

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 8-K**

**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 13, 2024

**Windtree Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

001-39290  
(Commission  
File Number)

94-3171943  
(I.R.S. Employer  
Identification No.)

2600 Kelly Road, Suite 100, Warrington, Pennsylvania  
(Address of principal executive offices)

18976  
(Zip Code)

Registrant's telephone number, including area code: (215) 488-9300

Not Applicable  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	WINT	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

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**Item 7.01 Financial Statements and Exhibits.**

On September 13, 2024, Windtree Therapeutics, Inc. (the “Company”) updated information reflected in a slide presentation, which is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in various meetings with investors from time to time.

The information contained in this Item 7.01 (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

As disclosed in the Current Report on Form 8-K filed by the Company with the Securities and Exchange Commission (the “SEC”) on July 22, 2024, the Company previously entered into a Common Stock Purchase Agreement (the “ELOC Purchase Agreement”) pursuant to which the Company may sell to the Purchaser named therein shares of the Company’s common stock, par value \$0.001 per share (“Common Stock”) from time to time, subject to certain limitations as described in the ELOC Purchase Agreement.

As disclosed in the Current Reports on Form 8-K filed by the Company with the SEC on July 22, 2024 and July 29, 2024, the Company entered into certain private placement transactions (the “Private Placement”) to sell an aggregate of 27,668,106 shares of Common Stock, issuable upon (i) the conversion of shares (the “Preferred Shares”) of the Company’s Series C convertible preferred stock, par value \$0.001 per share, and (ii) the exercise of certain warrants.

The Registration Statement on Form S-3 (File No. 333-281688) filed by the Company with the SEC on August 21, 2024 and relating to the Private Placement, and the Registration Statement on Form S-1 (File No. 333-281755) filed by the Company with the SEC on August 23, 2024 and relating to the ELOC Purchase Agreement, each became effective on September 3, 2024. As of September 13, 2024, the Company (i) sold an aggregate of 949,948 shares of Common Stock for aggregate gross proceeds of approximately \$3.2 million pursuant to the ELOC Purchase Agreement, and (ii) converted 202.5 Preferred Shares into 68,877 shares of Common Stock pursuant to the Private Placement transaction documents. Accordingly, the shares of Common Stock outstanding increased from 591,909 shares as of June 30, 2024 to 1,610,734 shares as of September 13, 2024. Additionally, as a result of its sales of Common Stock pursuant to the ELOC Purchase Agreement, the Company redeemed 191.5 Preferred Shares as of September 13, 2024 for an aggregate redemption price of \$0.4 million pursuant to the Company’s Certificate of Designations of Rights and Preferences of Series C Convertible Preferred Stock.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits**

The following exhibits are being filed herewith:

<b>Exhibit No.</b>	<b>Document</b>
99.1	<a href="#">Investor Presentation of Windtree Therapeutics, Inc.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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## SIGNATURES

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

Dated: September 13, 2024

Windtree Therapeutics, Inc.

By: /s/ Craig E. Fraser

Name: *Craig E. Fraser*

Title: *President and Chief Executive Officer*



# Windtree Therapeutics Corporate Overview

September 2024

Nasdaq: WINT



## Forward-Looking Statements

This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, among other things, include statements about the Company's clinical development programs, business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development activities, or otherwise as to future events. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will," "should," "could," "targets," "projects," "contemplates," "predicts," "potential" or "continues" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. These risks and uncertainties are further described in the Company's periodic filings with the Securities and Exchange Commission ("SEC"), including the Company's most recent reports on Form 10-K, and any subsequent quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments thereto ("Company Filings"). Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Under no circumstances shall this presentation be construed as an offer to sell or as a solicitation of an offer to buy any of the Company's securities. In addition, the information presented in this deck is qualified in its entirety by the Company Filings. The reader should refer to the Company Filings for a fuller discussion of the matters presented here.



- ✓ Biopharmaceutical company focused on cardiovascular and oncology treatments intended to address markets with significant unmet need (NASDAQ: WINT)
- ✓ First in class, novel asset istaroxime has demonstrated positive efficacy and an attractive profile in three Phase 2 global studies, highlighted by improvements in cardiac function and increases in blood pressure with favorable renal function profile
- ✓ Istaroxime is in Phase 2b clinical development for cardiogenic shock (CS) and acute heart failure; platform also includes next generation oral, SERCA2a activators in preclinical development
- ✓ Expect top line results from istaroxime Phase 2b SEISMIC Extension Study in CS to be presented at a major cardiovascular meeting in late Q3 '24
- ✓ Cardiogenic shock is an estimated \$1.25B global market potential where patients have high mortality, morbidity and costs. It represents a significant opportunity for istaroxime because currently available drugs have undesirable side effects and can result in poor outcomes and there is a lack of competition in development or active competition in the market
- ✓ Global and regional license deals are in place with Windtree in active discussions on potential additional global license for cardiovascular assets
- ✓ Newly acquired first in class, novel, protein kinase C iota inhibitor oncology platform with both topical and oral formulations creates significant opportunity that we plan to advance this year
- ✓ Lean, capital efficient operation led by a highly experienced management team

## Multi-Asset / Indication Pipeline with Several Near-Term Milestones

Product Candidates	Indication	Phase	Development Status / Plans
<b>Istaroxime</b> (SERCA2a activator/ Na/K ATPase inhibitor)	<b>Cardiogenic Shock</b>	<b>Phase 2b</b>	<ul style="list-style-type: none"> <li>Positive Phase 2 study</li> <li>Executing small follow-on studies intended to transition to Phase 3</li> </ul>
<b>Istaroxime</b>	Acute Heart Failure	Phase 2b	<ul style="list-style-type: none"> <li>Positive Phase 2a and 2b data</li> <li>Augment AHF data with cardiogenic shock data, if positive and adequate, for Phase 3 for AHF with partnership</li> <li>Greater China regional license with <b>Lee's Pharma</b> who is advancing and paying for Phase 3 AHF program in territory</li> </ul>
<b>SERCA2a Activators (oral)</b>	Chronic Heart Failure, including potentially HFpEF	Preclinical	<ul style="list-style-type: none"> <li>Chronic and Acute Heart Failure</li> <li>Target for collaboration/partnership</li> </ul>
<b>aPKCi inhibitor (topical and oral)</b>	<b>Cutaneous and systemic treatment in broad and/or rare malignant diseases</b>	Preclinical	<ul style="list-style-type: none"> <li><b>IND enabling studies</b></li> </ul>
<b>Rostafuroxin</b>	Treatment Resistant Hypertension – Genotypically identified patients	Phase 2b	<ul style="list-style-type: none"> <li>Phase 2 data in hypertension</li> <li>Company holding development to out-license and reposition for the attractive and large Resistant Hypertension market</li> </ul>
<b>KL4 Surfactant and AEROSURF</b>	KL4 surfactant Drug/Device Tx for RDS and potential other applications	Phase 2b	<ul style="list-style-type: none"> <li><b>Global out-license in place</b></li> <li>Partner responsible for all costs of development</li> </ul>

# Windtree Strategy for Value Creation – Deliver Data and Deals

## 1H 2024 Accomplishments

- ✓ FPI global Phase 2b Extension Study of istaroxime in Cardiogenic Shock
- ✓ \$138MM plus royalties regional license secured for CV products
- ✓ Eliminated \$15MM in liabilities with Deerfield, added to shareholder equity
- ✓ Delivered positive data with istaroxime and the pure SERCA2a in arrhythmias
- ✓ Started concomitant therapy Stage C study in more severe shock patients
- ✓ Acquired a novel pre-clinical atypical Protein Kinase C iota platform

## 2H 2024 Focus and Planned Deliverables<sup>1</sup>

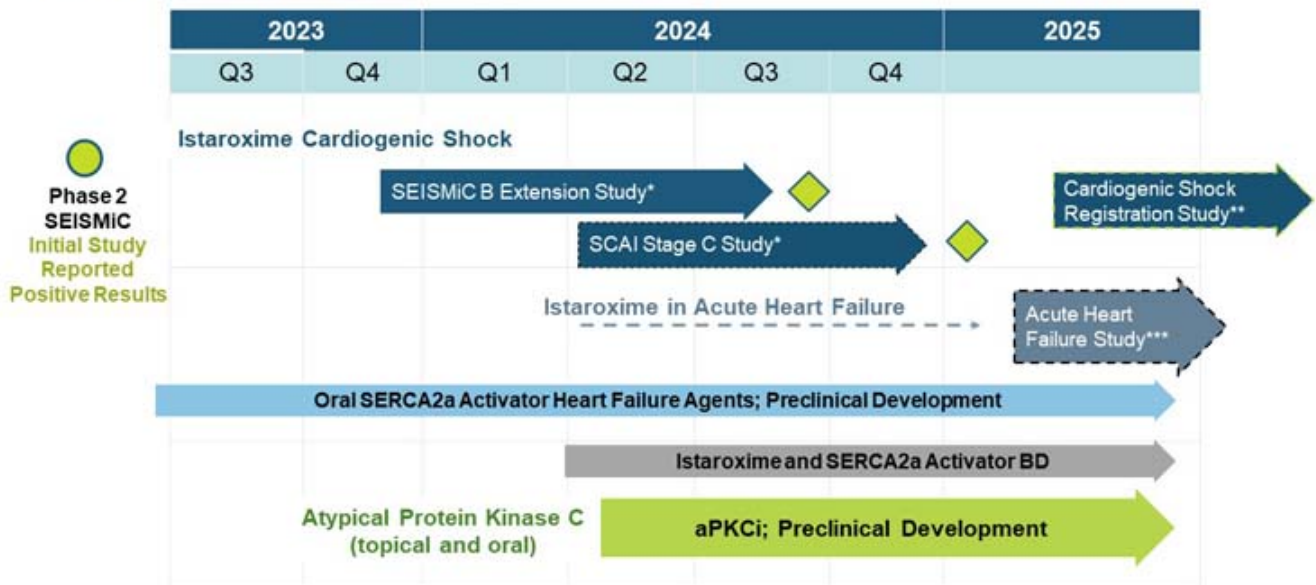
- Final data from istaroxime Phase 2b SEISMic Extension Study in Cardiogenic Shock (CS)
- Execute istaroxime in Stage C CS
- Support our license partner start up of Phase 3 Acute Heart Failure study in Asia/PAC
- Secure additional licenses for istaroxime and SERCA2a activators
- aPKCi inhibitor IND-enabling studies
- Explore additional acquisition and/or strategic transactions
- Drive capital efficacy and partnerships



WINDTREE 1) Assumes Windtree is able to obtain additional funding



# Milestone Strategy for Value Creation



Phase 2 SEISMIC Initial Study Reported Positive Results

\* Study and guidance depends upon adequate funding or partnership  
 \*\* Study and guidance pending positive EOP2 meeting and adequate funding  
 \*\*\* Study and guidance pending positive EOP2 meeting and adequate funding (via partnership)

◆ Represents planned data available





# Istaroxime

## Cardiogenic Shock

*Potential to transform the standard of care for critical patients*



## Cardiogenic Shock - A Critical Condition Caused by a Failing Heart

**A severe presentation of heart failure** characterized by **low blood pressure and inadequate blood flow to vital organs (hypoperfusion)** accompanied by congestion and high filling pressures of the heart. It **requires very urgent treatment.**



- Most often requires pharmacological or mechanical intervention with key clinical objective to increase SBP to >90mmHg and improve tissue perfusion
- Cardiogenic shock patients typically require hospital intensive care and consume significant hospital resources
- High mortality (~20-30%) and substantial morbidity in survivors<sup>1</sup>
- US + EU markets represent an ~\$1.0B market potential<sup>2</sup> with high unmet need
- Potential for relatively faster and less expensive developmental and regulatory pathway

1) Burgos, JSCAI (1) 2021; Kolte D, American Heart Association; 2014 Jan 13; (rates associated with classic, stage C shock)  
2) Estimates from claims data and epi data September 2021, multiplied by assumed various regional prices

## Significant Unmet Need and Reported Desire for Istaroxime

- **No satisfactory pharmacological intervention to reverse the condition**
  - Available therapies have unwanted side effects such as risk for arrhythmias, decreasing blood pressure, renal dysfunction and even increases in mortality that limit their usefulness and position them as “rescue medicines”
- A therapy that can be used **earlier** to rapidly **improve blood pressure and cardiac function without unwanted side effects** is needed

### Market research shows need and enthusiasm for istaroxime profile

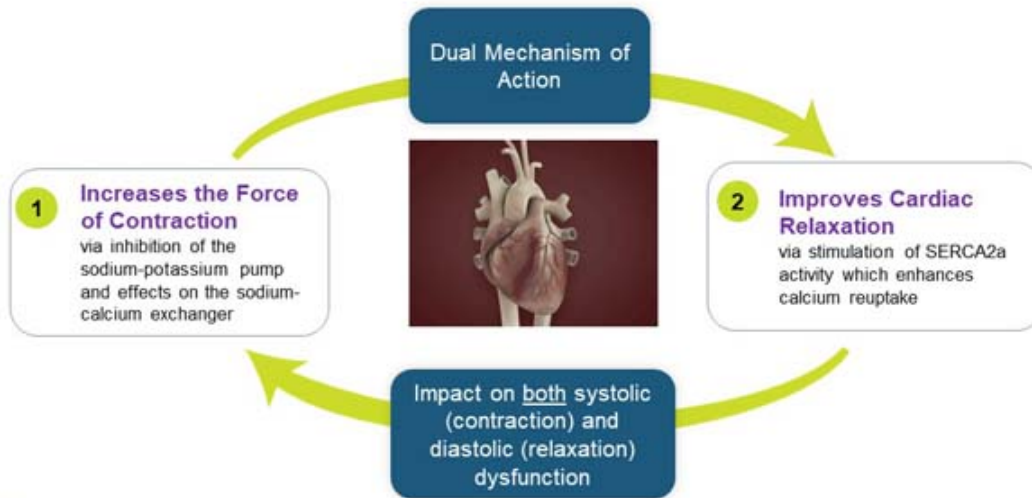
100 U.S. Cardiologists questioned on degree of unmet need for new innovative pharmacologic treatments for ECS<sup>1</sup>



<sup>1</sup>) Market research conducted by Sermo, a leading provider of real time physician insights

# Istaroxime – Novel First-in-Class Therapy

Novel intravenous agent designed to improve systolic contraction and diastolic relaxation of the heart



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## Istaroxime Cardiogenic Shock Program Came from AHF Phase 2 Trials and the Potential Attractive Regulatory Pathway

*In Phase 2a and 2b data in AHF istaroxime demonstrated:*



### **Cardiac Function Improved with Both Doses**

- Significant increase in stroke volume (amount of blood expelled with each heartbeat)
- Lowered cardiac filling pressures



### **Increased Systolic Blood Pressure**



### **Increased Renal Function (eGFR)**



### **Heart Rate Decreased**

### **Favorable Heart Rhythm Profile Observed**

- No increase in clinically significant arrhythmias or ventricular tachycardia

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## SEISMic Early Cardiogenic Shock Study

*Clinical strategy: Start development with patients in early cardiogenic shock caused by severe heart failure*



60 patients in early cardiogenic shock (SBP 75-90 mmHg) with AHF



Study drug was infused for 24 hours in a 1:1 randomization to placebo or istaroxime. Two istaroxime target doses were evaluated, 1.5  $\mu\text{g}/\text{kg}/\text{min}$  in the first group and 1.0  $\mu\text{g}/\text{kg}/\text{min}$  in the next group.



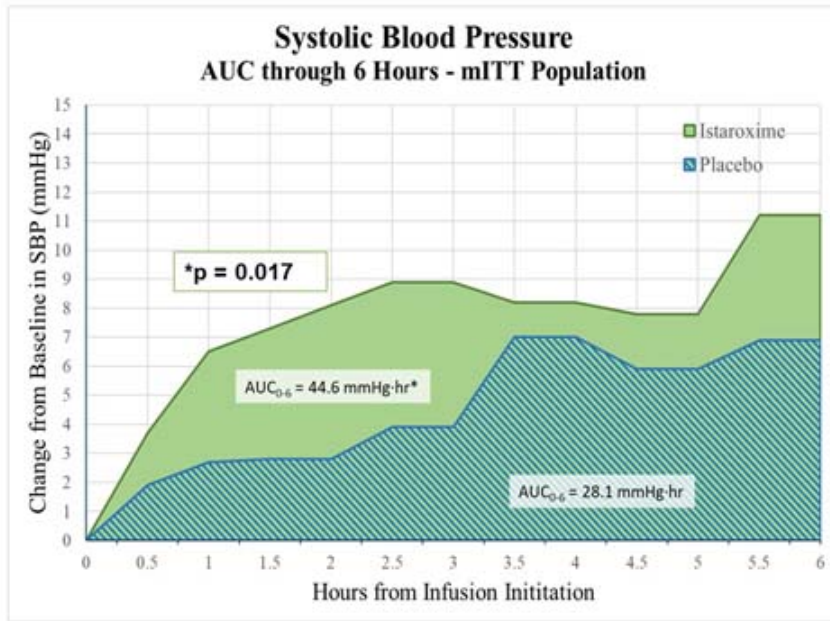
Primary endpoint was SBP AUC at 6 hours comparing istaroxime to placebo

Secondary measures included: SBP profile at 24 hours, echocardiology measures associated systolic and diastolic cardiac function, renal function, various safety and tolerability measures



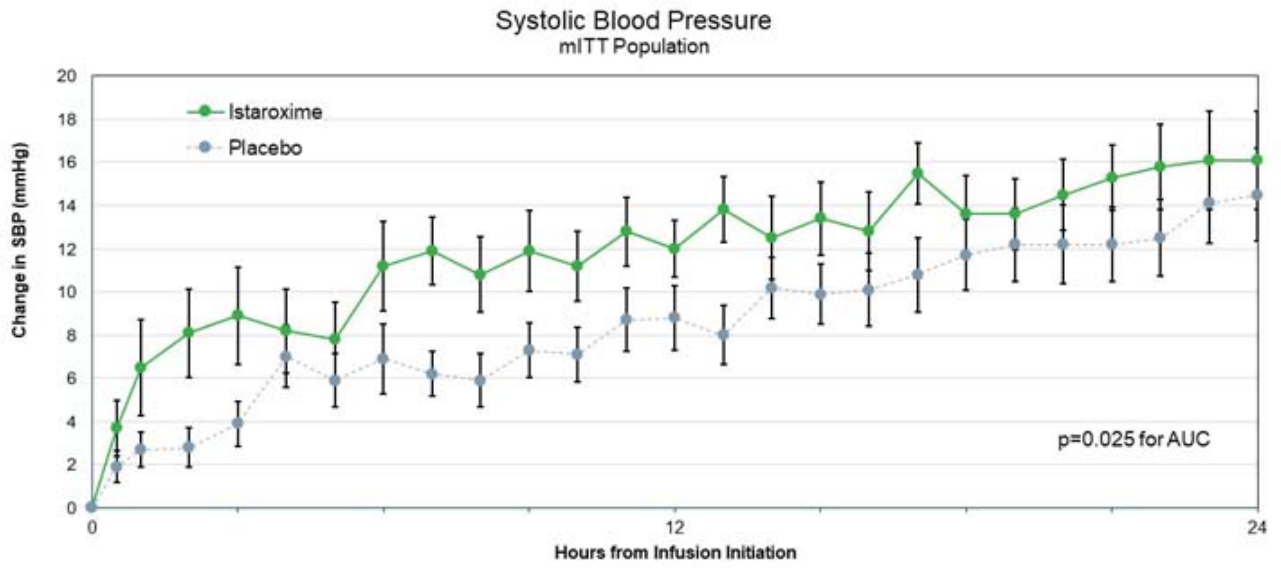
**Positive Results in the Early Cardiogenic Shock Study**

# Istaroxime Achieved Positive Primary Endpoint





## Systolic BP Improvements Persisted over 24 Hours



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## Cardiac Function Improvement

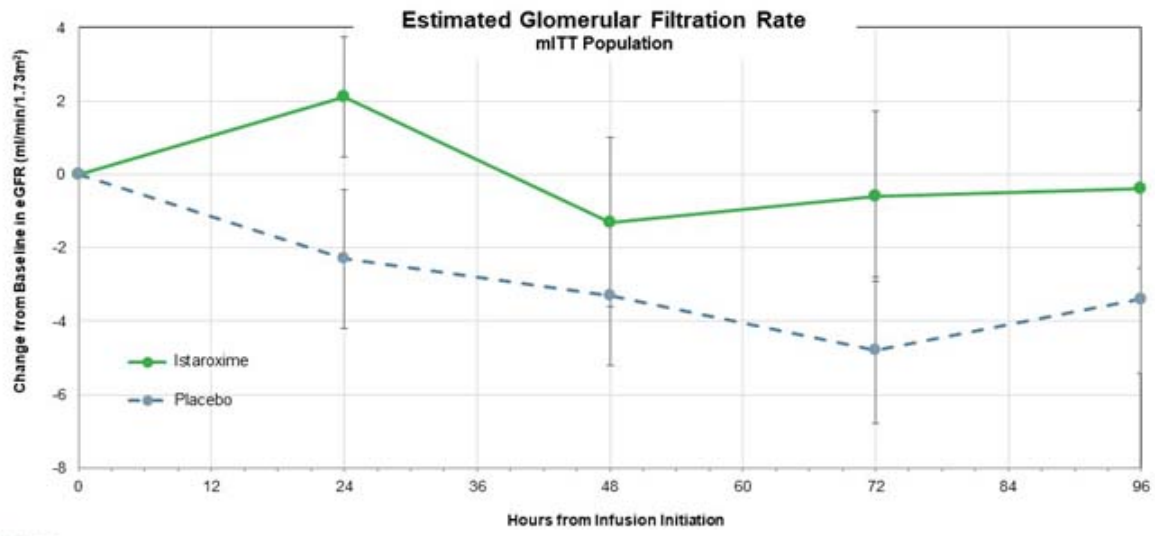
Echocardiography demonstrated improvements in key systolic and diastolic cardiac function measures including:

- ✓ **Cardiac index** (amount of output from the heart over a minute) significantly increased
- ✓ **Stroke volume** (amount of blood from the heart with each heartbeat) substantially increased
  - (4 mL/m<sup>2</sup>) approaching statistical significance
- ✓ **The strength and cardiac geometry of the heart improved including:**
  - Left atrial area was reduced
  - Left ventricular end systolic volume was reduced
  - Left ventricular end diastolic volume was reduced



# Treatment was Associated with a Favorable Renal Profile

Renal function was not decreased in istaroxime treated patients

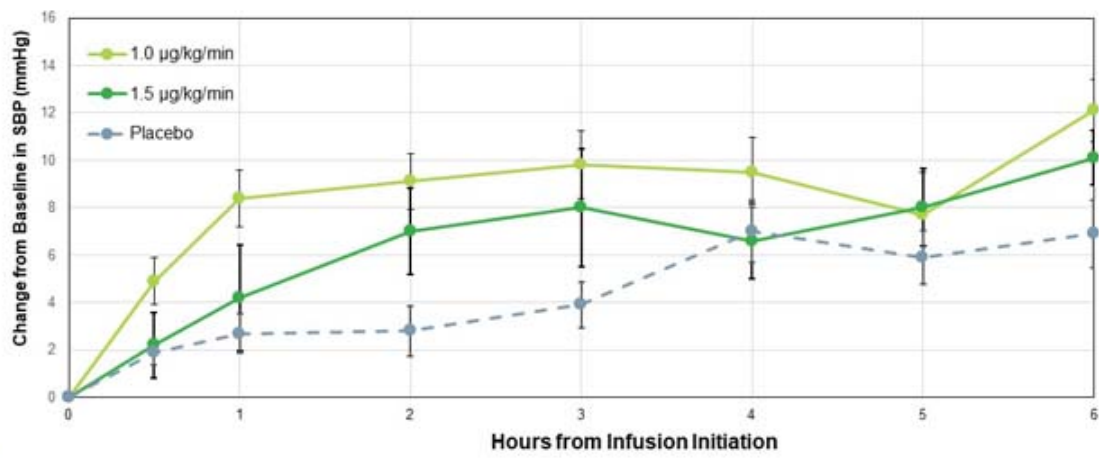


Data shown as means and standard errors

## 1.0 $\mu\text{g}/\text{kg}/\text{min}$ Produced a Favorable Effect on SBP

1.0  $\mu\text{g}/\text{kg}/\text{min}$  dosing was associated with:

- Early, rapid SBP increase and improvement in more echocardiographic assessments of cardiac function
- More favorable adverse event, serious adverse event and clinical event profile



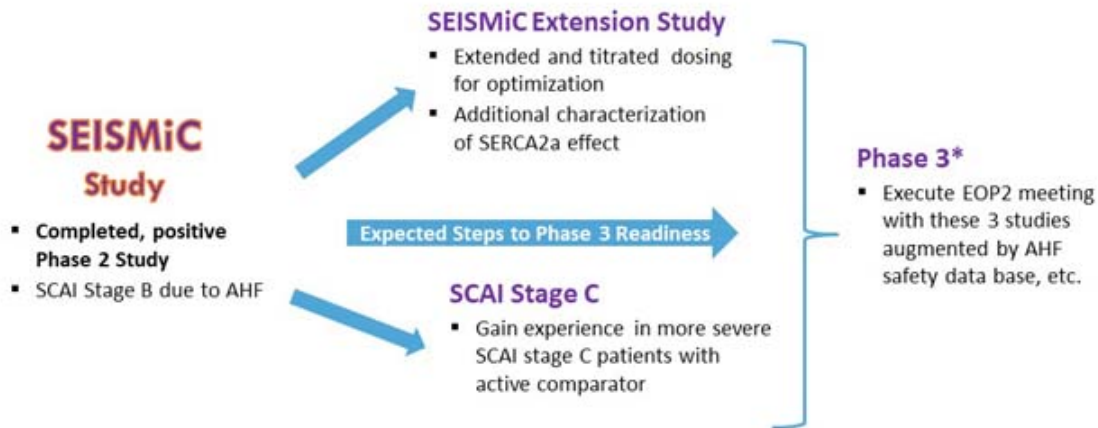
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## SEISMic Study Results Summary

- ✓ Systolic blood pressure significantly increased within the first 6 hours of initiating the infusion ( $p=0.017$ ) and the increase was maintained throughout the 24-hour infusion ( $p=0.025$ )
  - SBP increases were rapid within the first hour and sustained through the 96-hour post-infusion measure
- ✓ Key secondary endpoints of systolic and diastolic cardiac function and performance were improved
- ✓ Renal function was maintained
- ✓ SEISMic provided valuable information for optimizing our dose moving forward
- ✓ These data substantiate and advance the rationale for istaroxime as a potential treatment for cardiogenic shock and align with the existing data from the program in AHF

# Cardiogenic Shock Development Strategy

Focus on thoroughness, speed and relatively low cost of trials



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**SEISMiC Extension Study Desired Results:**  
*Good Efficacy and Safety Data Support an Optimized Dose for Phase 3 Planning*

- ✓ SBP significantly increased versus control with a profile of rapid correction that is sustained through the 96-hour post-infusion measure
- ✓ Secondary endpoints of cardiac function and performance improved
- ✓ Heart rate not significantly increased during the infusion
- ✓ Renal function maintained
- ✓ Balanced safety profile (no clinically significant increase in arrhythmias, etc.)



## Cardiogenic Shock Represents a Significant Opportunity for Istaroxime and Windtree

- ✓ Significant opportunity for Istaroxime to make a difference:
  - ~20-30% mortality in classic shock and high morbidity
  - Very long average length of hospital stay (~ 19.5 days<sup>1</sup>) means high cost of hospital care (estimated >\$175k<sup>2</sup>) and creates opportunity for pharmacoeconomic benefits
- ✓ Currently available pharmacologic treatments have undesirable side effects and can result in poor outcomes
- ✓ Lack of competition in development or active competition in the market
- ✓ Attractive \$1.25B valuation of market potential versus time and cost of development supports potential deals



<sup>1</sup> US Hospital Claims Data, 2022

<sup>2</sup> Healthcare.gov, Department of Health & Human Services, estimated from average cost of hospital stay

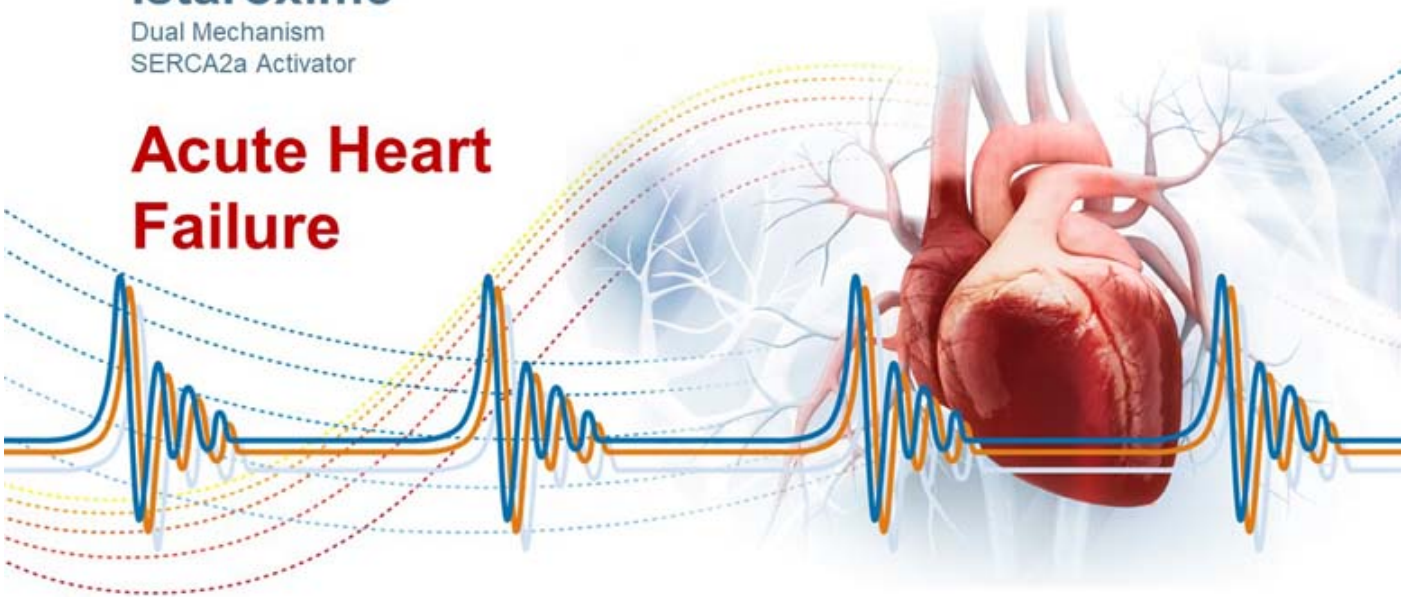
<sup>3</sup> Long et al, USC Cardiology Review, Describing and Classifying Shock: Recent Insights, Sept 2021



# Istaroxime

Dual Mechanism  
SERCA2a Activator

## Acute Heart Failure



## Heart Failure –

*A Large and Growing Market with Significant Mortality and Unmet Need*

**#1 cause of U.S. hospitalization in patients > 65 years old**

Annual Admissions  
**~1.3M** U.S.  
**~1.5M** E.U.



Patients  
**7M** U.S.,  
**25M+** worldwide



**~7%**

In-patient mortality

**30-day mortality can exceed 10%**



**>\$18B**

annual U.S. hospital costs

**Most expensive of the Medicare diagnoses**



**0**

New pharmacologic advancements in acute heart failure for decades




Lack of therapeutic advances led the FDA to issue new Heart Failure Guidance in July 2019 for greater development flexibility in acceptable endpoints, specifically acknowledging mortality is not required

# Istaroxime AHF Phase 2a & 2b Studies

## Phase 2a

 n=120  
ADHF Patients

 Dosing=  
0.5, 1.0, 1.5 µg/kg/min

 6 hour  
Infusion

- Primary: PCWP significantly improved
- Stroke Vol & SBP – significant increase
- Heart Rate (HR) - lowered

## Phase 2b

n=120  
ADHF Patients  
(dyspnea plus need  
for IV furosemide ≥ 40mg)

Dosing=  
0.5, 1.0 µg/kg/min

24 hour  
Infusion

### Results

**Positive Phase 2 trial results demonstrated improved cardiac function without unwanted side effects of existing rescue therapies**

# Istaroxime – Acute Heart Failure

## Development Strategy

### Regional Strategy: Licensing Partner in Asia / Pac Intends to Start Phase 3 AHF Study

#### Global Phase 3 AHF Program Strategy



Augment our data from the positive phase 2a and phase 2b AHF studies with the efficacy, safety and dosing and characterization learnings from the extension and other studies in the severe AHF patients experiencing cardiogenic shock. If positive and adequate, move istaroxime into phase 3 for AHF.



Our strategy is to focus on treating heart failure patients with low blood pressure, who also tend to be diuretic resistant, as a patient population that we believe could particularly benefit from the unique profile and potential ability of istaroxime to increase cardiac function and increase blood pressure while maintaining or improving renal function.

*Currently seeking partnership to finance global program*

# Next Generation, Oral SERCA2a Activators Platform has Potential for *both Major Types* of HF in Acute *and* Chronic Therapy

**Today:**

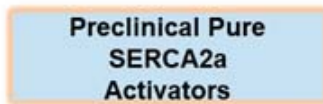


- Dual Mechanism (SERCA2a & Na+/K+)
- IV only, Acute Heart Failure with Reduced Ejection Fraction (HFrEF) with normal / low blood pressure

**Future:**



&



- Same mechanism as Istaroxime with potential for oral / chronic use
- Granted composition of matter IP (U.S. and EU)
- Strategy: Fast follow-on to Istaroxime in AHF; then add on hospital discharge / chronic use development
- Innovative pure SERCA2a activator (without the Na+/K+ mechanism) with newly granted composition of matter IP (EU)
- Develop for Heart Failure including Preserved Ejection Fraction (HFpEF) for chronic and acute use

**Development Strategy:**

AHF Hospital, i.v.
HFrEF

AHF Hospital, i.v.	CHF Home, oral
HFrEF	

AHF Hospital, i.v.	CHF Home, oral
HFrEF	HFpEF



# Atypical Protein Kinase C iota (aPKCi) Inhibitors

## Potential Multiple Tumor Types

*Innovative topical and oral formulations*

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## Oncology Assets: aPKCi Topical (VAR-101) and Oral (VAR-102)

### *Newly acquired, first in class atypical protein kinase C iota inhibitors (aPKCi)*

#### ✓ **Novel, emerging oncogenic target**

- Protein kinase inhibitors are a class of anti-cancer therapeutics that have made a significant impact on the treatment of cancers.
- aPKCi is a promising atypical PKC iota isozyme with defined oncogenic role in multiple signaling pathways, and in the initiation and development of multiple tumor types
- aPKCi inhibitors represent a next generation of Hedgehog (Hh) pathway inhibitors targeting the most downstream component of the pathway and are fundamental components of the Hh resistance pathway

#### ✓ **Advanced preclinical studies with early promising signals**

- The active pharmaceutical ingredient has demonstrated dose responsive characteristics in murine and human basal cell carcinoma (BCC) cell lines, as well as non-small cell lung cancer (NSCLC) mice models
- Initial ADME studies (in rat dog, primate), kinase selectivity/potency, and protein binding studies have been done as have skin permeation studies of the active pharmaceutical ingredient

#### ✓ **Multiple clinical development opportunities-** Specific, potent approach with a topical formulation for cutaneous cancers (i.e. BCC, Gorlin Syndrome, CTCL, etc.) and oral formulation to focus on broader tumor types as monotherapy or in combination

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## Oncology Assets: aPKCi inhibitor Topical and Oral

### Next Steps

- ✓ Progress the IND-enabling activities including pre-IND meeting, toxicology (including topical)
- ✓ Create a comprehensive clinical and CMC development plan that leverages the assets' unique characteristics and mechanisms of action on the highest unmet disease needs

- Decide on **leading with rare disease** option such as Gorlin Syndrome **vs. more prevalent tumor type** such as Basal Cell Carcinoma
- Ensure differentiation and **maximizing benefit vs. risk / toxicity as a key evaluation element**. For example, focus on **topical formulation** as a potential way to optimize benefit, minimize toxicity, treat earlier and improve patient compliance compared to systemic treatment options
- Fully identify and **rigorously assess various opportunities across tumor types** with the Scientific Advisory Committee where the mechanism is important, there are preclinical data signals and clinically feasible pathway to registration and commercialization.



# Matching Preclinical Data, Attributes, Scientific Rationale and Market Opportunities for Optimal Development Path

Early Observations of the Key Attributes of Active Pharmaceutical Agent	
<b>Rational Design</b>	✓ Molecules designed through med chem, SAR, and in vitro and in vivo testing
<b>Selectivity</b>	✓ High degree of kinome selectivity
<b>Biomarker Activity</b>	✓ There is potential for a biomarker-driven approach targeting aPKCi/Gli-1/K-RAS positive tumors
<b>Potential for Less Resistance</b>	✓ aPKCi is a potential GLI regulator; upregulation of GLI occurs in resistance
<b>PK</b>	✓ Preliminary PK and ADME characterization has been done in rodent, dog and primates. Tolerability has been good in these studies
<b>Therapeutic Index</b>	✓ Dose dependent potential and potential biomarker activity observed across <i>in vitro</i> murine and human BCC cells lines and in explanted human BCC cells from Moh's sections

## Cutaneous Malignancies (lead)

- Assessment may include Basal Cell Carcinoma (BCC), Gorlin Syndrome, Cutaneous T-Cell Lymphoma (CTCL), etc.

## Oral, Systemic Treatment Tumors

- Assessment may include Non-Small Cell Lung (NSCL), Pancreatic, Colorectal, Ovarian, Acute Myeloid Leukemia (AML)



# Financial and Deal Summary

## Cash

June 30, 2024	\$1.8M
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## Common Stock Outstanding

September 13, 2024	1,610,734
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## Driving Capital Efficiency to Program Investment

- In 2023, significantly reduced company expenses and cash burn (28%) via out-licensing KL4 platform, focusing resources on istaroxime lead priority program

## Completed Deals- \$217MM in Potential Milestones Plus Royalties

- Istaroxime, Dual-Mechanism SERCA2a Activators, Rostafuroxin**
  - Exclusive Greater China regional license to Lee's Pharm
  - Potential proceeds: Up to **\$138.1 million** in potential milestone payments, low double-digit % royalties; Partner pays for development, regulatory and commercial costs
- AEROSURF / KL4 Platform –**
  - Exclusive global license to Lee's Pharm and Zhaoke
  - Potential proceeds: Up to **\$78.9 million** in potential milestone payments, low double-digit % royalties; Partner pays for all costs

## Potential Next Deal

- Global (ex-Greater China) license for Istaroxime, SERCA2a Activators**

