

acasti

January 2024

Company Overview



NASDAQ: ACST

Forward Looking Statements

Statements in this presentation that are not statements of historical or current fact constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and "forward-looking information" within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Such forward looking statements involve known and unknown risks, uncertainties, and other factors that could cause the actual results of Acasti to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements containing the terms "believes," "belief," "expects," "intends," "anticipates," "estimates", "potential," "should," "may," "will," "plans," "continue", "targeted" or other similar expressions to be uncertain and forward-looking. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. The forward-looking statements in this presentation, including statements regarding the Company's anticipated cash runway, the timing of the planned initiation of the Company's STRIVE-ON trial and the resulting data readout, the timing of the Company's anticipated NDA submission with the FDA, GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH, any future patent filings made by the Company for new developments and the anticipated trial design of STRIVE-ON are based upon Acasti's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions of the planned Phase 3 safety trial for GTX-104; (ii) regulatory requirements or developments and the outcome and timing of the proposed NDA application for GTX-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; (v) actual costs associated with Acasti's clinical trials as compared to management's current expectations; and (vi) the other risk factors identified in the Company's Annual Report on Form 10-K for the year ended March 31, 2023. The foregoing list of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and are filed by Acasti from time to time with the Securities and Exchange Commission and Canadian securities regulators. All forward-looking statements contained in this presentation speak only as of the date on which they were made. Acasti undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by applicable securities laws.



Summary

Late-stage, biopharma company poised to disrupt Standard of Care (SoC) in treatment of aneurysmal Subarachnoid Hemorrhage (aSAH)

Nimodipine is the SoC and clinically de-risked *however*, significant unmet needs with its only available dosage form (oral)

GTX-104 – novel intravenous nimodipine – well positioned to solve oral challenges and potentially displace it as the SoC

Regulatory pathway to NDA filing is de-risked requiring one safety trial; Compelling safety data in over 160 subjects

STRIVE-ON trial is expected to enroll first patient in 4Q 2023

\$300M+ annual US market opportunity with ODD and strong patent estate

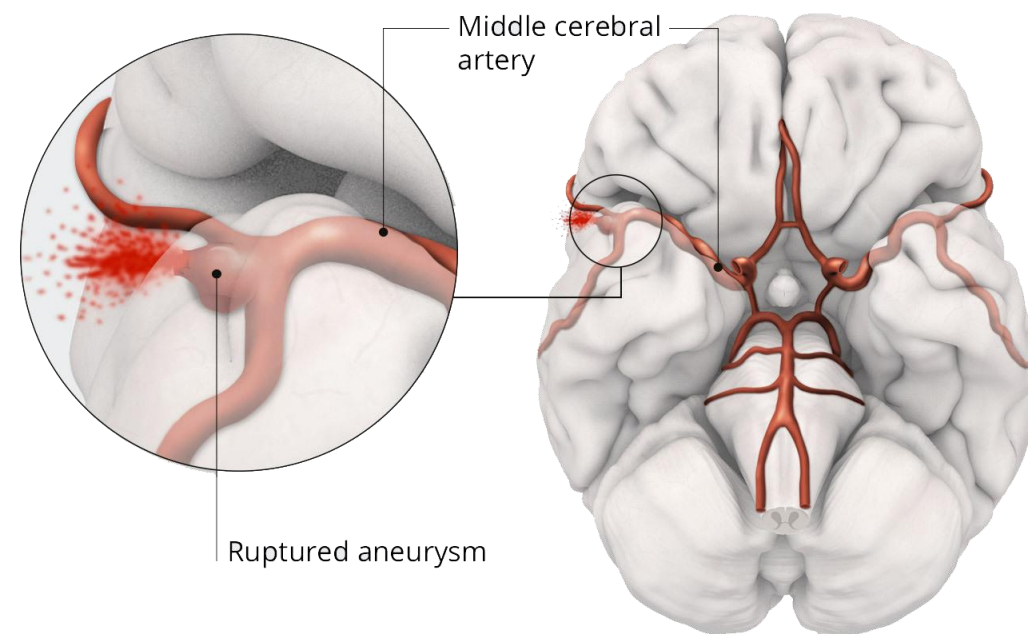
Reported cash anticipated to fund STRIVE-ON trial and potential NDA filing (1H 2025); Incremental \$7.5M PIPE (Sep 2023)

aSAH Overview

Life threatening acute brain injury associated with high mortality and morbidity

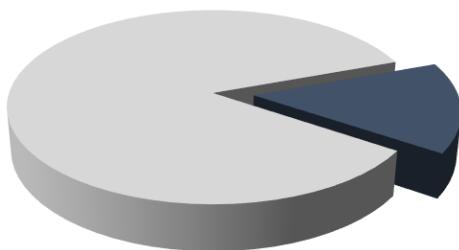
- aSAH results in bleeding over the surface of the brain in the space between the brain and skull
- Primary cause is rupture of an aneurysm; ~50,000 cases of aSAH annually in the US
- Condition can occur quickly, immediate intervention key to survival
- Patients require surgical intervention and oral nimodipine therapy for up to 21 days to help improve neurological symptoms

Subarachnoid hemorrhage



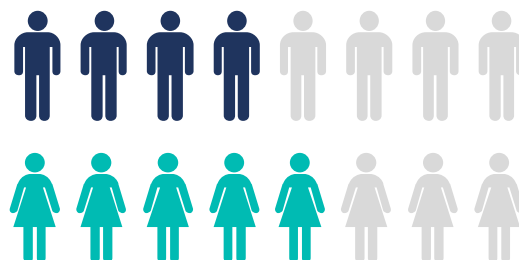
Outcomes are poor:

10-15% of aSAH patient die before reaching hospital. Death/dependence occurs in ~70% of patients



aSAH often occurs in relatively young people

~50% of affected patients <60 yrs



aSAH Current Standard of Care

Substantial barriers to administering oral nimodipine

Oral Nimodipine

60 mg (two large 30 mg capsules) every four hours

Current limitations

- Many aSAH patients are unconscious, cannot swallow oral medication - delivery via nasogastric tube often necessary, resulting in significant dose variability
- Highly variable absorption and first pass effect (CYP3A4 drugs) - leading to unpredictable hypotension
- Narrow and burdensome administration window

Side-effects

- Dose-limiting side-effects such as hypotension due to unpredictable absorption, low bioavailability and high first-pass metabolism

Reduction of dose

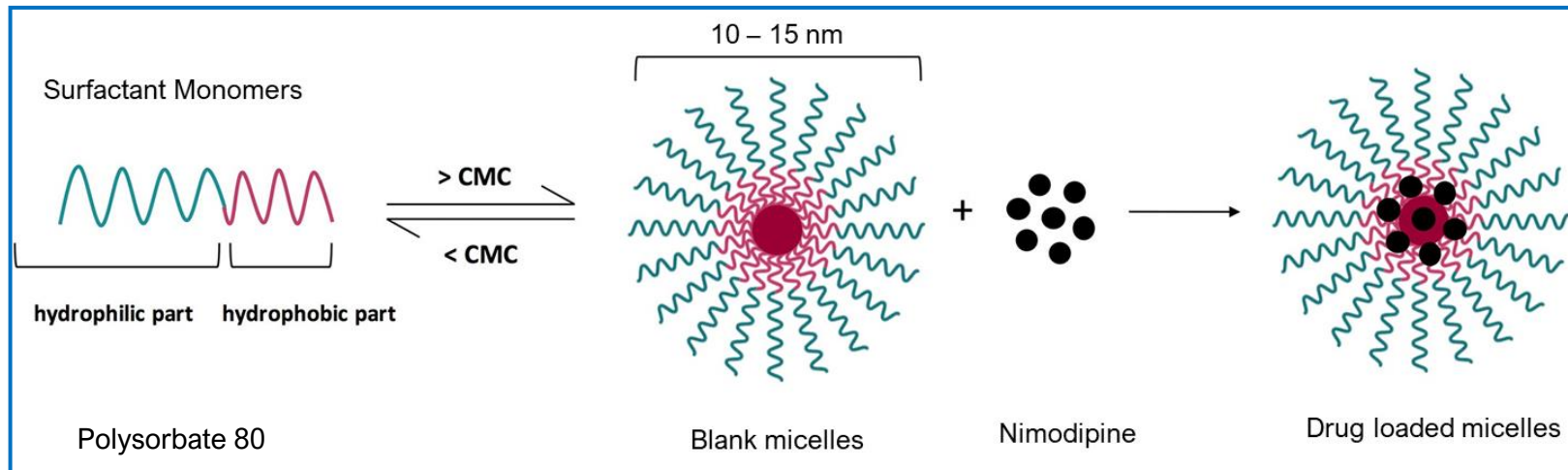
- Dose reduction or discontinuation of nimodipine is common, potentially leading to poor outcomes

GTX-104: Technology Overview

Potentially improve administration of nimodipine and better manage hypotension

- GTX-104 is a novel formulation of nimodipine for IV infusion in aSAH patients
- Overcomes solubility limitations of nimodipine in current formulations
- Patented formulation uses non-ionic surfactant micelles as the drug carrier to solubilize nimodipine
- Simple to prepare in pharmacy, stable at room temperature

GTX-104 Drug Delivery Technology



GTX-104-002 Phase 1 Trial: Successful Proof of Concept

The Trial Met All Primary and Secondary Endpoints

Phase 1, Randomized, Two-Period Crossover Trial to Evaluate the Relative Bioavailability of IV GTX-104 Compared to Oral Nimodipine Capsules at Steady State in Healthy Male and Female Subjects (n=58)



Conclusions

Results met the scientific bridge criteria (bioequivalence) of GTX-104 with oral nimodipine – paving the way for pivotal safety trial and 505(b)2 pathway

- Achieved pharmacokinetic bridge of IV GTX-104 with oral nimodipine
- Bioavailability of GTX-104 was 100% compared to ~7% for oral nimodipine capsules
- Consequently, only ~1/12 nimodipine is delivered with GTX-104 to achieve comparable pharmacokinetics as with oral capsules
- No serious adverse events

GTX-104-002 Phase 1: Results

Established pharmacokinetic bridge with oral nimodipine

Mean Plasma Nimodipine Concentration

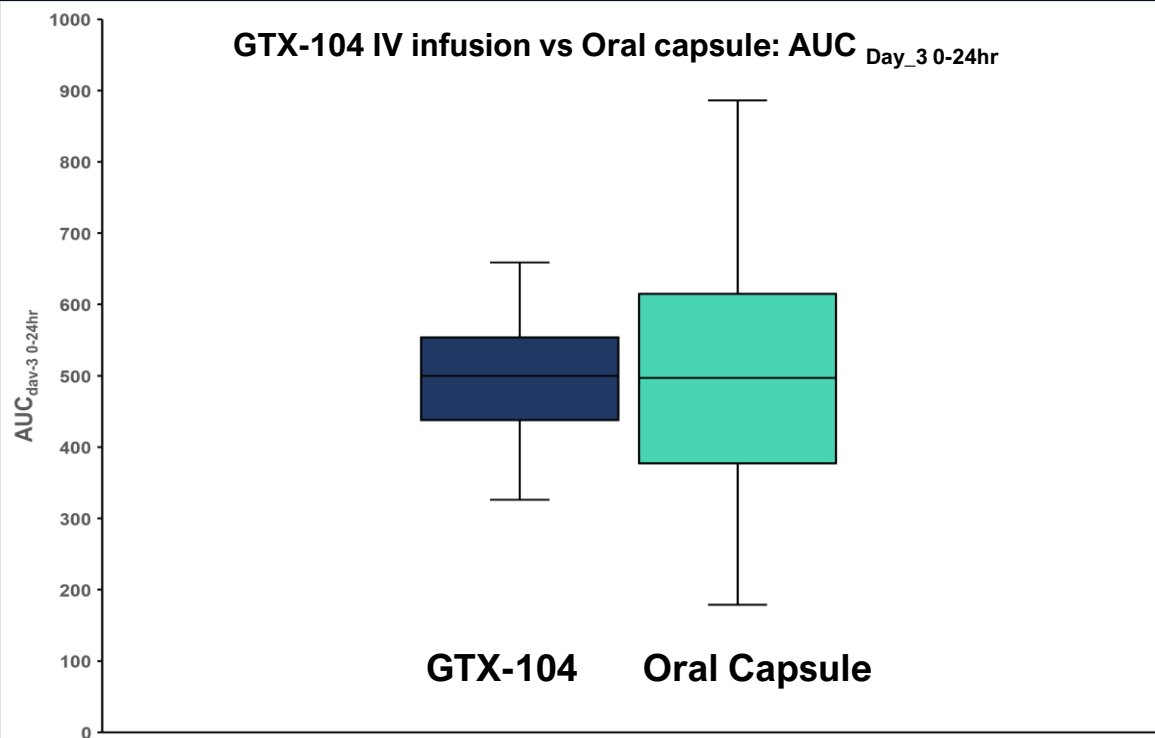
	GTX-104 (IV)	Nimodipine Capsules	90% Confidence Limits (%)	
PK Parameters	Geometric Mean	Geometric Mean	Lower	Upper
C_{\max} Day_1 0-4 hr (ng/mL)	63.1	68.6	81.7	103.6
AUC _{Day_3 0-24hr} (ng.h/mL)	491.6	462.6	99.3	114.0
F (%) fraction of drug	100%	7.2%	-	-

GTX-104 equivalent at ~1/12th oral dose
(27.6 mg/day of IV vs. 360 mg/day of oral)

GTX-104 is 100% bioavailable
vs. 7.20% for oral

GTX-104-002 Phase 1: Results

Consistent, predictable plasma concentrations allow for tighter control of hypotension



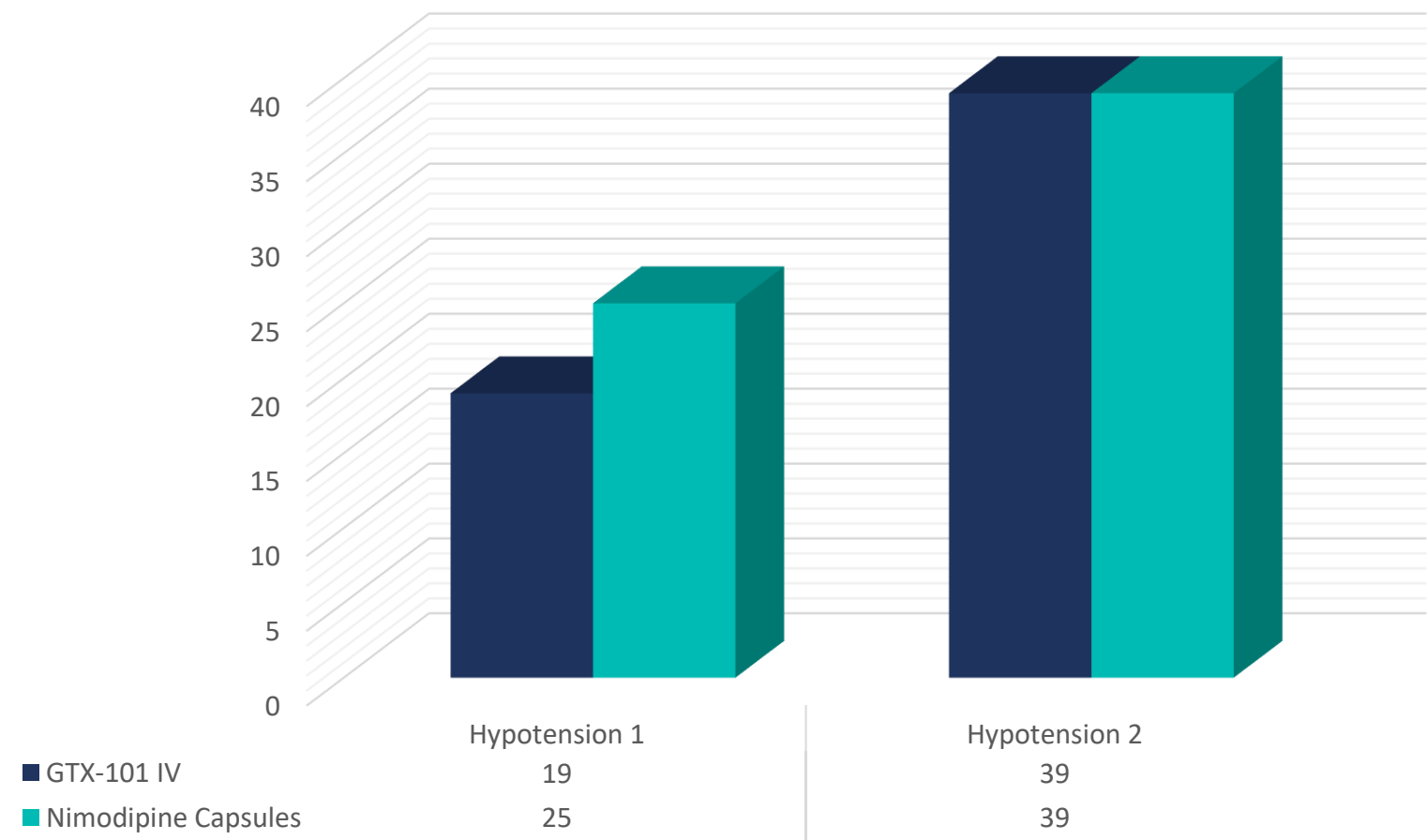
GTX-104

Significantly lower dose variability relative to oral capsule

Consistent and predictable plasma concentrations

GTX-104-002 Phase 1: Results

Demonstrated improved or comparable hypotension and safety profile



Hypotension 1
SBP <90 mmHg or DBP <60 mmHg

Hypotension 2
SBP <90 mmHg or DBP <60 mmHg
or decrease in SBP or DBP >10 mm Hg compared with baseline

GTX-104: Potentially Strong Value Proposition

Effective hypotension management, ensure compliance, and reduce hospital resources

Clinical Value



- ✓ Predictable drug concentration
- ✓ Effective hypotension management
- ✓ Therapeutic dose compliance
- ✓ Reduced drug intake
- ✓ No food effects and reduced DDI

Hospital Value



- ✓ Reduce medication errors
- ✓ Reduce nursing burden
- ✓ Reduce rescue therapy
- ✓ Shorter ICU stay
- ✓ Joint Commission compliance

Patient Value

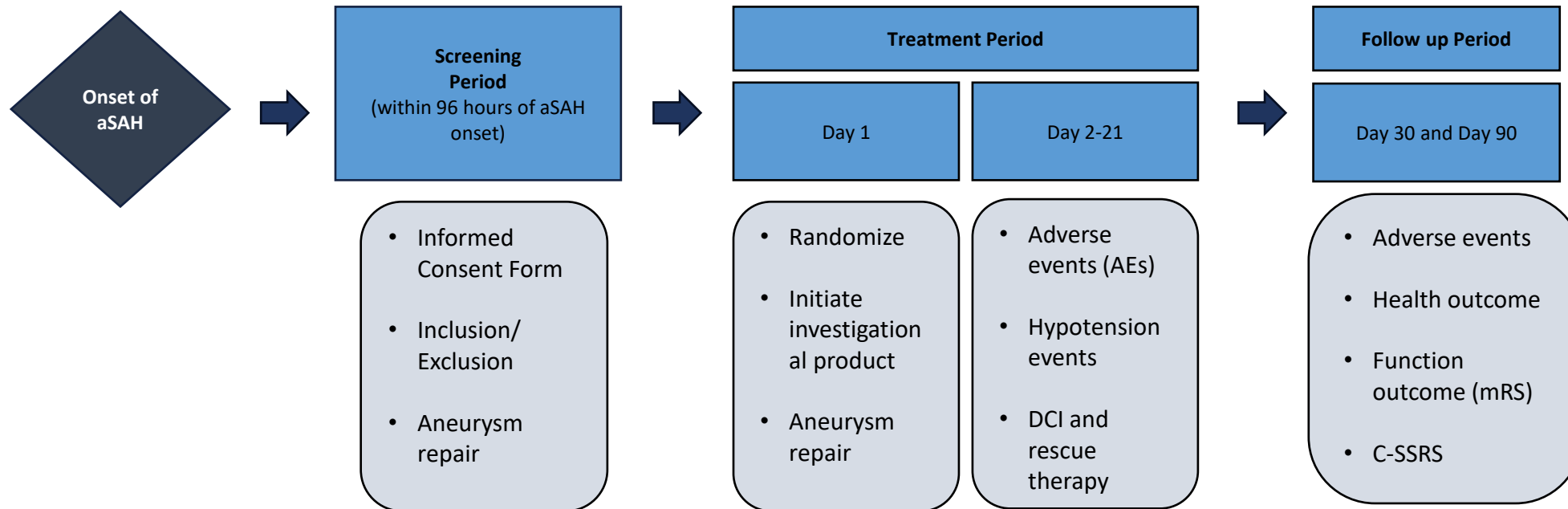


- ✓ Improved outcomes
- ✓ Convenient dosing
- ✓ Faster recovery
- ✓ Safer
- ✓ Lower disease burden

GTX-104 Next Steps: STRIVE-ON Phase 3 Pivotal Safety Trial

First patient enrolled in Oct 2023 – potential NDA submission 1H 2025

STRIVE-ON (NCT05995405) is a 100-patient prospective, open-label, randomized (1:1 ratio), parallel group trial of GTX-104 compared with oral nimodipine in patients hospitalized for aSAH



Primary Endpoint is Safety Measured by Comparative AEs

aSAH Addressable Market

~\$300 million US market opportunity

~50,000 individuals experience aSAH annually in US

Average cost per patient hospital stay is ~\$220,000, one of the most expensive acute conditions to treat in the US

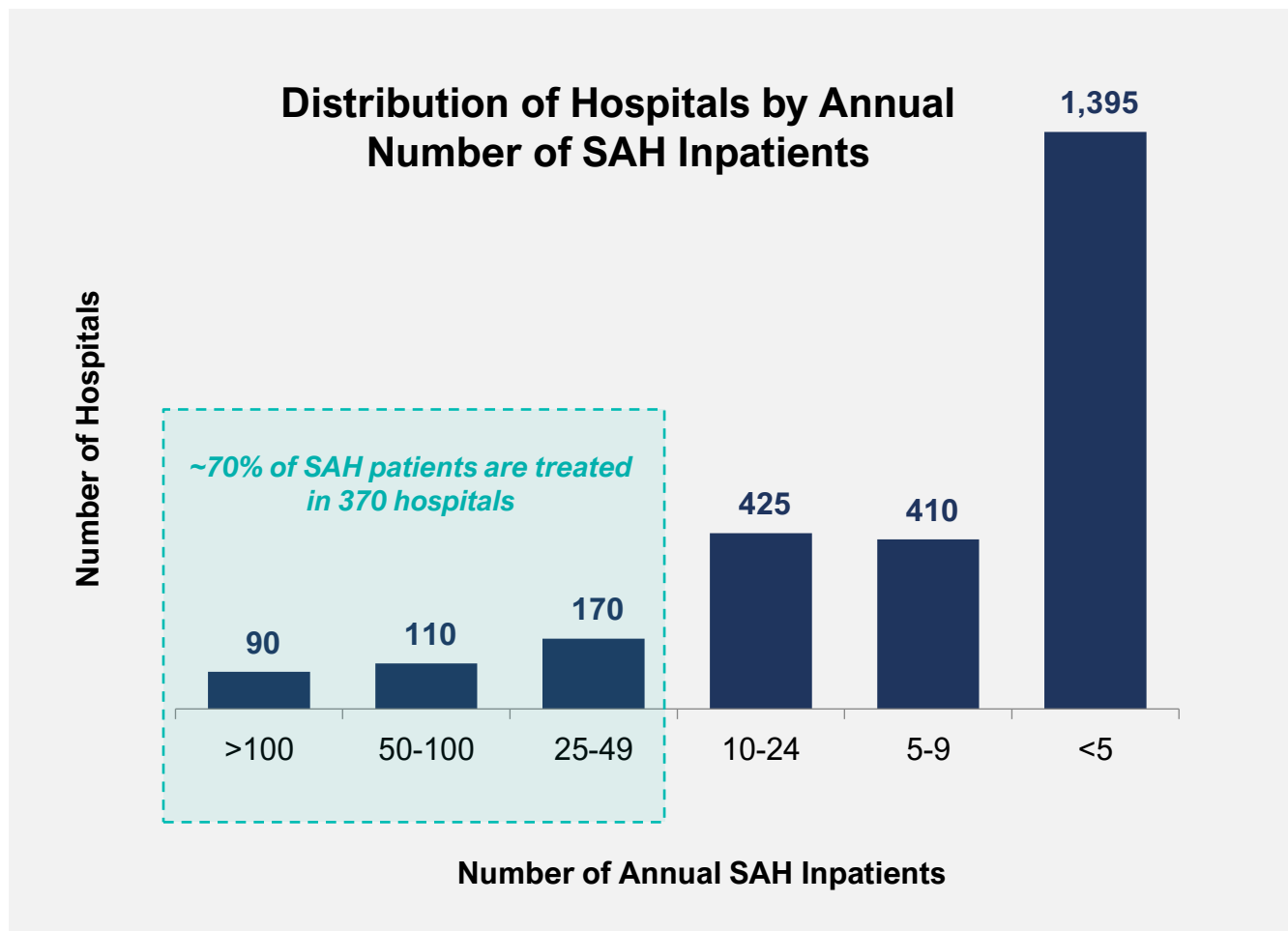
Total addressable US market for aSAH ~ \$300 million

Concentrated volume of aSAH patients in ~400 hospitals

Potential commercialization with ~40 reps

Evaluating partnering strategies opportunistically

Potential additional upside in EU (~55,000 patients) and China (~150,000 patients)



Intellectual Property Portfolio

Strong and multi-layered intellectual property protection strategy

GTX-104 received orphan drug status designation from the FDA



- Potential 7 years of marketing exclusivity in US, 10 years in Europe

Strong US and international patent estate



- Consists primarily of composition and method-of-use patents to extend exclusivity beyond what is granted through the orphan drug designation.
- Multiple patents granted worldwide, including five patents in the US
- Intend to continue to build our patent portfolio by filing for patent protection on new developments

Experienced Leadership Team

Proven drug development and commercialization expertise



Prashant Kohli
Chief Executive Officer



Loch Macdonald, MD, PhD
Chief Medical Officer



Brian D. Ford
Interim Chief Financial Officer



Carrie D'Andrea
VP Clinical Operations



Amresh Kumar, PhD
VP Program Management



Financial Overview

Acasti Pharma Inc. Cap Table (as of October 11, 2023)

Cash Balance (9/30/23)	USD \$27.0 M
Common Shares	9,399,404
Debt	NONE
Stock options granted and outstanding	561,365
Total Fully Diluted Shares Outstanding (including unallocated stock options)*	15,525,788

Capital Market Profile (as of January 5, 2024)

Exchange/Ticker	NASDAQ: ACST
Closing Stock Price	USD \$2.87
52 Wk High/Low	USD \$5.05 / \$1.72
Market Cap	USD \$26.98M

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The Acasti logo is displayed in a large, white, lowercase sans-serif font. It is positioned on the right side of the image, which has a dark teal background with a large, lighter teal circular graphic element behind the text.