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): October 18, 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.)**
2572 boul. Daniel-Johnson 2nd Floor Laval, Quebec		**H7T 2R3**
(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 1.01 Entry into a Material Definitive Agreement.

On October 18, 2023, Acasti Pharma Inc. (the "Company") entered into a Settlement Agreement with Aker BioMarine Antarctic AS, a corporation organized and existing under the laws of the Kingdom of Norway ("AKBM"), to settle any and all potential claims regarding amounts due under that certain supply agreement, dated October 25, 2019, by and between the Company and AKBM (the "Supply Agreement").

As previously disclosed, the Company entered into the Supply Agreement with AKBM to purchase raw krill oil product for a committed volume of commercial starting material for CaPre® ("CaPre"), one of the Company's former drug candidates, for a total fixed value of $3.1 million. During the second calendar quarter of 2022, AKBM informed the Company that AKBM believed it had satisfied the terms of the Supply Agreement as to their obligation to deliver the remaining balance of raw krill oil product, and that the Company was therefore required to accept the remaining product commitment and to pay AKBM the remaining balance under the Supply Agreement. The Company disagreed with AKBM's position and believed that AKBM was not entitled to further payment under the Supply Agreement. Accordingly, no liability was recorded by the Company. As of October 18, 2023, the remaining disputed balance of the commitment with AKBM amounted to approximately $2.6 million.

Pursuant to the terms of the Settlement Agreement, in exchange for a release and waiver of claims arising out of the Supply Agreement by AKBM and any of AKBM's affiliates, the Company and AKBM agreed to the following:

a)AKBM shall retain ownership of all raw krill oil product, including amounts previously delivered to the Company.

b)AKBM shall acquire and take ownership of all production equipment related to the production of CaPre.

c)AKBM shall acquire and take ownership of all data from research, clinical trials and pre-clinical studies with respect to CaPre.

d)AKBM shall acquire and take ownership over all rights, title and interest in and to all intellectual property rights related to CaPre owned by the Company, including all patents and trademarks.

Pursuant to the terms of the Settlement Agreement, AKBM acknowledged that the CaPre Assets (as defined in the Settlement Agreement) are being transferred on an "as is" basis, and in connection therewith the Company disclaimed all representations and warranties in connection with the CaPre Assets, including any representations with respect to performance or sufficiency.

The description of the material terms of the Settlement Agreement set forth herein does not purport to be complete and is qualified in its entirety by the full text of the Settlement Agreement, which is attached hereto as Exhibit 10.1, and incorporated herein by reference.

Item 8.01 Other Events.

On October 23, 2023, the Company issued a press release announcing the dosing of the first patient in the Company's GTX-104 STRIVE-ON clinical trial and the extension of the Company's anticipated cash runway. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit	Description
10.1	Settlement Agreement, dated October 18, 2023, by and between the Company and Aker BioMarine Antarctic AS.
99.1	Press Release, dated October 23, 2023.
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: October 23, 2023

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

SETTLEMENT AGREEMENT

This Settlement Agreement (the "Settlement Agreement") is entered into as of October 18, 2023 by and between

(1)Acasti Pharma Inc., a corporation organized and existing under the laws of Québec, Canada, with its principal place of business located at 2572 boul. Daniel-Johnson, 2nd Floor, Laval, Québec, Canada H7T 2R3 ("Acasti"), and

(2)Aker BioMarine Antarctic AS, a corporation organized and existing under the laws of the Kingdom of Norway, with its principal place of business located at Oksenøyveien 10, 1366 Lysaker ("AKBM").

Collectively, Acasti and AKBM may be referred to as the "Parties".

WHEREAS, on the 25th of October 2019, the Parties entered into a Supply Agreement for the sale and purchase of 40 metric tons of RKO (the "Supply Agreement"; all capitalized terms not defined herein shall have the meaning set forth in the Supply Agreement), and;

WHEREAS, after having taken delivery of 4 metric tons of RKO and paid AKBM USD 500,000, a dispute arose between the Parties as to whether Acasti was obligated to take delivery of the remaining RKO, and;

WHEREAS, since then there have been discussions and negotiations between the Parties, and;

WHEREAS, the Parties desire to amicably settle and resolve all outstanding claims and disputes arising under the Supply Agreement without the need for litigation.

NOW THEREFORE, in consideration of the foregoing and other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, Acasti and AKBM agree as follows:

1.Settlement Amount

1.1.The Parties agree that the outstanding amount under the Supply Agreement and thus the total settlement amount is USD 2,600,000 (the "Settlement Amount"), and furthermore, the Parties agree that the transfer of cash or assets with a value equaling the Settlement Amount shall be considered as full and final settlement of all outstanding claims and disputes arising under the Supply Agreement.

2.Payment and Transfer of Assets

2.1.In satisfaction of the Settlement Amount in accordance with this Settlement Agreement, Acasti shall and hereby does, effective as of the Effective Date (as defined below), assign and transfer its entire ownership of all assets set forth in the appendices attached hereto and described below related to Acasti's work with developing and commercializing the pharmaceutical drug candidate CaPre® to AKBM (collectively, the "CaPre® Assets"), which CaPre® Assets shall include:

2.1.1.Inventory of RKO; AKBM shall keep ownership of all RKO, including the 4 metric tons

already delivered to Acasti. Acasti shall arrange transportation of the volumes of RKO already received to AKBM's facilities in Houston, Texas, and cover the cost of such transport.

2.1.2.Production equipment; AKBM shall acquire all production equipment related to the production of CaPre® (the "Production Equipment") as set out in the Production Equipment inventory list attached to this Settlement Agreement as Appendix 1. Acasti shall arrange professional disassembly, packing and transportation of the Production Equipment including any related and available documentation such as operating manuals to AKBM's facilities in Houston, Texas, and cover the cost of such disassembly, packing and transport.

2.1.3.CaPre® Data; AKBM shall acquire and take ownership over all data from all research, clinical and pre-clinical trials and studies, manufacture, handling, use, storage, commercialization or otherwise related to the conduct of the business conducted by or behalf of Acasti in respect of CaPre® or otherwise, as set forth in Appendix 2.

2.1.4.CaPre® IP; AKBM shall acquire and take ownership over all right, title, and interest in and to all intellectual property rights (registered and unregistered) related to CaPre® and owned by Acasti, including, specifically, the patents, trademarks, and other intellectual property specified in Appendix 3 hereto (collectively, the "CaPre® IP"), in each case to the extent Acasti owns all such right, title, and interest. Acasti shall instruct it's intellectual property agent to execute transfer of ownership of the CaPre® IP and cover the cost of such instruction and transfer.

2.2.The transfer of ownership of the CaPre® Assets shall occur at 9:00 a.m. (New York City Time) on October 19, 2023 (the "Effective Date"). Upon the Effective Date, AKBM shall assume ownership of the CaPre® Assets free and clear of any liens, encumbrances, or claims by third parties. The delivery of the CaPre® Assets from Acasti to AKBM shall take place as soon as reasonably possible after the Effective Date, and the Parties shall hold good faith discussions regarding all practicalities that may arise in connection with the transfer of the CaPre® Assets.

3.Release and Waiver

3.1.Upon transfer of the CaPre® Assets as set forth herein, and in consideration thereof, AKBM, together with and on behalf of all divisions, affiliates, parent corporations, sister corporations, subsidiary corporations, transferees, assignees, predecessors, and successors of AKBM, and all officers, directors, shareholders, employees, agents, representatives, administrators, executors, and insurers of each of the foregoing, hereby releases and discharges Acasti, together with all divisions, affiliates, parent corporations, sister corporations, subsidiary corporations, transferees, assignees, predecessors, and successors of Acasti, and all officers, directors, shareholders, employees, agents, representatives, administrators, executors, and insurers of each of the foregoing, from any and all claims, liabilities, demands, actions, suits, debts, damages, attorneys' fees and costs, losses, claims for payment of unpaid fees, requests for indemnity, remedies of any kind, causes of action, and all other manner of liability whatsoever, in law or in equity, whether arising on, prior to, or after the Effective Date, arising out of or related in any way to the Supply Agreement or any CaPre® IP, whether known or unknown, disclosed or undisclosed, asserted or unasserted, under or pursuant to any agreement, statute, or regulation, common law, or equity. AKBM acknowledges that rights to the CaPre® Assets are being provided on an "as is" basis, and Acasti hereby disclaims all representations and warranties with respect thereto, whether express, implied, or statutory, including any representations with respect to performance or sufficiency.

4.Governing Law

4.1.This Settlement Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to its conflict of laws principles. Any disputes arising under or relating to this Settlement Agreement shall be solved pursuant to the agreed dispute resolution mechanisms set out in the Supply Agreement.

5.Entire Agreement

5.1.This Settlement Agreement contains the entire understanding between the Parties and supersedes all prior and contemporaneous agreements and understandings, whether oral or written, with respect to the subject matter hereof.

6.Assignment

6.1.Neither this Agreement nor any of the rights, interests or obligations under this Agreement may be assigned or delegated, in whole or in part, by operation of Law or otherwise, by any of the Parties without the prior written consent of the other Party, however so that AKBM as part of its ongoing segment restructuring shall be allowed to assign this Settlement Agreement to Aker BioMarine Human Ingredients AS (under incorporation) if and when deemed necessary by AKBM in its sole discretion. Subject to the preceding sentences, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and assigns.

7.Modification

7.1.This Settlement Agreement may only be modified in writing and signed by both Parties.

8.Counterparts

8.1.This Settlement Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, the Parties hereto have executed this Settlement Agreement as of the date first above written.

For Acasti Pharma Inc.:

/s/ Prashant Kohli
Name: Prashant Kohli
Title: Chief Executive Officer

For Aker BioMarine Antarctic AS:

/s/ Matts Johansen
Name: Matts Johansen
Title: Chief Executive Officer

Appendix 1: Production Equipment Inventory List

Appendix 2: List of CaPre® Data

Appendix 3: List of CaPre® IP

Acasti Announces Dosing of First Patient in GTX-104 STRIVE-ON Trial

- *With achievement of enrollment milestone, pivotal STRIVE-ON safety trial on track for potential NDA submission anticipated to occur in the first half of calendar 2025*
- *Recently announced $7.5 million private placement financing extends projected cash runway to the first calendar quarter of 2026*

PRINCETON, N.J., October 23, 2023 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (Nasdaq: ACST) (Acasti or the Company), a late-stage, biopharma company advancing GTX-104, its novel formulation of nimodipine that addresses the high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced enrollment of the first patient in the Company's pivotal Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial–NCT05995405). UTHealth Houston is the first site to enroll an aSAH patient in the STRIVE-ON trial.

"The dosing of our first patient in the STRIVE-ON trial is a significant milestone for Acasti, demonstrating our ability to execute our clinical development program for GTX-104," said Prashant Kohli, CEO of Acasti. "We're pleased to be working with a prestigious neurocritical care team such as UTHealth Houston, and look forward to welcoming additional centers. After the completion of our recently announced $7.5 million private placement offering, we have the balance sheet strength and are well positioned to continue GTX-104 development towards realizing its clinical and commercial prospects as a potential new treatment standard for aSAH."

The Company previously announced alignment with the U.S. Food and Drug Administration (FDA) on the protocol and dosing regimen for the STRIVE-ON trial, at which time the FDA provided guidance regarding a potential New Drug Application (NDA) submission for GTX-104, currently anticipated in the first half of calendar 2025. GTX-104 has already been administered in over 160 healthy subjects in prior Phase 1 trials and has a well-established safety profile. GTX-104 has the potential to disrupt the oral nimodipine dosage form and become the standard of care in aSAH patients addressing critical unmet medical needs.

Acasti also recently hosted a virtual key opinion leader event featuring W. Taylor Kimberly, MD, PhD (Massachusetts General Hospital) who discussed the high unmet medical need and current treatment landscape for patients suffering from aSAH.

A replay of the webinar is available here.

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 the rupture of an aneurysm. Approximately 70% of aSAH patients experience death or dependence, and more than 30% die within one month of hemorrhage. Approximately 50,000 patients in the United States are affected by aSAH per year, based on market research.

About GTX-104

GTX-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous infusion (IV) in aSAH patients to address significant unmet medical needs. The unique nanoparticle

technology of GTX-104 facilitates aqueous formulation of insoluble nimodipine for a standard peripheral IV infusion.

GTX-104 provides a convenient IV delivery of nimodipine in the Intensive Care Unit potentially eliminating the need for nasogastric tube administration in unconscious or dysphagic patients. Intravenous delivery of GTX-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTX-104 has the potential to better manage hypotension in aSAH patients. GTX-104 has been administered in over 150 healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine. The addressable market in the United States for GTX-104 is estimated to be about $300 million, based on market research.

About Acasti

Acasti is a late-stage biopharma company with 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. Acasti's lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provides 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 asset, GTX-104, is 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.

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

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, including statements regarding the Company's anticipated cash runway, the anticipated timing of the completion of the Company's STRIVE-ON trial, the Company's anticipated NDA submission with the FDA, the anticipated use of proceeds raised in the Company's recent private placement offering, and GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH and become the new standard of care in aSAH treatment 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; 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.

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