UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): April 01, 2024

ACASTI PHARMA INC.

(Exact name of Registrant as Specified in Its Charter)

Quebec	**001-35776**	**98-1359336**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

103 Carnegie Center **Suite 300** **Princeton, New Jersey** **(Address of Principal Executive Offices)**	**08540** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 609 649-9272

(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:

☐ 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 Shares, no par value per share	ACST	The Nasdaq Stock Market LLC

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. ☐

Item 7.01 Regulation FD Disclosure.

The following information is furnished pursuant to Item 7.01 "Regulation FD Disclosure."

On April 1, 2024, Acasti Pharma Inc. updated its corporate presentation. A copy of the updated corporate presentation is furnished as Exhibit 99.1 to this Form 8-K.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, 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, nor shall it be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing or document.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Corporate Presentation, dated April 1, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

ACASTI PHARMA INC.

Date: April 1, 2024

By: /s/ Prashant Kohli
Prashant Kohli
Chief Executive Officer

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Company Overview

April 2024

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.

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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
- Pivotal Phase 3 STRIVE-ON safety trial began enrolling patients 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 in 1H 2025; cash runway into 2Q 2026

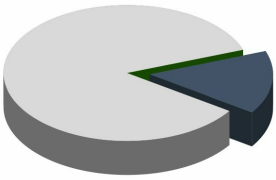
Sources: Fletcher Spaght market research report. Dates based on calendar year.

aSAH Overview

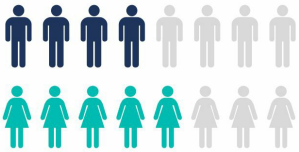
Life threatening acute brain injury associated with high mortality and morbidity

- 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

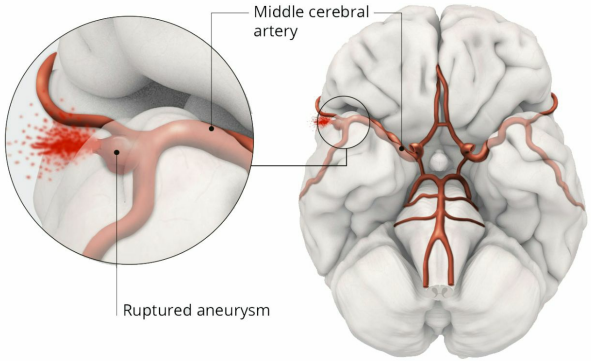
Outcomes are poor:
10-15% of aSAH patient die before reaching hospital. Death/dependence occurs in ~70% of patients



aSAH often occurs in relatively young people
~50% of affected patients <60 yrs



Subarachnoid hemorrhage



Sources: Fletcher Spaght market research report; Rinkel G. (2016); Becske T. (2018)

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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

Soppi V. (2007); Abboud T. (2015); Connolly ES. (2012)

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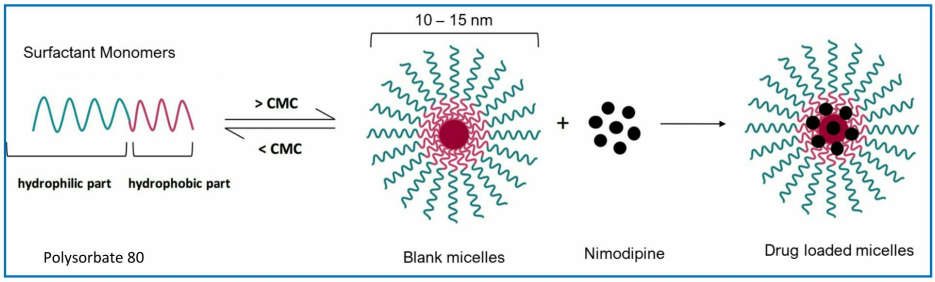
GTX-104: Technology Overview

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



CMC: Critical micelle concentration

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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

Nimodipine administration in aSAH patients is a key Joint Commission (JC) quality measure for hospitals with stroke certification
Sources: Nimodipine capsule packaging insert; Fletcher Spaght market research report; Soppi V. (2007)

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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

Source: GTX-104-002 CSR; results announced May 2022. Cmax: Maximum observed concentration; AUC: Area under the Curve

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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
$C_{max\ Day\_1\ 0\text{-}4\ hr}$ (ng/mL)	63.1	68.6	81.7	103.6
$AUC_{Day\_3\ 0\text{-}24hr}$ (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

Source: GTX-104-002 CSR; results announced May 2022

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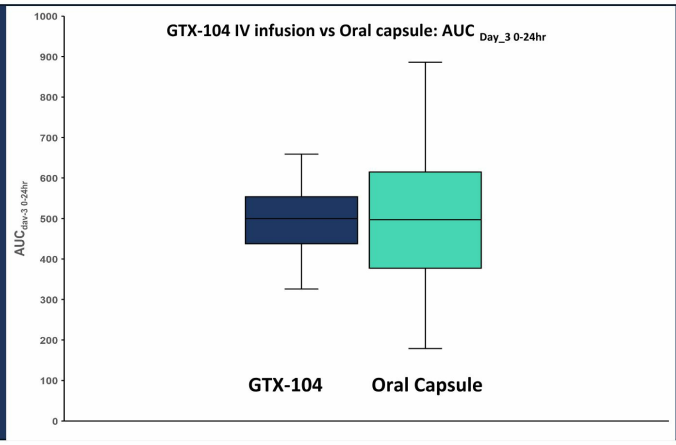
GTX-104-002 Phase 1: Results

Consistent, predictable plasma concentrations allow for tighter control of hypotension



GTX-104

Significantly lower dose variability relative to oral capsule

Consistent and predicable plasma concentrations

Source: GTX-104-002 CSR; results announced May 2022

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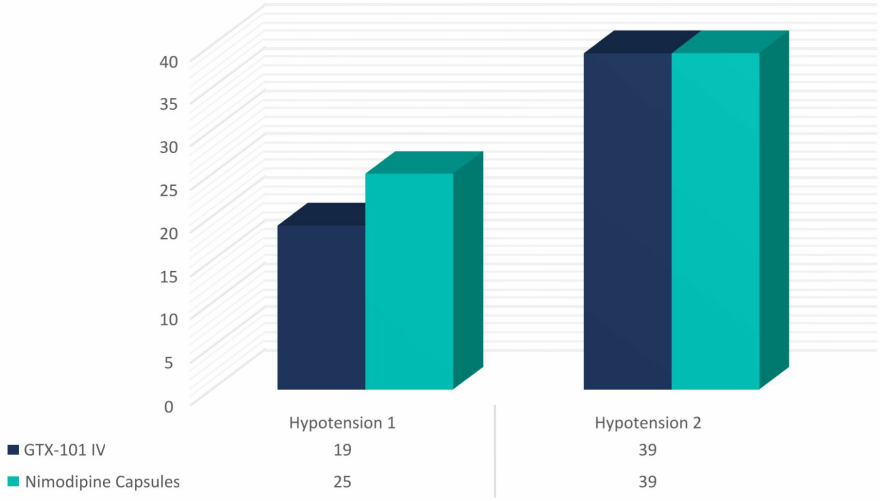
GTX-104-002 Phase 1: Results

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

Source: GTX-104-002 CSR; results announced May 2022

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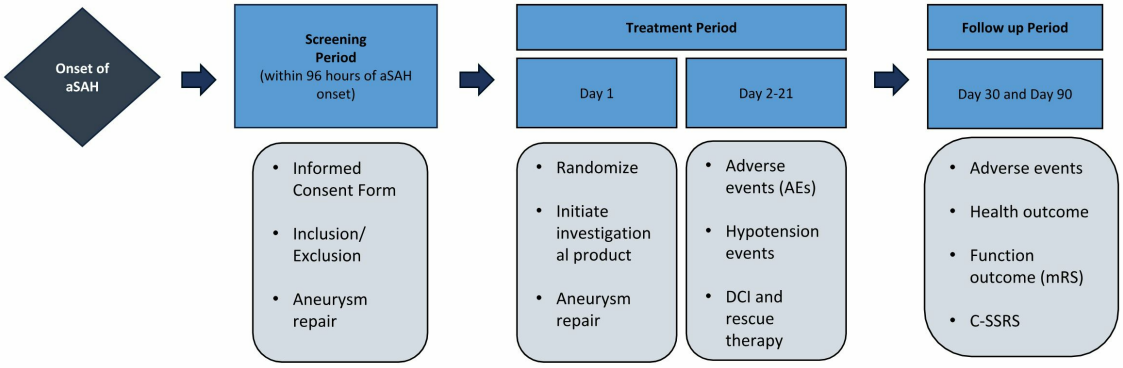
GTX-104 Next Steps: STRIVE-ON Phase 3 Pivotal Safety Trial

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

 DCI: delayed cerebral ischemia; mRS: modified Rankin Scale; C-SSRS: Columbia-Suicide Severity Scale

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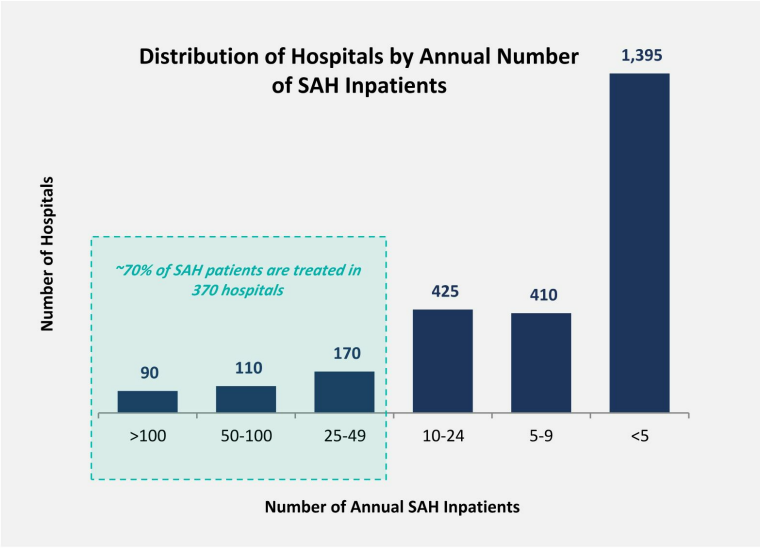
aSAH Addressable Market

~$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
- Total addressable US market for aSAH ~ $300 million
- Concentrated volume of aSAH patients in ~400 hospitals
- Potential commercialization with 35 - 40 reps
- Evaluating partnering strategies opportunistically
- Potential additional upside in EU (~55,000 patients) and China (~150,000 patients)



Sources: Fletcher Spaght market research report; Rinkel G. (2016); Becske T. (2018)

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GTX-104 Market Opportunity

Insights from Hospital Pharmacy & Therapeutics (P&T) Committee Decision Makers

Survey Design

31 hospital administrators, critical and neuro intensive care physicians at Comprehensive or Advanced Stroke Centers involved in purchasing decisions

20 respondents are current or former members of P&T committees

No GTX-104 investigators currently participating in STRIVE-ON trial included

Market opportunity

Respondents report **80% likelihood of adopting GTX-104** assuming 100% bioavailability, better safety, no food effects, effective hypotension management, and potential hospital & patient value

Challenges with current standard of care

Respondents ranked risk of hypotension as the most problematic issue that may arise when administering oral formulations of nimodipine

 Sources: January 2024 third-party market research survey targeting hospital decision makers view of GTX-104

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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 upon NDA approval

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
- Long patent shelf-life
  - First patent filed life 2037
  - Newest patent life 2042
- Continue building our patent portfolio by filing for patent protection on new developments

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Experienced Leadership Team

Proven drug development and commercialization expertise

Prashant Kohli
Chief Executive Officer

GRACE THERAPEUTICS · Archi-Tech · Cardinal Health · imshealth

Loch Macdonald, MD, PhD
Chief Medical Officer

EDGE Therapeutics, Inc. · St. Michael's Inspired Care. Inspiring Science. · The University of Chicago UChicago Medicine · Community Health Partners

Robert J. DelAversano
Principal Financial Officer and Principal Accounting Officer

oncosec IMMUNOTHERAPIES

Carrie D'Andrea
VP Clinical Operations

EDGE Therapeutics, Inc. · EryDel INNOVATION INTO BLOOD

Amresh Kumar, PhD
VP Program Management

ForeSee CCC · SUN PHARMA · GRACE THERAPEUTICS

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Financial Overview

Acasti Pharma Inc. Cap Table (as of December 31, 2023)	
Cash Balance	**USD $25.1 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 March 28, 2024)	
Exchange/Ticker	**NASDAQ: ACST**
Closing Stock Price	**USD $3.43**
52 Wk High/Low	**USD $3.84 / $1.72**
Market Cap	**USD $32.2M**

* Pre-Paid Warrants, Common Warrants, and Outstanding Grants

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Acasti Contact:
Prashant Kohli
Chief Executive Officer
Email: p.kohli@acasti.com
Website: www.acasti.com

Investor Contact:
Mike Moyer
LifeSci Advisors
Email: mmoyer@lifescieadvisors.com