



NASDAQ: THTX

TSX: **TH** 



## **Forward-Looking Information**

The following presentation contains statements that are considered forward-looking information ("FLI") within the meaning of securities regulation.

The FLI in this presentation relates to future events or our future performance. The FLI are based on a number of assumptions and are associated with a number of risks, uncertainties and other unknown factors that may cause our actual results, levels of activity, performance or achievements to be materially different from those implied by the FLI.

Such FLI reflects our current views with respect to future events and is given as of October 13, 2022. We undertake no obligation and do not intend to update or revise the FLI contained in this presentation, except as required by law.

All figures in this document are in United States Dollars (USD) unless otherwise stated.

Certain assumptions made in preparing the FLI include, but are not limited to, the following:

- (1) sales of EGRIFTA SV® and Trogarzo® will continue to grow;
- (2) the known safety and efficacy profile of EGRIFTA SV® and Trogarzo® will not change as a result of their long-term use:
- (3) we will meet all of the timelines set forth in this presentation and related thereto;
- (4) we will meet all of the terms and conditions of the credit facility agreement to be able to draw down on each loan facility tranche available thereunder;
- (5) no biosimilar versions of EGRIFTA SV® will be approved by the FDA;
- (6); we will be able to continue the recruitment of patients to conduct the Phase 1 clinical trial in oncology;
- (7) we will obtain positive results from our Phase 1 clinical trial evaluating TH1902 for the treatment of various cancers;
- (8) we will be able to secure additional resources to initiate our Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH, including finding a partner with resources and capabilities;
- (9) our 2022 planned business strategies will not change.

The FLI in our presentations may not materialize; accordingly, investors should not place undue reliance on it. We refer you to the "Forward-Looking Information" section of our Management's Discussion and Analysis dated October 12, 2022 and to the "Risk Factors" section of our Annual Information Form dated February 23, 2022. These documents are available at www.sedar.com, and on Edgar at www.sec.gov for a description of the risks related to the conduct of our business.

Notes: EGRIFTA SV are registered trademarks of Theratechnologies Inc.; Trogarzo is a registered trademark of TaiMed Biologics, Inc. under license to Theratechnologies Inc.; SORT1+ Technology is a trademark of Theratechnologies Inc.



## Theratechnologies (NASDAQ:THTX; TSX:TH)

### **Corporate Profile**

- Founded in 1993 in Montreal, Canada, Theratechnologies is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs
- **Incorporated in Quebec,** with primary offices in Montreal, subsidiary locations in Dublin, Ireland, and the United States
- The company has approximately ~165 employees\* across Canada, the United States and Europe
- Dual listed on the Nasdaq Stock Exchange under ticker (NASDAQ:THTX) since 2019 and the Toronto Stock Exchange under ticker (TSX:TH) since 1993

### **Stock Information**

Stock Price (as of 12/10/2022)	\$2.08
--------------------------------	--------

Shares Outstanding (as of 12/10/2022)

~95M

Market Cap (as of 12/10/2022) ~\$198.8

Cash, cash equivalents (as of 08/31/22) ~\$36.5M

• Convertible notes outstanding \$27.5M (5.75% coupon; due 6/30/23; \$14.85 conversion price)

<sup>\*</sup>Full-time employees and dedicated third parties

## **Promising R&D Pipeline and Commercial Portfolio**

### **Promising R&D Pipeline**

Novel therapies in Oncology, NASH, and HIV

- Phase 1 trial initiated in sortilin-expressing cancers
- NASH in non-HIV and HIV populations
- Next-generation administration method for Trogarzo<sup>®</sup> and new formulation of tesamorelin

### **Two Commercially Approved Therapies**

Improving standard of care for people living with HIV

- Trogarzo<sup>®</sup> for multidrug resistant (MDR) HIV-1 in adults
- EGRIFTA SV® for HIV-associated lipodystrophy



Innovative therapies for patients with high unmet need



Commercial initiatives that drive revenues and support patients



Targeted investments in R&D that will fuel future growth

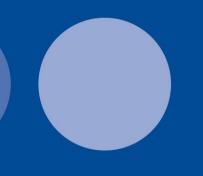


Continued financial performance to reinvest in business

## Oncology, NASH and HIV R&D Pipeline

	Product			Phase of Do	Milestones		
			Pre-clinical	Phase 1	Phase 2	Phase 3	Milestones
	Oncology	<b>TH1902 (PDC)</b> SORT1+ Technology™					Dose escalation completed Basket trial underway
	Ouco	<b>TH1904 (PDC)</b> SORT1+ Technology™					Assessing development alternatives
	NASH	<b>Tesamorelin</b> F8 Formulation				•	Ongoing discussions with the FDA; Seeking potential partnership to launch Phase 2b/3,
		Trogarzo <sup>®</sup> IV Push Multi-drug resistant HIV-1					FDA approved on October 3, 2022.
	₽	Trogarzo <sup>®</sup> Intramuscular Multi-drug resistant HIV-1					Intramuscular study is underway. Patient enrollment is complete.
		Tesamorelin F8 HIV-associated lipodystrophy					In-house bioequivalence study completed. Secured third-party manufacturer of BWFI.

- Clinical study for Trogarzo IV Push was conducted by TaiMed Biologics, Inc.
- Clinical study for Trogarzo Intramuscular (IM) is being conducted by Theratechnologies





## Oncology: SORT1+ Technology™

# SORT1+ Technology™: First-in-Class Peptide Drug Conjugate (PDC) Platform Targeting Sortilin (SORT1) Receptors for Cancer



**Targets SORT1**, a novel receptor that is highly expressed in many types of cancer and is associated with poor prognosis and decreased survival.



Rapid internalization leading to high cytotoxic concentration inside the cancer cells for improved efficacy, safety, and durable response.



Overcomes two key resistance mechanisms: Bypasses the MDR1 efflux pump and inhibits vasculogenic mimicry (VM) formation.



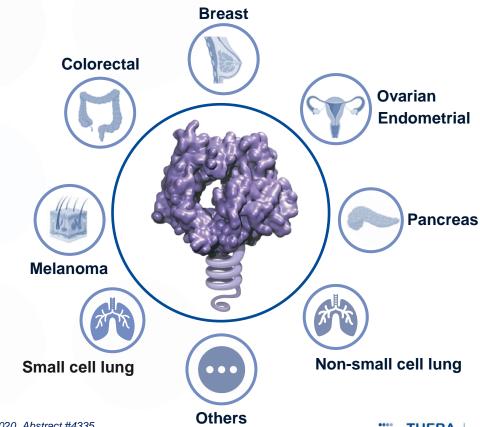
**TH1902** is the lead **PDC** and is currently in Phase 1 clinical development. FDA has granted **fast track designation** for TH1902 to be developed as a **single agent** for treatment of patients with **SORT1+ recurrent advanced solid tumors** that are **refractory to standard therapy.** 

### The SORT1 Receptor Is an Attractive Novel Target for Cancer Therapy

### SORT1

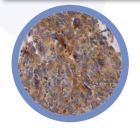
## Key receptor used by cancer cells that:

- Is highly expressed in many cancer cells compared to normal healthy cells
- Normal function is to transport proteins across cell membrane
- Leads to aggressive behavior (cancer progression and invasion), metastases, and poor survival
- By targeting SORT1, can bypass MDR1 efflux pump and inhibit vasculogenic mimicry (VM) formation two key resistance mechanisms

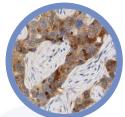


### **SORT1** is Highly Expressed in Cancer Cells Compared to Normal Cells

**Attractive target:** As cancer aggressiveness increases, SORT1 expression increases<sup>1</sup>



Metastatic lymph node from breast carcinoma

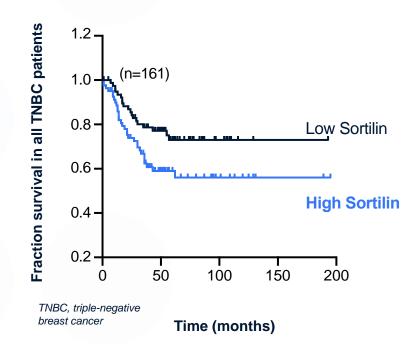


Infiltrating ductal carcinoma of breast



Normal adjacent breast tissue

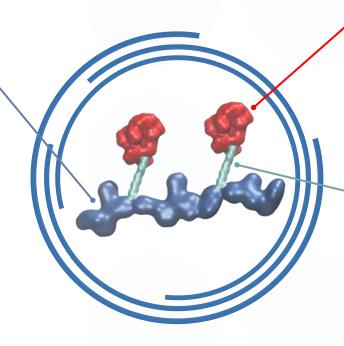
**Affects outcomes:** High SORT1 gene expression is associated with decreased survival<sup>2</sup>



## TH1902: Lead PDC Using Theratechnologies' Exclusive SORT1+ Technology™

### Peptide<sup>1,2</sup>

- Targets SORT1 receptor, expressed in multiple cancers
- Can be conjugated to variety of anti-cancer agents with consistent number of payload molecules
- Provides rapid internalization and delivery of payload inside the cell, limiting degradation in the circulation and off target toxicity



### Cytotoxic payload<sup>2-4</sup>

- For TH1902 is docetaxel (2:1 ratio), a well-established agent for a variety of cancers with known safety profile
- Increases therapeutic window of docetaxel
  - Use smaller dose to get greater efficacy and less toxicity (neutropenia)

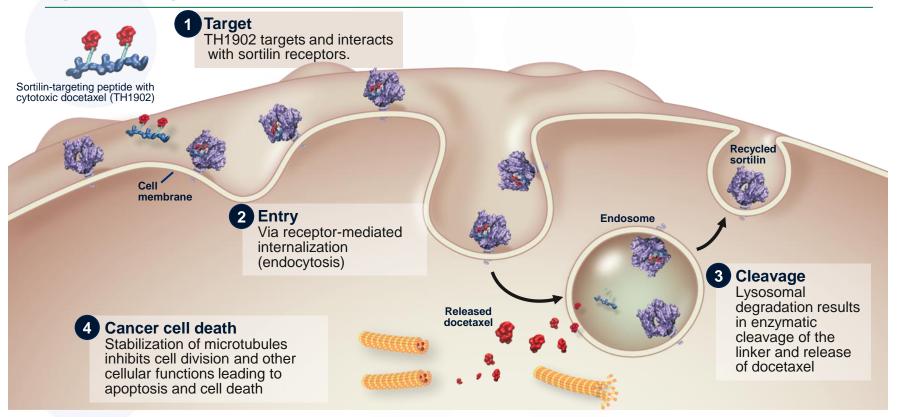
#### Cleavable linker<sup>2,3</sup>

- Links the SORT1-targeting peptide to the cytotoxic docetaxel
- Increased stability in plasma with improved distribution into targeted cancer cells
- Enables rapid release of docetaxel inside the cancer cell

#### Notes:

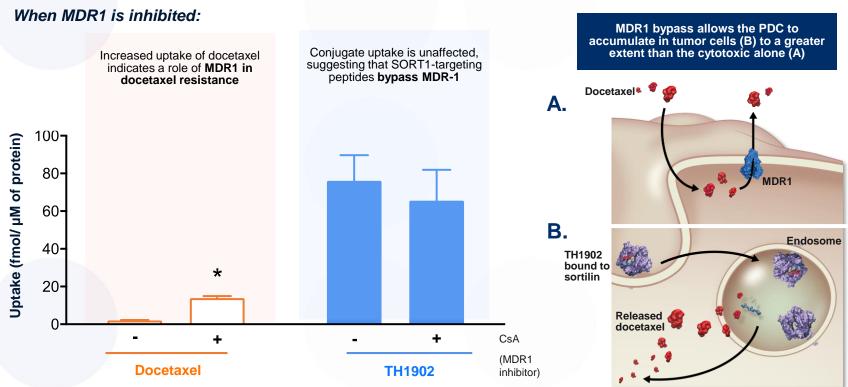
- 1) Annabi B et al. AACR 2020, Abstract #4386.
- 2) Hoppenz P et al. Front Chem. 2020; 8: 571.
- 3) Currie JC et al. AACR 2020, Abstract #4472.
- 4) Zhang E et al. Expert Opin Drug Deliv. 2019 Mar;16(3):301-31.

# TH1902: Delivering Cancer-Killing Docetaxel Directly Into Cancer Cells



# SORT1+ Technology™: Potentially Increased Efficacy in Refractory/Resistant Tumors (bypass of MDR1 pump)

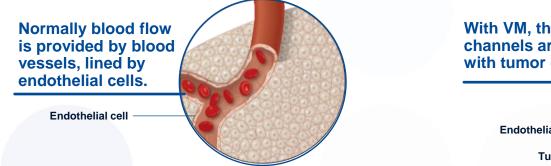
MDR1 efflux pump is often used by cancer cells to resist treatment

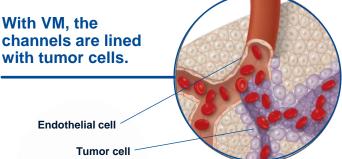


Notes: TH1902, docetaxel peptide conjugate; CsA, cyclosporin A Source: Theratechnologies, Data on File.

# Theratechnologies' PDCs Inhibit Vasculogenic Mimicry – A Key Survival Mechanism for Some Tumors

- Cancer cells need blood, nutrients and oxygen to sustain growth and cell division
- This is achieved by either forming new blood vessels (angiogenesis) or by forming new channels lined with cancer cells that extend from the existing vasculature - a process called vasculogenic mimicry (VM)
- VM is SORT1-dependent and is associated with cancer resistance and aggressive disease

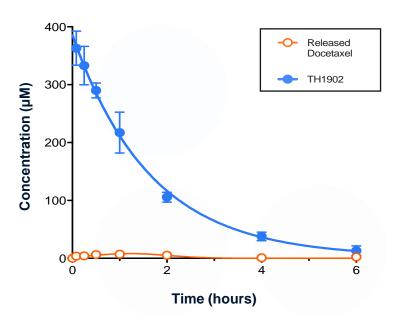




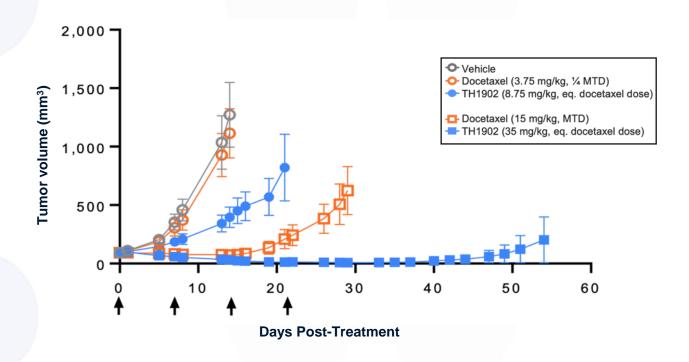
Preliminary pre-clinical data using SORT1+ Technology<sup>™</sup> suggests it can potentially inhibit the formation of VM structures associated with cancer resistance mechanisms

# TH1902 Demonstrates Improved Tolerability in Pre-clinical Models

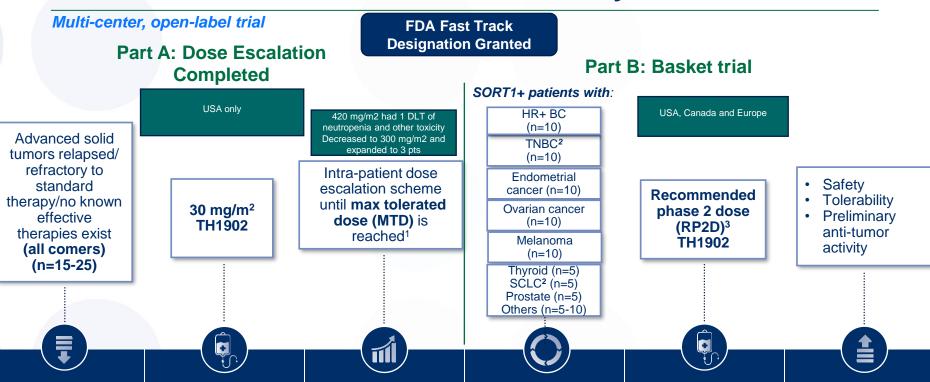
### Minimal docetaxel released in blood further limiting off-target toxicity



### TH1902: Pre-clinical Data in Endometrial Cancer



## Phase 1/Part B Trial of TH1902 Underway



#### Notes

<sup>&</sup>lt;sup>3</sup>RP2D is defined as one dose level below the MTD and is the recommended phase 2 dose to further assess TH1902 for safety/tolerability and preliminary anti-tumor activity



¹ If ≥2 patients in a dose cohort experience an emergent DLT by Day 21 of the first treatment cycle, dose escalation will stop, and the prior dose level will be declared as the MTD. MTD is defined as highest dose level at which ≤1 of 6 patients in a cohort develop an emergent dose-limiting toxicity;

<sup>&</sup>lt;sup>2</sup>As indicated; TNBC, triple-negative breast cancer; SCLC, Small Cell Lung Cancer

## TH1902 Phase 1/Part B Basket Study Initiated

- Phase 1/Part B dose established at 300 mg/m<sup>2</sup>, or 1.5 times the therapeutic dose of docetaxel alone.
- No dose limiting toxicities were observed following the completion of the first cycle in the last 6 patients treated at 300 mg/m<sup>2</sup>.
- Expansion study is evaluating TH1902 as a monotherapy in solid tumors with high expression of Sortilin receptor, including Hormone Receptor-positive (HR+) Breast Cancer, Triple Negative Breast Cancer, Ovarian Cancer, Endometrial Cancer, and Melanoma with approximately 10 patients per tumor type.
- One arm includes a mix of tumor types including Thyroid, Small Cell Lung, Prostate and
  potential other high Sortilin expressing cancers with approximately 15 patients in total. In
  addition to evaluating the anti-tumor activity of TH1902, the study continues to evaluate the
  safety and pharmacokinetics of TH1902.

## **Safety in Dose Escalation Portion of TH1902**



A total of 13 heavily pre-treated patients were enrolled in the cohorts of 300 and 420 mg/m<sup>2</sup> in the dose escalation portion of the study.

Cohort Dose	Number of Patients	Dose Limiting Toxicity	Noted Toxicity		
420 mg/m <sup>2</sup>	6	Eye toxicity, neutropenia & leukopenia in one patient	Eye toxicity in 3 patients (delayed treatment)  Neuropathy in 2 patients		
300 mg/m <sup>2</sup>	7	None	Grade 2 eye toxicity in 2 patients Infusion related reaction in 2 patients		

Notably, the levels of free docetaxel are low, at only 11% of those observed at docetaxel treatment dosage of 75 mg/m<sup>2</sup>.

## **Efficacy in Dose Escalation Portion of TH1902**

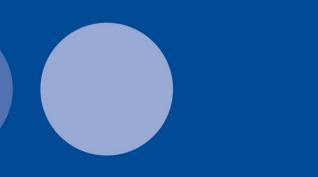


# 18 heavily pretreated patients with average of 8 prior cancer treatments

Patient	Cycles	Response in Target Lesions	Other Response	Comments
Prostate Cancer	3	Partial Response (- 53%)		Discontinued due to rising PSA (delayed visits and treatment due to COVID)
Prostate Cancer	6	Stabilized Disease (- 3%)	PSA response	
Endometrial Cancer	11	Stabilized Disease (- 8 %)		Personal decision to leave cancer treatment in general.

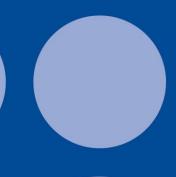
## **SORT1+ Technology™: Future Opportunities**

- Explore different dosing schedules (weekly, intermittent vs continual) in order to increase the therapeutic window in terms of efficacy and safety.
- Gain better understanding of the exact MOA, impact on surrounding tissue/tumor microenvironment (TME) and fate of conjugate once it enters the cell and is degraded.
- Explore conjugation with a variety of anti-cancer agents (cytotoxics, TKIs etc) and potential synergistic new partnerships (proprietary molecules).
- Explore **rational combinations** of SORT1+ Technology™ with other treatments, especially immunotherapies.
- Explore the need for a **companion diagnostic** for SORT1 to determine correlation of sortilin expression with response, improve patient selection, track treatment efficacy and identify early metastases.





## General and HIV-Associated NASH: Tesamorelin



# Tesamorelin: A Growth Hormone Releasing Hormone (GHRH) Targeting the Underlying Mechanisms of NASH

### **1** Direct effect:

Tesamorelin stimulates endogenous production of GH

- √ Reduces visceral fat
- ✓ Decreases lipogenesis
- ✓ Decreases triglyceride accumulation
- ✓ Decreases oxidative stress and inflammation
- ✓ Improves mitochondrial function



### **Decreases fat toxicity**

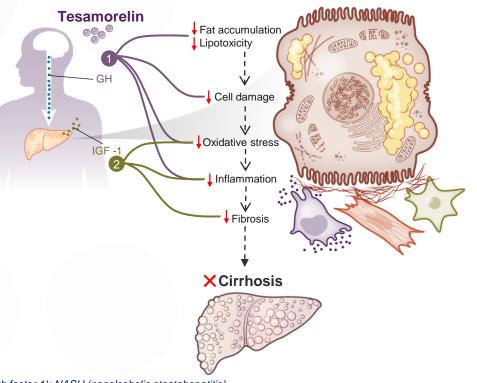
2 Indirect effect:

GH stimulates endogenous production of IGF-1 in the liver

- ✓ Decreases insulin resistance
- ✓ Decreases oxidative stress and inflammation
- ✓ Deactivates hepatic stellate cells (liver cells that contribute to fibrosis)



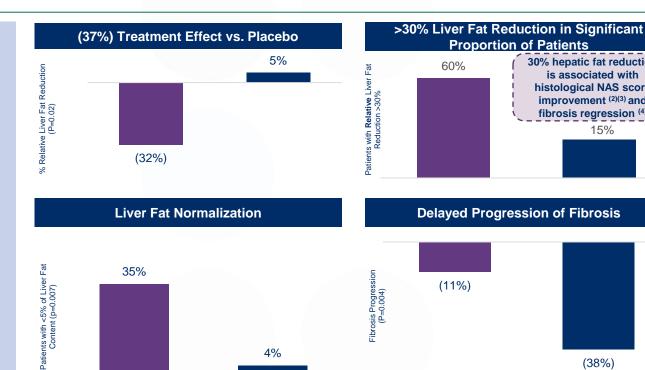
Decreases hepatocyte injury and fibrosis



### Effects of Tesamorelin in HIV NAFLD/NASH Patients (1)

### **Baseline Characteristics**

- 61 men and women with HIV infection
- Hepatic fat levels of 13.8%
- 43% of patients had fibrosis
- 33% of patients had NASH (score 2.7)
- Study discontinuation: 14 patients
- Without biopsies
  - o 3 patients at baseline
  - 18 patients at year 1



4%

esamorelin

Placebo





(4) Tamaki et al. Gut. 2021.

30% hepatic fat reduction

is associated with

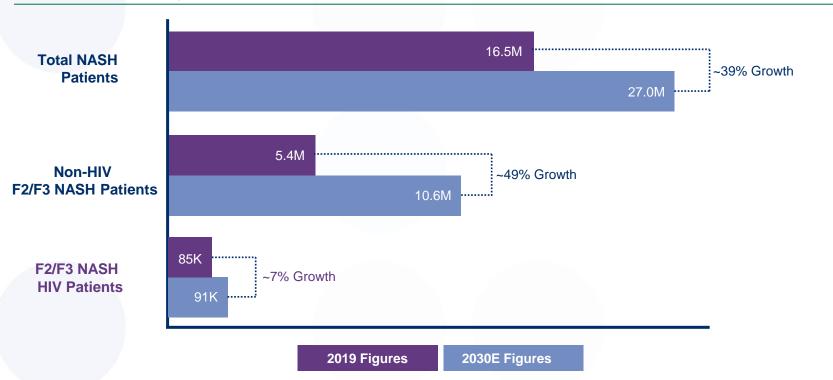
histological NAS score

improvement (2)(3) and fibrosis regression (4)

15%

(38%)

## U.S. Market Represents a Significant and Growing **Opportunity in NASH**

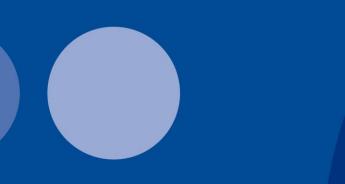


## **Update on Tesamorelin Development Pathway in NASH**

- Unique Proposition: Phase 2b/3 seamless study design submitted to FDA. Molecule with a 10+ year known safety profile.
- This design would allow for the first 350 patients' data to be analyzed by a data monitoring committee to inform a go/no-go decision to complete the study with 1094 patients.
  - Approach will generate end-point data on a subset of patients thereby de-risking the program.
  - Actively pursuing discussions with companies that have interest, capabilities and resources.
  - Trial to be conducted with a new F8 formulation that allows weekly reconstitution.
  - Multi-dose pen injector is being evaluated for added convenience and competitive value.

#### IP Status

- F8 U.S. formulation patent expiring in 2033.
- Two U.S. patents covering the use of tesamorelin to NAFLD and NASH expiring in 2040.





## **HIV Therapies:**

Trogarzo® (ibalizumab-uiyk)/
EGRIFTA SV® (tesamorelin for injection)

### **Commercial HIV Portfolio**

	Des des d	Phase of Development					Milestenes	
	Product	Pre-clinical	Phase 1	Phase 2	Phase 3	Approved	Marketed	Milestones
≥H	Trogarzo* (ibalizumab-uiyk) Injection 200 mg/133 mL (150 mg/mL)							Increase sales in the United States. Launch IV Push method of administration.
I	EGRIFTA SV' tesanorelin für injection							Enhanced patient education and prescriber engagement.

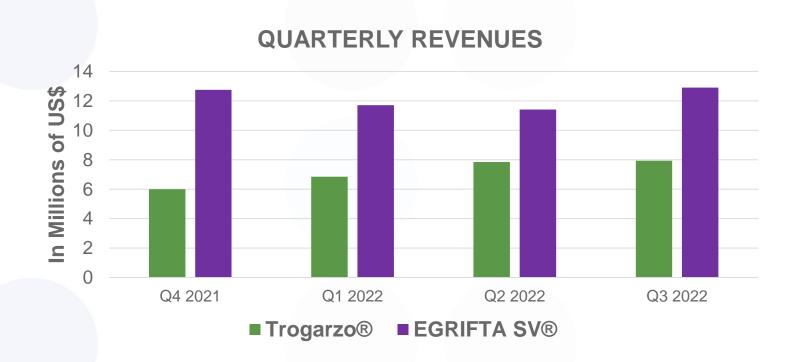
### **HIV Franchise – Initiatives Launched**

- ✓ Enhance communications of clinical / scientific evidence to close the education gap with providers
- ✓ Develop patient activities to increase understanding of disease progression and benefits of *EGRIFTA SV*®
- ✓ Utilize digital strategies to increase brand awareness among physicians and KOLs
- ✓ We have launched an internal field force with superior capabilities

## Next-Generation Administration and Delivery

- ✓ Life Cycle Management: Multi-dose pen injector in development for tesamorelin F8 formulation; Trogarzo<sup>®</sup> IM study patient enrollment completed
- ✓ Continued Commitment: Providing best-in-class treatments for people living with HIV; HIV patient cohort to be included in Phase 3 NASH trial
- ✓ Open to new business development opportunities to leverage our new capabilities

## **Strong Revenues From HIV Franchise**



Latest twelve month revenues - \$77.4 million

## Trogarzo® (ibalizumab-uiyk) injection

- Ibalizumab a monoclonal antibody targeting the CD4 receptor
- Indicated for MDR HIV-1 in adults
- Helps people living with HIV to attain an undetectable viral load
  - Potency: novel mechanism of action that is fully active with no expected cross-resistance
  - o *Durability*: powerful and durable virologic response
  - Long Activity: the first and only long-acting ARV
  - Simplicity: no drug-drug interactions with ibalizumab, wellestablished safety profile
- Regulatory exclusivity in the U.S. until March 2030
- Intramuscular method of administration study underway
  - Last patient visit is scheduled for November 2022

#### Notes:

- Most common drug-related adverse reactions include diarrhea, dizziness, nausea and rash
- Very good antiviral activity with Ibalizumab, reference to internal investigators brochure
- Clinical study for Trogarzo IV Push was conducted by TaiMed Biologics, Inc.
- Clinical study for Trogarzo Intramuscular (IM) will be conducted by Theratechnologies
- For more information visit www.trogarzo.com

### **Key Highlights**

- ✓ First HIV treatment approved with a new mechanism of action in more than 10 years
- ✓ Infused every two weeks, the first and only anti-retroviral therapy (ART) that does not require daily dosing
- ✓ No drug-drug interactions with other ARTs

## EGRIFTA SV® (tesamorelin for injection)

### **Key Highlights**

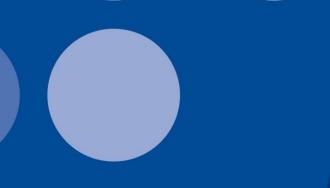
- ✓ Single vial with small volume injection at room temperature
- ✓ Unique mechanism of action that regulates growth hormone (GH) secretion.
- Tesamorelin's ability to increase endogenous GH secretion is the foundation for development in NASH
- ✓ **Only approved treatment available** for adults with HIV and lipodystrophy that reduces excess visceral abdominal fat.
- **Tesamorelin** a growth hormone-releasing hormone (GHRH) that stimulates the pituitary gland to release endogenous GH in a pulsatile way
  - o **Specificity**: unique mechanism of action that regulates GH secretion
  - Maintained Efficacy: results shown at week 26 and maintained at week 52 with 27% decrease in visceral abdominal fat
  - Simplicity: a single vial with a small volume of injection storable at room temperature
  - Medical Benefit: left untreated, excess visceral abdominal fat is linked to potential severe health consequences that could lead to an increased risk in mortality
- Well-established safety profile as evidenced by 10+ years of commercial availability with a high degree of tolerability



#### Notes:

Most commonly reported adverse reactions (>5%): Arthralgia, injection site erythema, injection site pruritus, pain in extremity, peripheral edema, and myalgia







## **Business Review**

## Financial Strength and Stability as at August 31, 2022



### NON-DILUTIVE NEW TERM LOAN WITH MARATHON ASSET MANAGEMENT

- Senior secured term loan of up to \$100 million across multiple tranches;
- \$40 million received on July 27, 2022 (Tranche 1);
- \$20 million to be made available through June 2023 (Tranche 2);
- \$15 million to be made available through March 2024 (Tranche 3);
- An additional \$25 million will be available until December 2024 (Tranche 4);
- The facility will have an initial term of five years (six years if Tranche 3 is drawn); and,
- The Company has bought back \$30 million of principal amount of the Convertible Notes due June 2023.







## **Thank You**

https://www.theratech.com