
**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): May 08, 2023

ACASTI PHARMA INC.

(Exact name of Registrant as Specified in Its Charter)

Quebec
(State or Other Jurisdiction
of Incorporation)

001-35776
(Commission File Number)

98-1359336
(IRS Employer
Identification No.)

**3009, boul. de la Concorde East
Suite 102
Laval, Quebec**
(Address of Principal Executive Offices)

H7E 2B5
(Zip Code)

Registrant's Telephone Number, Including Area Code: 450 686-4555

(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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On May 8, 2023, the Company appointed Dr. R. Loch Macdonald, MD, PhD, as Chief Medical Officer, effective immediately. Dr. Macdonald, 61, is a world-renowned practicing neurosurgeon-scientist and respected authority in subarachnoid hemorrhage. Dr. Macdonald acted as Professor, Department of Surgery, Division of Neurosurgery at the University of Toronto from January 2007 until December 2019, and was Head, Division of Neurosurgery, St. Michael's Hospital, University of Toronto from January 2007 until December 2015. He was Professor, Department of Neurological Surgery, Barrow Neurological Surgery, Barrow Neurological Institute, Phoenix, Arizona, from April 2018 until August 2018; Fellow, Department of Neurosurgery, University of Illinois Hospitals in Chicago, Illinois from December 2018 until June 2019; Clinical Professor, Department of Neurological Surgery, University of California San Francisco Fresno, in Fresno, California from July 2019 until September 2021; and from October 2021 to the present has been Neurosurgeon, Community Physicians Group, Community Neurosciences Institute, Community Regional Medical Center and Medical Director of Neurosciences Research, Community Health Partners. Dr. Macdonald was also a founder of Edge Therapeutics, Inc. in 2009, where he was a member of the board of directors between 2009 and 2018 and was Chief Scientific Officer between 2011 and 2018. Dr. Macdonald completed his medical degree at the University of British Columbia, Vancouver, British Columbia and his PhD in Experimental Surgery at the University of Alberta in Edmonton, Alberta. He completed his Neurosurgery residency at the University of Toronto.

On May 8, 2023, the Company appointed Carrie D'Andrea as its VP Clinical Operations, effective immediately. Ms. D'Andrea, 51, is a highly experienced professional with 25 years of experience in the pharmaceutical and biotechnology industry who has built and led the planning, implementation, management, and execution of global Phase 2 and Phase 3 trials for a drug candidate for subarachnoid hemorrhage. Ms. D'Andrea was the Vice President of Clinical Operations for Edge Therapeutics Inc. from October 2014 until March 2019 and for EryDel SpA from October 2020 until April 2021. Ms. D'Andrea received her master's degree in Pharmaceutical Quality and Regulatory Affairs from Temple University and teaches Clinical Trial Design and Operations at Rutgers University in the Master of Business and Science Program.

On May 8, 2023, the Company appointed Amresh Kumar, PhD, as its VP of Program Management, effective May 15, 2023. Mr. Kumar, 43, is an experienced drug development, CMC, and program management expert supporting investigational and marketed products for rare diseases and neurology. Mr. Kumar is the former product leader of GTX-104 while at Grace Therapeutics Inc. (which was acquired by the Company in August 2021). Mr. Kumar acted as the Sr. Director of Program Management at Foresee Pharmaceuticals Inc. from April 2022 until May 2023 and as Program Leader and Associate Director - R&D at Grace Therapeutics Inc. between March 2015 and January 2022. Mr. Kumar received a PhD in Pharmaceutical Science from Sunrise University, India, focusing on complex injectable drug delivery systems of highly soluble oncology drugs. He has published many research articles and has more than 10 granted patents and many patent applications worldwide to his credit.

None of Dr. Macdonald, Ms D'Andrea or Mr. Kumar is a party to any transaction with the Company that would require disclosure under Item 404(a) of SEC Regulation S-K. In addition, there are no family relationships between any of Dr. Macdonald, Ms. D'Andrea or Mr. Kumar and any current director or executive officer of the Company.

The Company will file an amendment to this Form 8-K disclosing the compensation arrangements for Dr. Macdonald, Ms. D'Andrea or Mr. Kumar for their respective new roles with the Company, once available.

On May 8, 2023, the Company terminated the employment of Brian Ford, Chief Financial Officer; Pierre Lemieux, Chief Operating Officer (Canada); and George Kottayil, Chief Operating Officer (US). Mr. Ford will remain as interim Chief Financial Officer of the Company until June 30, 2023, subject to potential extension of that term by the Company. Under the terms of their employment arrangements, Mr. Ford, Mr. Lemieux and Mr. Kottayil will receive severance payments.

Item 8.01 Other Events.

On May 8, 2023, the Company announced the successful submission to the FDA of GTX-104's full protocol of its pivotal Phase 3 Safety Study and implementation of a strategic realignment plan to maximize shareholder value.

The realignment follows a comprehensive strategic review of the Company by Prashant Kohli, its recently appointed chief executive officer, and its Board of Directors.

Key strategies being implemented are:

1. Prioritizing resources to GTX-104. The Company has submitted the full pivotal Phase 3 Safety Study protocol with all supporting documentation. Pending final feedback and approval from the FDA, the first patient, first dose for the pivotal Phase 3 Safety Study is expected in calendar Q4 2023.
2. Strategic transformation of the Company's operating model to an agile biopharma reflecting its complete focus on GTX-104. In alignment with the operating model, the Company has brought on a highly experienced new management team with deep subject matter knowledge and direct, hands-on clinical trial experience in aSAH.
3. Significant extension of the Company's cash runway expected to be sufficient to fund the Company through calendar Q2 2025, facilitating achievement of critical value inflection milestones, including a potential New Drug Application (NDA) filing for GTX-104.
4. Evaluation of strategic alternatives to maximize value of de-prioritized pipeline assets (GTX-102 and GTX-101) including out-licensing or sale.

In connection with the transformation of the operating model, the Company has moved to appoint the following industry experts to its senior management team:

- Dr. R. Loch Macdonald, MD, PhD, as Chief Medical Officer. A world-renowned practicing neurosurgeon-scientist and respected authority in SAH, Dr. Macdonald is the former founder of a clinical-stage biotechnology company focused on subarachnoid hemorrhage.
- Carrie D'Andrea, as VP Clinical Operations. Ms. D'Andrea is a highly experienced professional who has built and led the planning, implementation, management, and execution of global Phase 2 and Phase 3 trials for a drug candidate for subarachnoid hemorrhage.
- Amresh Kumar, PhD, as VP Program Management. Mr. Kumar is an experienced drug development, CMC, and program management expert. Amresh is the former product leader of GTX-104 while at Grace Therapeutics (which was acquired by the Company).

As a result of this strategic realignment, the Company is over time discontinuing its operations in Canada, and has proceeded to lay off substantially all its workforce, allowing the Company's new management team to rebuild a leaner organization in the United States. All of the Company's finance team will remain in their current role for a transition period until at least the end June 2023.

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 hereunto duly authorized.

Acasti Pharma Inc.

Date: May 11, 2023

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