of two (2) years, subject to certain adjustments, as provided in the Restricted Stock Purchase Agreement dated May 17, 2022.

On August 22, 2022, we issued a convertible promissory note in the amount of $50,000 to Glynn Wilson, a director, which bears interest at 6% and matures on September 13, 2025. The note was converted into 50,000 shares of Common Stock at a conversion price equal to $1.00 upon consummation of the initial public offering.

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 the Sarbanes-Oxley Act.

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 Accounting 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 year ended December 31, 2023 and the period from January 25, 2022 (inception) to December 31, 2022 by our auditors:

	Year Ended December 31, 2023	January 25, 2022 (inception) through December 31, 2022
Audit Fees	$ 112,300	$ 59,130
Tax Fees	—	—
Audit-Related Fees	37,901	110,522
All Other Fees	—	—
Total	$ 150,201	$ 169,652

*** Audit-related fees represents 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)
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)
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)

Exhibit No.	Description
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 10.5 to the Current Report on Form 8-K (001-41596) filed with the SEC on January 25, 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 10.6 to the Current Report on Form 8-K (001-41596) filed with the SEC on January 25, 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 10.7 to the Current Report on Form 8-K (001-41596) filed with the SEC on January 25, 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)
19.1	Insider Trading Policy
21.1*	Subsidiaries of Registrant
23.1*	Consent of Independent Registered Public Accounting Firm

Exhibit No.	Description
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
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 2023 Annual Report to Stockholders 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, 2023. 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 8th date of March, 2024.

Cadrenal Therapeutics, Inc.
(Registrant)

Dated: March 8, 2024

/s/ Quang Pham
Quang 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 Pham Quang Pham	Chairman of the Board and Chief Executive Officer	March 8, 2024
/s/ Matthew Szot Matthew Szot	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 8, 2024
/s/ John R. Murphy John R. Murphy	Director	March 8, 2024
/s/ Glynn Wilson Glynn Wilson	Director	March 8, 2024
/s/ Steven Zelenkofske Steven Zelenkofske	Director	March 8, 2024
/s/ Robert Lisicki Robert Lisicki	Director	March 8, 2024

NASDAQ: CVKD

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