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 04, 2023

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.)**

3009, boul. de la Concorde East **Suite 102** **Laval, Quebec**	**H7E 2B5**
(Address of Principal Executive Offices)	**(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 April 4, 2023, Acasti Pharma Inc. (the "Company") announced it has appointed Prashant Kohli as the Company's Chief Executive Officer, succeeding Jan D'Alvise, who has mutually agreed with the Company to depart. Ms. D'Alvise will also be stepping down from the Company's board of directors.

Mr. Kohli, aged 51, served as the Company's Chief Commercial Officer since September 2022, where he was responsible for developing commercialization strategy and go to market plans for the Company's drug candidate pipeline, and was the Company's VP, Commercial Operations since August 2021. Prior to that, Mr. Kohli was VP Commercial Operations at Grace Therapeutics Inc. (which was acquired by the Company in August 2021) since December 2017. Mr. Kohli has also held a variety of commercial, corporate, and business development roles at Archi-Tech Systems Inc., Cardinal Health, Inc., IQVIA, Rosenbluth International Inc. and Dun & Bradstreet Corporation. He has a BA in Computer Science from Augustana College and an MBA from The Wharton School of Business.

There are no transactions between Mr. Kohli or any member of his immediate family and the Company, or any of its subsidiaries, that would be reportable as a related party transaction under the rules of the Securities and Exchange Commission. In addition, there are no family relationships between Mr. Kohli 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 Mr. Kohli's service as Chief Executive Officer, once available.

In connection with her departure, Ms. D'Alvise will will receive the separation benefits payable in accordance with the terms of her employment agreement.

Item 7.01 Regulation FD Disclosure.

On April 4, 2023, the Company issued a press release announcing the appointment of Prashant Kohli as Chief Executive Officer. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

On April 4, 2023, the Company also issued a press release announcing that the Company received a Type C written meeting response and clarifying feedback from the United States Food and Drug Administration on the Company's proposed Phase 3 Safety Study for GTX-104. A copy of the press release is furnished as Exhibit 99.2 to this Form 8-K.

The information in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 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 they be deemed 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 shall be expressly set forth by specific reference in such a filing or document.

Item 8.01 Other Events.

On April 4, 2023, the Company announced that it received a Type C written meeting response and clarifying feedback from the United States Food and Drug Administration ("FDA") on the Company's proposed Phase 3 Safety Study for GTX-104. The FDA provided additional comments on the Company's development plan that, pending submission of the final clinical protocol and FDA approval of same, will allow the Company to proceed with the initiation of a Phase 3 safety clinical trial in aneurysmal Subarachnoid Hemorrhage (aSAH) patients.

The FDA concurred with the suitability of the 505(b)(2) regulatory pathway with the selected Reference Listed Drug (RLD) Nimotop oral capsules (NDA 018869), and that the Company's GTX-104-002 PK study may have met the criteria for a scientific bridge.

Based on the FDA's proposed Phase 3 Study Design, the Company will target enrollment of aSAH patients (across all grades of severity) in a 1:1 randomized trial with oral nimodipine, to be conducted in an estimated 25-30 sites in the U.S. The FDA confirmed the use of the Hunt and Hess scale to stratify patients based on severity. The primary endpoint is safety, and it will be measured as the percentage of significant adverse events of hypotension related to study drugs in both arms.

An application filed under Section 505(b)(2) is one that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated April 4, 2023 announcing the appointment of Prashant Kohli as Chief Executive Officer
99.2	Press Release dated April 4, 2023 announcing that the Company received a Type C written meeting response and clarifying feedback from the United States Food and Drug Administration on the Company's proposed Phase 3 Safety Study for GTX-104

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: April 5, 2023

By: /s/ Prashant Kohli
Chief Executive Officer

Acasti Announces Appointment of Prashant Kohli as CEO

LAVAL, Québec, April 4, 2023 -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST), a late-stage specialty pharma company advancing drug candidates for rare and orphan diseases, today announced the appointment of Prashant Kohli as Acasti’s new Chief Executive Officer, succeeding Jan D’Alvise. The parties have mutually agreed to part ways, and Ms. D’Alvise will be stepping down from the board.

Prashant Kohli has served as Chief Commercial Officer of Acasti since 2022. Mr. Kohli has over 20 years of commercialization experience leading strategy, sales, marketing, and product management. Recently, Mr. Kohli was VP, Commercial Operations of Acasti and at Grace Therapeutics, prior to its acquisition by Acasti in August 2021. Mr. Kohli has developed a broad network of KOL physicians who treat Subarachnoid Hemorrhage (SAH) at leading comprehensive stroke centers across the country; Acasti’s late-stage clinical program, GTX-104, is for the treatment of SAH. Mr. Kohli has also held a variety of commercial, corporate, and business development roles at Archi-Tech Systems, Cardinal Health, IQVIA, Rosenbluth, and Dun & Bradstreet. He has a BA in Computer Science and Math, and an MBA from The Wharton School.

“Acasti is at an exciting point in its development as we advance GTX-104 into its upcoming Phase 3 safety study and are fortunate to have someone with Prashant’s wealth of experience to lead us into this next stage in our evolution,” commented Vimal Kavuru, Acasti’s Board Chair. “Prashant’s expertise crafting go-to-market plans for products with unique value proposition that address critical unmet needs, coupled with his commercial partnering capabilities, will serve us well going forward.”

Over his career, Mr. Kohli has built, deployed, and led sales and marketing efforts from the ground-up with significant experience in P&L accountability, product development, salesforce design and deployment, branding, market access, and distribution. He has successfully implemented evidence-based, consultative-selling model that are rooted in deep understanding of the health ecosystem including patients, providers, health systems, government, and payers.

Mr. Kohli added, “I am extremely excited for the opportunity to lead Acasti going forward. We have a tremendous opportunity ahead of us to bring effective treatments to severely underserved patient population, led by GTX-104’s advancement to a Phase 3 safety study in patients with SAH. I look forward to leveraging my commercialization and partnering experience in this new role to bring value to Acasti.”

"We thank Jan for her dedicated service and many contributions to the advancement of Acasti, and we wish her well in her future endeavors,” said Mr. Kavuru.

About Acasti

Acasti is a late-stage specialty pharma company with drug delivery technologies and drug candidates addressing rare and orphan diseases. Acasti's novel drug delivery technologies have the potential to improve the performance of currently marketed drugs by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery—all which could help to increase

treatment compliance and improve patient outcomes. Acasti's three lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provide the assets with seven years of marketing exclusivity post-launch in the United States, and additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical assets target underserved orphan diseases: (i) GTX-104, an intravenous infusion targeting Subarachnoid Hemorrhage (SAH), a rare and life threatening medical emergency in which bleeding occurs over the surface of the brain in the subarachnoid space between the brain and skull; (ii) GTX-102, an oral mucosal spray targeting Ataxia-telangiectasia (A-T), a progressive, neurodegenerative genetic disease that primarily affects children, causing severe disability, and for which no treatment currently exists; and (iii) GTX-101, a topical spray targeting Postherpetic Neuralgia (PHN), a persistent and often debilitating neuropathic pain caused by nerve damage from the varicella zoster virus (shingles), which may persist for months and even years.

For more information, please visit: https://www.acasti.com

Forward-Looking Statements

Statements in this press release 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 press release. The forward-looking statements in this press release 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 study for GTX-104; (ii) regulatory requirements or developments and the outcome and timing of the proposed IND application for GTX-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with Acasti’s clinical trials as compared to management’s current expectations. 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 press release 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. The NASDAQ does not accept responsibility for the adequacy or accuracy of this release.

Acasti Contact:

Prashant Kohli
Chief Executive Officer

Tel: 450-686-4555
Email: info@acasti
www.acasti.com

Investor Relations:
Robert Blum
Lytham Partners, LLC
602-889-9700
ACST@lythampartners.com

Acasti to Proceed with Phase 3 Clinical Safety Study for GTX-104 Following FDA Feedback, and Upon Approval of the Full Study Protocol to be Submitted to the IND

Company expects the first patient to be enrolled during the second half of 2023

LAVAL, Québec, April 4, 2023 -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST), a late-stage, specialty pharma company advancing drug candidates for rare and orphan diseases, today announced that it received a Type C written meeting response and clarifying feedback from the United States Food and Drug Administration (FDA) on Acasti's proposed Phase 3 Safety Study for GTX-104. The FDA provided additional comments on the Company's development plan that, pending submission of the final clinical protocol and FDA approval of same, will allow Acasti to proceed with the initiation of a Phase 3 safety clinical trial in aneurysmal Subarachnoid Hemorrhage (aSAH) patients.

The FDA concurred with the suitability of the 505(b)(2) regulatory pathway with the selected Reference Listed Drug (RLD) Nimotop oral capsules (NDA 018869), and that Acasti's GTX-104-002 PK study may have met the criteria for a scientific bridge.

Based on FDA's proposed Phase 3 Study Design, the company will target enrollment of aSAH patients (across all grades of severity) in a 1:1 randomized trial with oral nimodipine, to be conducted in an estimated 25-30 sites in the U.S.A. The FDA confirmed the use of the Hunt and Hess scale to stratify patients based on severity. The primary endpoint is safety, and it will be measured as the percentage of significant adverse events of hypotension related to study drugs in both arms.

Prashant Kohli, CEO of Acasti Pharma, commented, "We expect to move quickly to submit the final clinical protocol and all required study documentation to the FDA. Once these documents are submitted and following any final feedback and approval from the FDA, the Phase 3 safety study can be initiated. If the Phase 3 study meets the primary endpoint, an NDA filing for GTX-104 under Section 505(b)(2) is expected to follow."

An application filed under Section 505(b)(2) is one that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

About aneurysmal Subarachnoid Hemorrhage (aSAH)
aSAH is bleeding over the surface of the brain in the subarachnoid space between the brain and the skull, which contains blood vessels that supply the brain. A primary cause of such bleeding is rupture of an aneurysm. The result is a relatively uncommon type of stroke that accounts for about one-in-twenty (5%) of all strokes and has an incidence of six per 100,000 person years (Becske, 2018). In contrast to more common types of strokes in elderly individuals, aSAH often occurs at a relatively young age, with half the affected patients being younger than 60 years (Becske, 2018). Particularly devastating for patients younger than 45, approximately 10% to 15% of aSAH patients die before reaching the hospital (Rinkel, 2016), and those who survive the initial hours post hemorrhage are admitted or transferred to neurointensive care centers to manage the high risk of complications, including rebleeding, vasospasm

and delayed cerebral ischemia (DCI). Systemic manifestations affecting cardiovascular, pulmonary, and renal function are common, and often complicate the management of DCI.

Approximately 70% of aSAH patients experience death or dependence, and half die within one month after the hemorrhage. Of those who survive the initial month, half remain permanently dependent on someone else to maintain daily living (Becske, 2018).

About GTX-104

GTX-104 is a clinical stage, novel formulation of nimodipine being developed for IV infusion in aSAH patients. It incorporates surfactant micelles as the drug carrier to solubilize nimodipine. This nimodipine injectable formulation is comprised of a nimodipine base, an effective amount of a hydrophilic surfactant, and a pharmaceutically acceptable carrier for injection. GTX-104 is an aqueous solution substantially free of organic solvents, such that the nimodipine is contained in a concentrated injection solution, suspension, emulsion or complex as a micelle, a colloidal particle or an inclusion complex, and the formulation is stable and clear. The addressable market in the United States for GTX-104 is estimated to be about $300 million based on market research conducted by Fletcher Spaght.

About Acasti

Acasti is a late-stage specialty pharma company with drug delivery technologies and drug candidates addressing rare and orphan diseases. Acasti's novel drug delivery technologies have the potential to improve the performance of currently marketed drugs by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery—all which could help to increase treatment compliance and improve patient outcomes. Acasti's three lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provide the assets with seven years of marketing exclusivity post-launch in the United States, and additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical assets target underserved orphan diseases: (i) GTX-104, an intravenous infusion targeting aneurysmal Subarachnoid Hemorrhage (aSAH), a rare and life threatening medical emergency in which bleeding occurs over the surface of the brain in the subarachnoid space between the brain and skull; (ii) GTX-102, an oral mucosal spray targeting Ataxia-telangiectasia (A-T), a progressive, neurodegenerative genetic disease that primarily affects children, causing severe disability, and for which no treatment currently exists; and (iii) GTX-101, a topical spray targeting Postherpetic Neuralgia (PHN), a persistent and often debilitating neuropathic pain caused by nerve damage from the varicella zoster virus (shingles), which may persist for months and even years.

For more information, please visit: https://www.acasti.com.

Forward-Looking Statements

Statements in this press release 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 press release. The forward-looking statements in this press release 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 study for GTX-104; (ii) regulatory requirements or developments and the outcome and timing of the proposed IND application for GTX-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with Acasti’s clinical trials as compared to management’s current expectations. 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 press release 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. The NASDAQ does not accept responsibility for the adequacy or accuracy of this release.

Acasti Contact:

Prashant Kohli
Chief Executive Officer
Tel: 450-686-4555
Email:info@ acasti.com
www.acasti.com

Investor Relations:
Robert Blum
Lytham Partners, LLC
602-889-9700
ACST@ lythampartners.com