



Nuvation Bio

Nuvation Bio's Acquisition of AnHeart Therapeutics

DRIVEN BY SCIENCE
FOCUSED ON LIFE

March 25, 2024

Forward looking statements

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Acquisition of AnHeart Therapeutics will be transformational for Nuvation Bio and potentially for patients



Creates a **global oncology company** with multiple assets in development including two new **mid-to-late-stage** programs, taletrectinib and safusidenib



Taletrectinib, which is currently **completing two pivotal studies**, is a next-generation, potentially best-in-class **ROS1 inhibitor differentiated by response rate, duration, and tolerability**



Taletrectinib, which has been **granted Breakthrough Therapy Designations¹** in the **U.S. and China**, has the potential to **transform Nuvation Bio into a commercial stage organization** by the end of **2025**



Safusidenib is a potentially best-in-class **mIDH1 inhibitor** in **Phase 2 development** for the treatment of patients with **grades 2 and 3 IDH1-mutant glioma**



All-stock transaction maintains Nuvation Bio's **robust cash balance** and potentially eliminates need to raise capital in the near term



1. Taletrectinib has been granted Breakthrough Therapy Designations from the U.S. Food and Drug Administration (FDA) and China's National Medical Products Administration (NMPA) for the treatment of advanced or metastatic ROS1-positive NSCLC.

Acquisition of AnHeart Therapeutics positions Nuvation Bio to potentially become a commercial stage company by the end of 2025

Upon regulatory approval, the combined company is positioned to commercialize a novel targeted therapy for ROS1-positive NSCLC patients in need of better treatment options

Currently granted:

Priority review of two NDAs for taletrectinib by China's NMPA¹; Breakthrough Therapy Designations from U.S. FDA and China's NMPA²

Intends to commercialize:

Taletrectinib, led by David Hung, M.D., who successfully developed and commercialized XTANDI[®], with current annual worldwide sales of ~\$6 billion³

Will receive:

Royalties from Innovent Biologics' commercial launch in China and Nippon Kayaku's commercial launch in Japan



Transaction will significantly increase potential upside, diversify risk, and position company for future growth

Details & Structure

- Nuvation Bio to acquire all share capital of AnHeart Therapeutics
- Immediately following closing, the former shareholders of AnHeart will own ~33% and the current stockholders of Nuvation Bio will own ~67% of Nuvation Bio on a fully diluted basis
- Acquisition is intended to qualify as a tax-free reorganization

Consideration

- Nuvation Bio will issue to AnHeart shareholders Class A common stock, Series A Non-Voting Convertible Preferred Stock, and warrants
- Preferred Stock converts to Class A Common Stock upon approval by Nuvation Bio's stockholders

Closing

- Transaction has been approved by the board of directors of Nuvation Bio and AnHeart
- Transaction is expected to close in the second quarter of 2024
- Closing is subject to approval by AnHeart's shareholders and other customary closing conditions
- Transaction does not require Nuvation Bio stockholder approval

Cash balance

- Nuvation Bio had \$611.2 million in cash and cash equivalents as of December 31, 2023



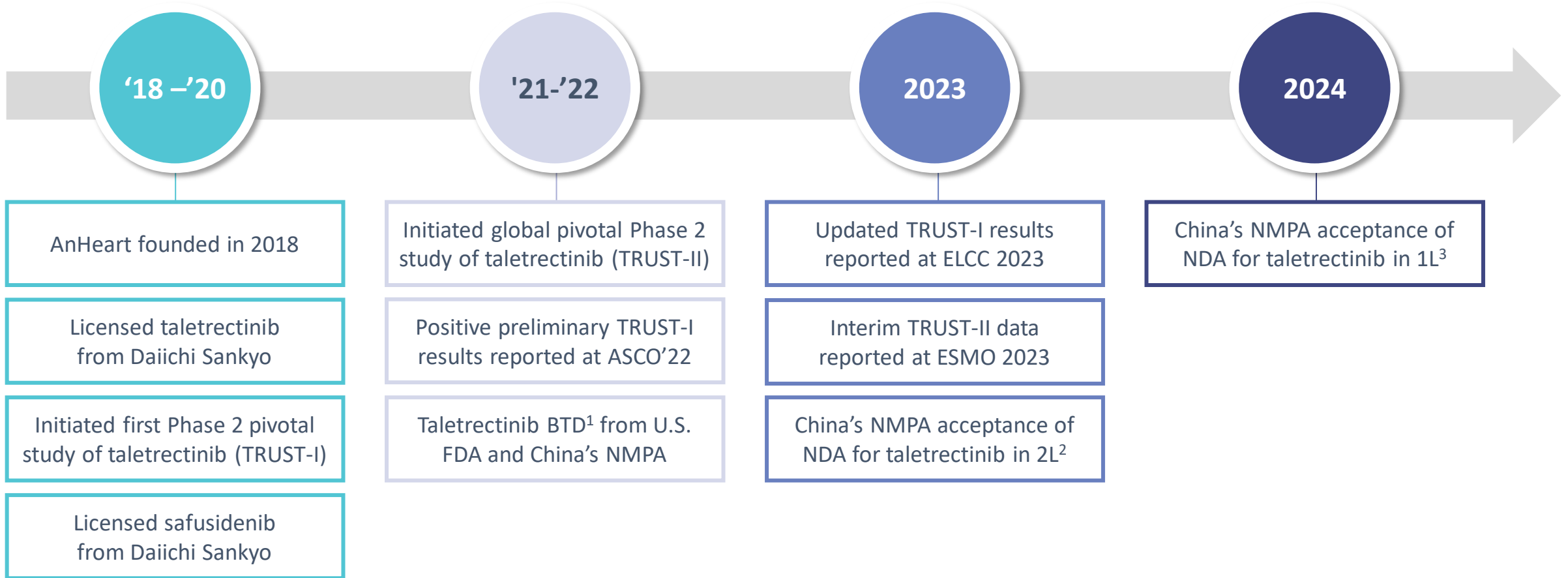
Nuvation Bio's robust cash balance can support continued development of the combined pipeline without a need to finance in the near term

Program	Potential Indication(s)	Current Stage of Development				Anticipated Milestones & Recent Updates
		Preclinical	Phase 1	Phase 2	Pivotal	
Taletrectinib ¹ (ROS1)	ROS1-positive NSCLC	Completing two Phase 2 pivotal trials				China NDAs under priority review by China's NMPA ⁵ ; Interim Phase 2 (TRUST-II) data presented at ESMO 2023
Safusidenib ² (mIDH1)	Grades 2 and 3 IDH1-mutant glioma	Phase 2 study ongoing				Phase 2 study ongoing
NUV-868 (BET)	Advanced solid tumors	Monotherapy	Phase 1 dose escalation study ongoing			Maximum tolerated dose determined
	Advanced solid tumors ³	NUV-868 + olaparib	Phase 1b dose escalation study ongoing			Phase 1b dose escalation study ongoing
	mCRPC	NUV-868 + enzalutamide	Phase 1b dose escalation study ongoing			Phase 1b dose escalation study ongoing
NUV-1511 (DDC)	Advanced solid tumors ⁴	Phase 1 dose escalation study ongoing				Phase 1 dose escalation study ongoing



BET: Bromodomain and extra-terminal motif proteins; DDC: Drug-drug conjugate; IND: Investigational New Drug. 1. Taletrectinib has been granted Breakthrough Therapy Designations from the U.S. FDA and China's NMPA for the treatment of advanced or metastatic ROS1-positive NSCLC; AnHeart licensed worldwide development and commercial rights from Daiichi Sankyo; Taletrectinib has been out-licensed in China, Japan, and Korea. 2. AnHeart owns global rights to safusidenib excluding Japan, where Daiichi Sankyo retains development and commercial rights. 3. Includes patients with ovarian, triple-negative breast, pancreatic, and metastatic castration resistant prostate cancer (mCRPC). 4. Includes patients with advanced solid tumors who previously received and progressed on or after treatment with Enhertu® and/or Trodelvy® per approved U.S. FDA labeling, human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer, mCRPC, advanced pancreatic cancer, and platinum-resistant ovarian cancer. 5. Under priority review for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC that have and have not previously been treated with ROS1 tyrosine kinase inhibitors.

AnHeart Therapeutics was founded in 2018 in conjunction with the in-license of taletrectinib



1. Taletrectinib has been granted Breakthrough Therapy Designations from the U.S. FDA and China's NMPA for the treatment of advanced or metastatic ROS1-positive NSCLC. 2. NDA under priority review for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC who have previously been treated with ROS1 tyrosine kinase inhibitors (TKIs). 3. NDA under priority review for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC who have not previously been treated with a ROS1 TKI.

Taletrectinib is a next-generation, potentially best-in-class ROS1 inhibitor differentiated by response rate, duration, and tolerability



Commercial opportunity

- Breakthrough Therapy Designations (U.S. and China)¹
- China 1L & 2L NDAs accepted and granted priority review²
- Sizeable ROS1+ NSCLC commercial opportunity



Differentiated profile

- Potentially best-in-class efficacy and safety profile
- Highly brain penetrant
- Effective against common mutations



Strong partnerships

- In-licensed from Daiichi Sankyo
- Maintain global rights except major Asian markets where commercial rights have been out-licensed³

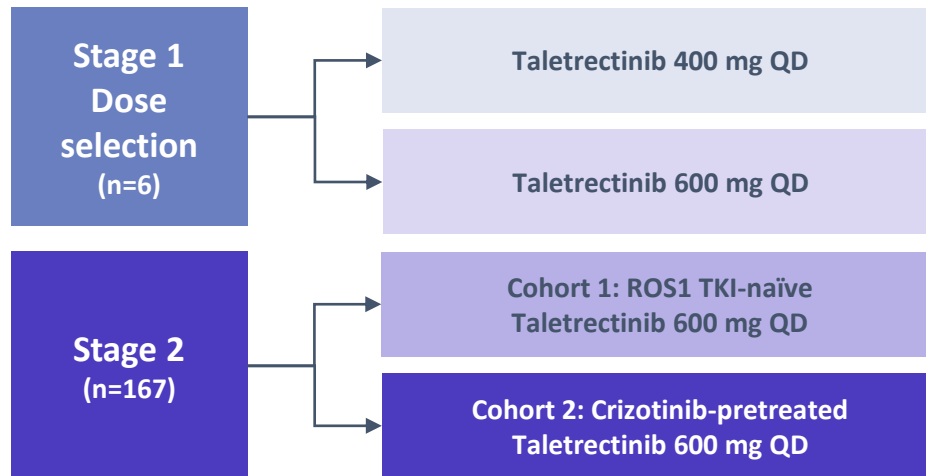


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Taletrectinib has been studied in two pivotal registrational trials that have included >300 patients in total, with results supporting BTDs³ in U.S. & China

TRUST-I

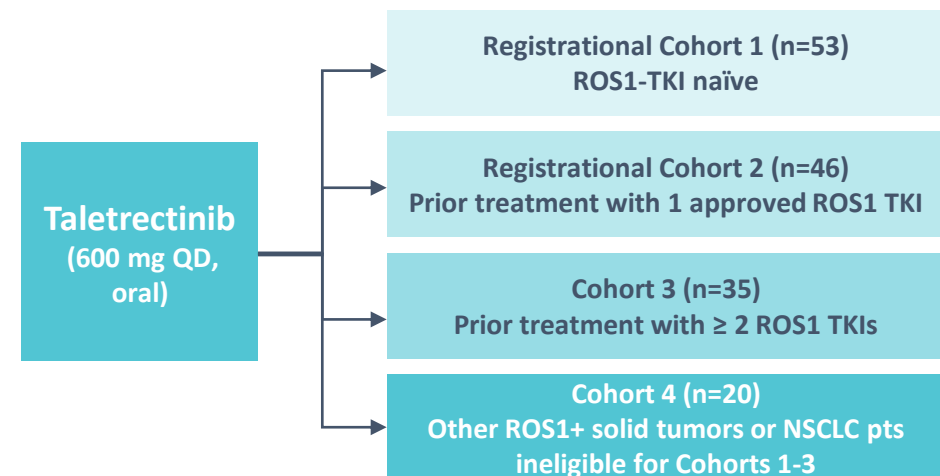
Pivotal China Phase 2¹ n=173



Updated TRUST-I data presented at ELCC in March 2023¹

TRUST-II

Pivotal Global Phase 2² n=154



Interim TRUST-II data presented at ESMO in October 2023²



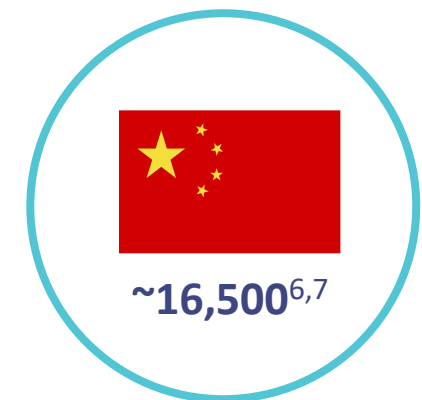
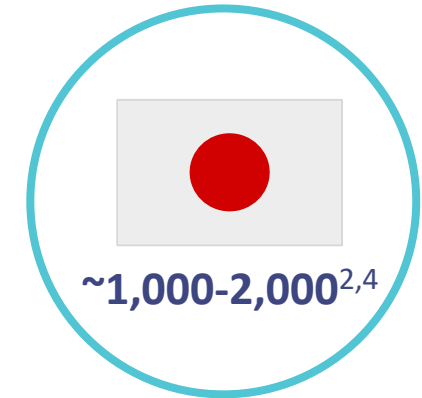
1. Li et al., ELCC 2023 presentation; 2. Perol et al., ESMO 2023 presentation. 3. Taletrectinib has been granted Breakthrough Therapy Designations (BTDs) from the U.S. FDA and China's NMPA for the treatment of advanced or metastatic ROS1-positive NSCLC.

The ROS1-positive NSCLC market represents a sizeable commercial opportunity

Key takeaways

- Non-small cell lung cancer (NSCLC) accounts for ~80-85%¹ of all lung cancers
- ROS1-positive lung cancer represents ~1-3%² of new NSCLC cases
- There are currently three therapies approved to treat patients with ROS1-positive NSCLC:
 - 1st Generation
 - Crizotinib (Pfizer, approved 2016³)
 - Entrectinib (Roche, approved 2019)
 - 2nd Generation
 - Repotrectinib (Bristol-Myers, approved 2023)

Estimated diagnosed patient population



AnHeart acquisition will also add safusidenib to Nuvation Bio's pipeline



Unmet need

- People diagnosed with glioma have no targeted treatment options



Validated target

- Positive Ph 3 data with vorasidenib¹ in glioma presented at ASCO '23²



Differentiated profile

- Encouraging early data³
- Potential in broad population
- Limited competition



Global rights

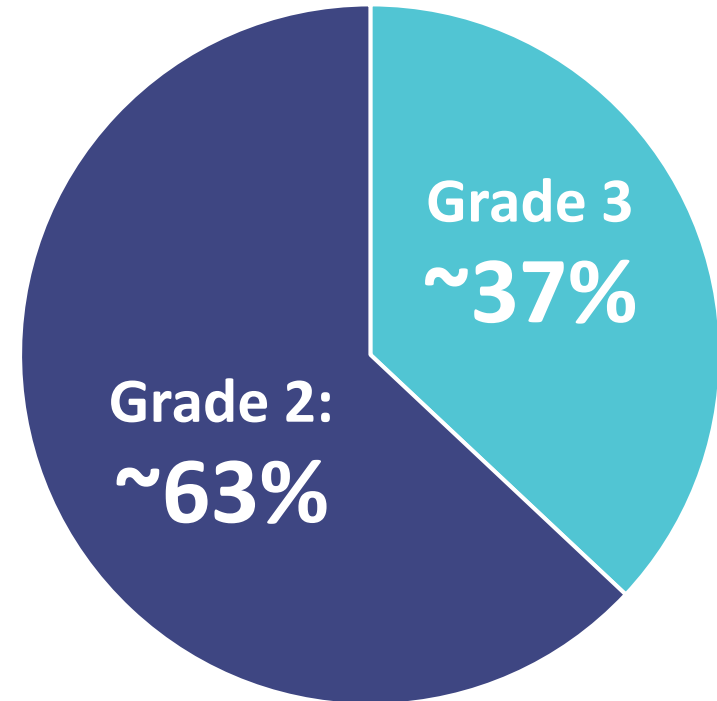
- In-licensed from Daiichi Sankyo
- Daiichi Sankyo retains rights in Japan⁴



The low grade IDH1-mutant glioma market represents a sizeable commercial opportunity

~13.3K – 18.3K

people living with low grade
IDH1-mutant glioma in the U.S.



Low grade IDH1-mutant glioma patients are in need of better treatment options



Safusidenib clinical trial data set approaches 100 patients

Sponsor: Daiichi Sankyo

J101 – Phase 1

Japan

Grades 2-4 IDH1-mutant glioma

n=47

J201 – Phase 2

Japan

Grade 2 IDH1-mutant glioma

n=27

Sponsor: AnHeart Therapeutics

G203 – Phase 2

Global

Grades 2-3 IDH1-mutant glioma

Part 1: Dose evaluation (n=25)

Part 2: Design under discussion



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