UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number: 001-35776

Acasti Pharma Inc.
(Exact name of registrant as specified in its charter)

Québec, Canada	**98-1359336**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

103 Carnegie Center Suite 300
Princeton, New Jersey 08540
(Address of principal executive offices, including zip code)

818-839-4378
(Registrant's telephone number, including area code)

2572 boul. Daniel-Johnson, 2nd Floor Laval
Québec, Canada H7T 2R3
(Former name, former address, and former fiscal year, if changed since last report)

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	Nasdaq Stock Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ☒

The number of outstanding common shares of the registrant, no par value per share, as of August 8, 2024, was 10,139,861.

ACASTI PHARMA INC.

QUARTERLY REPORT ON FORM 10-Q

For the Quarter Ended June 30, 2024

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report contains information that may be forward-looking statements within the meaning of Canadian securities laws and forward-looking statements within the meaning of U.S. federal securities laws, both of which we refer to in this quarterly report as forward-looking statements. Forward- looking statements can be identified by the use of terms such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "intend", "estimate", "predict", "potential", "continue" or other similar expressions concerning matters that are not statements about historical facts. Forward-looking statements in this quarterly report include, among other things, information or statements about:

- our ability to build a late-stage pharmaceutical company focused in rare and orphan diseases and, on developing and commercializing products that improve clinical outcomes using our novel drug delivery technologies;
- our ability to apply new proprietary formulations to existing pharmaceutical compounds to achieve enhanced efficacy, faster onset of action, reduced side effects, and more convenient drug delivery that can result in increased patient compliance;
- the potential for our drug candidates to receive orphan drug designation from the U.S. Food and Drug Administration ("FDA") or regulatory approval under the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act ("FDCA");
- the future prospects of our GTX-104 drug candidate, including but not limited to GTX-104's potential to be administered to improve the management of hypotension in patients with aneurysmal subarachnoid hemorrhage ("aSAH"); GTX-104's potential to reduce the incidence of vasospasm in aSAH patients resulting in better outcomes; the ability of GTX-104 to achieve a pharmacokinetic ("PK") and safety profile similar to the oral form of nimodipine; GTX-104's potential to provide improved bioavailability and the potential for reduced use of rescue therapies, such as vasopressors in patients with aSAH the timing and outcome of the Phase 3 safety study for GTX-104; our ability to ultimately file a new drug application ("NDA") for GTX-104 under Section 505(b)(2) of the FDCA; and the timing and ability to receive FDA approval for marketing GTX-104;
- our plan to prioritize the development of GTX-104;

- our plan to maximize the value of our de-prioritized drug candidates, GTX-102 and GTX-101, including through potential development, licensing or sale of those drug candidates;
- the future prospects of our GTX-102 drug candidate, including but not limited to GTX-102's potential to provide clinical benefits to decrease symptoms associated with Ataxia Telangiectasia; GTX-102's potential ease of drug administration; the timing and outcomes of a PK bridging study and Phase 3 efficacy and safety study for GTX-102; the timing of an NDA filing under Section 505(b)(2) in connection with GTX-102; and the ability to receive FDA approval for marketing GTX-102;
- the future prospects of our GTX-101 drug candidate, including but not limited to GTX-101's potential to be administered to postherpetic neuralgia ("PHN") patients to treat the severe nerve pain associated with the disease; assumptions about the biphasic delivery mechanism of GTX-101, including its potential for rapid onset and continuous pain relief for up to eight hours; and the timing and outcomes of single ascending dose/multiple ascending dose and PK bridging studies, and a Phase 2 and Phase 3 efficacy and safety study; the timing of an NDA filing under Section 505 (b)(2) for GTX-101; and the timing and ability to receive FDA approval for marketing GTX-101;
- the quality of our clinical data, the cost and size of our development programs, expectations and forecasts related to our target markets and the size of our target markets; the cost and size of our commercial infrastructure and manufacturing needs in the United States, European Union, and the rest of the world; and our expected use of a range of third-party contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") at multiple locations;
- expectations and forecasts related to our intellectual property portfolio, including but not limited to the probability of receiving orphan drug designation from the FDA for our leading pipeline drug candidates; our patent portfolio strategy; and outcomes of our patent filings and extent of patent protection;
- our intellectual property position and duration of our patent rights;
- our strategy, future operations, prospects and the plans of our management with a goal to enhance shareholder value our need for additional financing, and our estimates regarding our operating runway and timing for future financing and capital requirements;
- our expectation regarding our financial performance, including our costs and expenses, liquidity, and capital resources;
- our projected capital requirements to fund our anticipated expenses; and
- our ability to establish strategic partnerships or commercial collaborations or obtain non-dilutive funding.

Although the forward-looking statements in this quarterly report are based upon what we believe are reasonable assumptions, you should not place undue reliance on those forward-looking statements since actual results may vary materially from them.

In addition, the forward-looking statements in this quarterly report are subject to a number of known and unknown risks, uncertainties and other factors, many of which are beyond our control, that could cause our actual results and developments to differ materially from those that are disclosed in or implied by the forward-looking statements, including, among others:

- We are heavily dependent on the success of our lead drug candidate, GTX-104.
- Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.
- We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our drug candidates, could hinder or prevent our drug candidates' commercial success.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug products, if approved, we may be unable to generate any revenue.
- If we are unable to differentiate our drug products from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve products that compete with any of our drug products, our ability to successfully commercialize our drug products would be adversely affected.
- Our success depends in part upon our ability to protect our intellectual property for our drug candidates.
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.
- We do not have internal manufacturing capabilities, and if we fail to develop and maintain supply relationships with various third-party manufacturers, we may be unable to develop or commercialize our drug candidates.
- The design, development, manufacture, supply, and distribution of our drug candidates are highly regulated and technically complex.
- The other risks and uncertainties identified in Item 1A. Risk Factors and Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended March 31, 2024.

All of the forward-looking statements in this quarterly report are qualified by this cautionary statement. There can be no guarantee that the results or developments that we anticipate will be realized or, even if substantially realized, that they will have the consequences or effects on our business, financial condition, or results of operations that we anticipate. As a result, you should not place undue reliance on these forward-looking statements. Except as required by applicable law, we do not undertake to update or amend any forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are made as of the date of this quarterly report.

We express all amounts in this quarterly report in U.S. dollars, except where otherwise indicated. References to "$" are to U.S. dollars and references to "CAD$" are to Canadian dollars.

Except as otherwise indicated, references in this quarterly report to "Acasti," "the Company," "we," "us" and "our" refer to Acasti Pharma Inc. and its consolidated subsidiaries.

PART I. FINANCIAL INFORMATION

Item 1: Financial Information

Unaudited Condensed Consolidated Financial Statements

ACASTI PHARMA INC.
Condensed Consolidated Balance Sheets
(Unaudited)

(Expressed in thousands except share data)	June 30, 2024 $	March 31, 2024 $
Assets		
Current assets:		
Cash and cash equivalents	19,394	23,005
Short-term investments	15	—
Receivables	398	722
Prepaid expenses	622	283
Total current assets	20,429	24,010
Equipment, net	23	24
Intangible assets	41,128	41,128
Goodwill	8,138	8,138
Total assets	69,718	73,300
Liabilities and Shareholders' equity		
Current liabilities:		
Trade and other payables	2,600	1,684
Total current liabilities	2,600	1,684
Derivative warrant liabilities	2,964	4,359
Deferred tax liability	4,790	5,514
Total liabilities	10,354	11,557
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Class A common shares, no par value per share; unlimited shares authorized; 10,139,861 and 9,399,404 shares issued and outstanding as of June 30, 2024 and March 31, 2024, respectively	261,038	261,038
Class B, C, D and E common shares, no par value per share; unlimited shares authorized; none issued and outstanding	—	—
Additional paid-in capital	18,100	17,862
Accumulated other comprehensive loss	(6,038)	(6,038)
Accumulated deficit	(213,736)	(211,119)
Total shareholders' equity	59,364	61,743
Total liabilities and shareholders' equity	69,718	73,300

See accompanying notes to unaudited condensed consolidated financial statements.

ACASTI PHARMA INC.
Condensed Consolidated Statements of Loss and Comprehensive Loss
(Unaudited)

	Three months ended	
(Expressed in thousands, except share and per share data)	June 30, 2024 $	June 30, 2023 $
Operating expenses		
Research and development expenses, net of government assistance	(2,708)	(1,095)
General and administrative expenses	(2,255)	(1,874)
Restructuring cost	—	(1,485)
Loss from operating activities	(4,963)	(4,454)
Foreign exchange (loss) gain	(8)	8
Change in fair value of derivative warrant liabilities	1,395	—
Interest income and other expense, net	235	134
Total other income, net	1,622	142
Loss before income tax recovery	(3,341)	(4,312)
Income tax benefit	724	289
Net loss and total comprehensive loss	(2,617)	(4,023)
Basic and diluted loss per share	(0.24)	(0.54)
Weighted-average number of shares outstanding	10,928,543	7,435,533

See accompanying notes to unaudited condensed consolidated financial statements.

ACASTI PARMA INC.
Condensed Consolidated Statements of Shareholders' Equity
(Unaudited)

	Class A common shares					
(Expressed in thousands except share data)	Number	Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
		$	$	$	$	$
Balance, March 31, 2024	9,399,404	261,038	17,862	(6,038)	(211,119)	61,743
Issuance of common shares upon cashless exercise of pre-funded warrants	740,457	—	—	—	—	—
Net loss and total comprehensive loss for the period	—	—	—	—	(2,617)	(2,617)
Stock-based compensation	—	—	238	—	—	238
Balance at June 30, 2024	10,139,861	261,038	18,100	(6,038)	(213,736)	59,364

	Class A common shares					
(Expressed in thousands except share data)	Number	Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
		$	$	$	$	$
Balance, March 31, 2023	7,435,533	258,294	13,965	(6,038)	(198,266)	67,955
Net loss and total comprehensive loss for the period	—	—	—	—	(4,023)	(4,023)
Stock-based compensation	—	—	78	—	—	78
Balance at June 30, 2023	7,435,533	258,294	14,043	(6,038)	(202,289)	64,010

See accompanying notes to unaudited condensed consolidated financial statements.

ACASTI PHARMA INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three months ended	
	June 30, 2024	June 30, 2023
(Expressed in thousands)	$	$
Cash flows used in operating activities:		
Net loss	(2,617)	(4,023)
Adjustments:		
Depreciation expense	1	7
Stock-based compensation	238	78
Change in fair value of derivative warrant liabilities	(1,395)	—
Deferred income tax benefit	(724)	(289)
Loss on disposal of equipment	—	13
Changes in operating assets and liabilities:		
Receivables	326	(35)
Prepaid expenses	(339)	(529)
Trade and other payables	913	(1,449)
Operating lease right of use asset	—	(13)
Net cash used in operating activities	(3,596)	(6,240)
Cash flows from investing activities:		
Purchase of short-term investments	(15)	—
Net cash used in investing activities	(15)	—
Effect of exchange rate fluctuations on cash and cash equivalents	—	(2)
Net decrease in cash and cash equivalents	(3,611)	(6,242)
Cash and cash equivalents, beginning of period	23,005	27,875
Cash and cash equivalents, end of period	19,394	21,633
Cash and cash equivalents are comprised of:		
Cash	3,041	5,413
Cash equivalents	16,353	16,220

See accompanying notes to unaudited condensed consolidated financial statements.

1. Nature of operation

Acasti Pharma Inc. (“Acasti” or the “Company”) is incorporated under the Business Corporations Act (Québec) (formerly Part 1A of the Companies Act (Québec)). The Company is domiciled in Canada and its principal executive office is located in Princeton, New Jersey.

The Company’s Class A common shares, no par value per share (“Common Shares”), are listed on the Nasdaq Capital Market (“Nasdaq”).

The Company has incurred operating losses and negative cash flows from operations in each year since its inception. The Company expects to incur significant expenses and continued operating losses for the foreseeable future.

In May 2023, the Company implemented a strategic realignment plan to enhance shareholder value that resulted in the Company engaging a new management team, streamlining its research and development activities and greatly reducing its workforce. Following the realignment, the Company is a smaller, more focused organization, based in the United States, and concentrated on its development of its lead product candidate GTX-104. Further development of GTX-102 and GTX-101 will occur at such time when the Company is able to secure additional funding, or enters into strategic partnerships for license or sale with third parties.

On September 24, 2023, the Company entered into a securities purchase agreement with certain institutional and accredited investors. Gross proceeds to the Company from this private placement were approximately $7,500, before deducting fees and expenses. The Company issued and sold an aggregate of 1,951,371 Common Shares, pre-funded warrants (the "Pre-funded Warrants") to purchase up to an aggregate of 2,106,853 Common Shares, each at a purchase price of $1.848 per Common Share and accompanying common warrants (the "Common Warrants" and, together with the Pre-funded Warrants, the "Warrants") to purchase up to an aggregate of 2,536,391 Common Shares. The Company currently intends to use the net proceeds from the private placement for clinical trial expenses to further the Phase 3 clinical trial for GTX-104, pre-commercial planning, working capital and other general corporate purposes. The Company believes its existing cash and cash equivalents, will be sufficient to fund the Company’s operations into the second calendar quarter of 2026.

The Company will require additional capital to fund its daily operating needs beyond that time. The Company does not expect to generate revenue from product sales unless and until it successfully completes drug development and obtains regulatory approval, which the Company expects will take several years and is subject to significant uncertainty. To date, the Company has financed its operations primarily through public offerings and private placements of its Common Shares, warrants and convertible debt and the proceeds from research tax credits. Until such time that the Company can generate significant revenue from drug product sales, if ever, it will require additional financing, which is expected to be sourced from a combination of public or private equity or debt financing or other non-dilutive sources, which may include fees, milestone payments and royalties from collaborations with third parties. Arrangements with collaborators or others may require the Company to relinquish certain rights related to its technologies or drug product candidates. Adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategy. The Company plans to raise additional capital in order to maintain adequate liquidity. Negative results from studies or trials, if any, or depressed prices of the Company’s stock could impact the Company’s ability to raise additional financing. Raising additional equity capital is subject to market conditions that are not within the Company’s control. If the Company is unable to raise additional funds, the Company may not be able to realize its assets and discharge its liabilities in the normal course of business.

The Company remains subject to risks similar to other development stage companies in the biopharmaceutical industry, including compliance with government regulations, protection of proprietary technology, dependence on third-party contractors and consultants and potential product liability, among others. Please refer to the risk factors included in Part 1, Item 1A of the Company’s Annual Report on Form 10-K for the year ended March 31, 2024, filed with the SEC on June 21, 2024 (the “Annual Report”).

2. Summary of significant accounting policies:

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X under the Securities Exchange Act of 1934. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and as amended by Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements as of and for the year ended March 31, 2024, and, in the opinion of management, reflect all adjustments, consisting of

normal recurring adjustments, necessary for the fair presentation of the Company's consolidated financial position as of June 30, 2024, the consolidated results of its operations for the three months ended June 30, 2024 and 2023, its statements of shareholders' equity for the three months ended June 30, 2024 and 2023, and its consolidated cash flows for the three months ended June 30, 2024 and 2023.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the accompanying notes for the year ended March 31, 2024 included in the Company's Annual Report. The condensed consolidated balance sheet data as of March 31, 2024 presented for comparative purposes was derived from the Company's audited consolidated financial statements. The results for the three months ended June 30, 2024 are not necessarily indicative of the operating results to be expected for the full year or for any other subsequent interim period.

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended March 31, 2024 included in the Annual Report. There have been no changes to the Company's significant accounting policies since the date of the audited consolidated financial statements for the year ended March 31, 2024 included in the Annual Report.

Use of estimates

The preparation of these unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, income, and expenses. Actual results may differ from these estimates.

Estimates are based on management's best knowledge of current events and actions that management may undertake in the future. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Estimates and assumptions include the measurement of stock-based compensation, derivative warrant liabilities, accruals for research and development contracts and contract organization agreements, and valuation of intangibles and goodwill. Estimates and assumptions are also involved in determining the extent to which research and development expenses qualify for research and development tax credits. The Company recognizes tax credits once it has reasonable assurance that they will be realized.

Reclassifications

Certain reclassifications have been made to prior period amounts to conform to current period reporting classifications.

Recent accounting pronouncements

The Company has considered recent accounting pronouncements and concluded that they are either not applicable to the Company's business or that the effect is not expected to be material to the unaudited condensed consolidated financial statements as a result of future adoption.

3. Fair Value Measurements

Assets and liabilities measured at fair value on a recurring basis as of June 30, 2024 are as follows:

	Total $	Quoted prices in active markets (Level 1) $	Significant other observable inputs (Level 2) $	Significant unobservable inputs (Level 3) $
Assets				
Treasury bills and term deposits classified as cash equivalents	16,353	16,353	—	—
Guaranteed investment certificate classified as short-term investments	15	15	—	—
Total assets	16,368	16,368	—	—
Liabilities				
Derivative warrant liabilities	2,964	—	—	2,964
Total liabilities	2,964	—	—	2,964

Assets and liabilities measured at fair value on a recurring basis as of March 31, 2024 are as follows:

	Total $	Quoted prices in active markets (Level 1) $	Significant other observable inputs (Level 2) $	Significant unobservable inputs (Level 3) $
Assets				
Guaranteed investment certificates and term deposits classified as cash equivalents	19,725	19,725	—	—
Total assets	19,725	19,725	—	—
Liabilities				
Derivative warrant liabilities	4,359	—	—	4,359
Total liabilities	4,359	—	—	4,359

There were no changes in valuation techniques or transfers between Levels 1, 2 or 3 during the three months ended June 30, 2024. The Company's derivative warrant liabilities are measured at fair value on a recurring basis using unobservable inputs that are classified as Level 3 inputs. Refer to Note 8 for the valuation techniques and assumptions used in estimating the fair value of the derivative warrant liabilities.

4. Receivables

	June 30, 2024 $	March 31, 2024 $
Sales tax receivables	373	316
Government assistance	—	356
Interest receivable	5	15
Other receivables	20	35
Total receivables	398	722

Government assistance is comprised of research and development investment tax credits from the Québec provincial government, which relate to quantifiable research and development expenditures under the applicable tax laws. The amounts recorded as receivables are subject to a government tax audit and the final amounts received may differ from those recorded.

5. Short-term investments

The Company holds various marketable securities, with maturities greater than 90 days at the time of purchase, as follows:

	June 30, 2024 $	March 31, 2024 $
Guaranteed investment certificate issued in CAD currency earning interest at 3% and maturing on April 1, 2025	15	—
Total short-term investments	15	—

6. Trade and other payables

	June 30, 2024 $	March 31, 2024 $
Trade payables	1,549	1,007
Accrued liabilities and other payables	814	176
Employee salaries and benefits payable	237	501
Total trade and other payables	2,600	1,684

7. Leases

The Company has historically entered into lease arrangements for its research and development and quality control laboratory facility located in Sherbrooke, Québec. In March 2022, the Company renewed the lease agreement effective April 1, 2022, resulting in a commitment of $556 over a 24-month base lease term with an option to renew for an additional 48-month term. In April 2023, the Company elected not to renew the additional 48-month option to renew, and terminated the lease on March 31, 2024. As of June 30, 2024, the Company had one month to month lease for its principal executive offices in Princeton Junction, NJ.

Supplemental lease expense related to leases is as follows:

	Three months ended	
	June 30, 2024	June 30, 2023
	$	$
Operating lease cost	—	23
Total lease expense	—	23

8. Shareholders' Equity

Private Placement

In September 2023, the Company entered into a securities purchase agreement (the "Purchase Agreement") with certain institutional and accredited investors in connection with a private placement of the Company's securities (the "Offering"). Pursuant to the Purchase Agreement, the Company agreed to offer and sell 1,951,371 Common Shares, at a purchase price of $1.848 per Common Share and Pre-funded Warrants to purchase up to 2,106,853 Common Shares at a purchase price equal to the purchase price per Common Share less $0.0001. Each Pre-funded Warrant is exercisable for one Common Share at an exercise price of $0.0001 per Common Share, is immediately exercisable, and will expire once exercised in full. Pursuant to the Purchase Agreement, the Company also issued to such institutional and accredited investors Common Warrants to purchase Common Shares, exercisable for an aggregate of 2,536,391 Common Shares. Under the terms of the Purchase Agreement, for each Common Share and each Pre-funded Warrant issued in the Offering, an accompanying five-eighths (0.625) of a Common Warrant was issued to the purchaser thereof. Each whole Common Warrant is exercisable for one Common Share at an exercise price of $3.003 per Common Share, is immediately exercisable, and will expire on the earlier of (i) the 60th day after the date of the acceptance by the U.S. Food and Drug Administration of a New Drug Application for the Company's product candidate GTX-104 or (ii) five years from the date of issuance.

The Offering closed on September 25, 2023. The Offering included the issuance of Common Shares, Pre-funded Warrants, and Common Warrants to related parties Shore Pharma LLC, an entity that was controlled by Vimal Kavuru, the Chair of our Board of Directors, at the time of the Offering and SS Pharma LLC, the beneficial owner of 5.5% of Common Stock outstanding prior to the Offering, resulting in proceeds of $2,500. The net proceeds to the Company from the Offering were $7,338, after deducting fees and expenses. In June 2024, of the 2,106,853 Pre-funded Warrants, 740,480 were exercised into Common Shares.

Warrants

As further discussed above, on September 25, 2023, the Company issued Pre-Funded Warrants and Common Warrants exercisable for an aggregate of 4,643,244 Common Shares in the Offering pursuant to the terms of the Purchase Agreement entered into with certain institutional and accredited investors.

The Common Warrants issued as a part of the Offering are derivative warrant liabilities given the warrant did not meet the fixed-for-fixed criterion and that the Common Warrants are not indexed to the Company's own stock. Proceeds were allocated amongst Common Shares, Pre-funded Warrants, and Common Warrants by applying the residual method, with fair value of the Common Warrants determined using the Black-Scholes model, resulting in an initial warrant liability of $1,631 and $45 of issuance costs allocated to Common Warrants. Accordingly, $2,822 and $3,047 of gross proceeds were allocated to Common Shares and Pre-funded Warrants, respectively; and $78 and $84 of issuance costs were allocated to Common Shares and Pre-funded Warrants, respectively.

The derivative warrant liabilities are measured at fair value at each reporting period and the reconciliation of changes in fair value is presented in the following table:

	June 30, 2024 $	June 30, 2023 $
Beginning balance	4,359	—
Change in fair value	(1,395)	—
Ending balance	2,964	—

The warrant liability was determined based on the fair value of warrants at the issue date and the reporting dates using the Black-Scholes model with the following weighted-average assumptions that will expire on the earlier of (i) the 60th day after the date of the acceptance by the U.S. Food and Drug Administration of a New Drug Application for the Company's product candidate GTX-104 or (ii) five years from the date on issuance.

	June 30, 2024	March 31, 2024
Risk-free interest rate	4.94%	4.69%
Share price	$2.92	$3.43
Expected warrant life	1.78	2.03
Dividend yield	0%	0%
Expected volatility	79.11%	85.94%

The weighted-average assumptions were prorated based on the probability of the warrant liability expiring on the 60th day after the date of the acceptance by the U.S. Food and Drug Administration of a New Drug Application for the Company's product candidate GTX-104 and of it expiring on five years from the date of issuance. The weighted-average fair values of the Common Warrants were determined to be $1.17 and $1.72 per Common Warrant, as of June 30, 2024 and March 31, 2024, respectively. The risk-free interest rate at the issue date and on the reporting date of June 30, 2024 was based on the interest rate corresponding to the U.S. Treasury rate issue with a remaining term equal to the expected term of the warrants. The expected volatility was based on the historical volatility for the Company.

At June 30, 2024, the Company had outstanding Common Warrants to purchase 2,536,391 Common Shares, with an exercise price of $3.003, all of which were classified as derivative warrant liability. In June 2024, 740,480 Pre-funded Warrants were exercised into 740,457 Common Shares. At June 30, 2024, the Company had outstanding Pre-funded Warrants to purchase 1,366,419 Common Shares, with an exercise price of $0.0001, all of which were classified within shareholders' equity.

9. Stock-based compensation

Stock option plan

At June 30, 2024, the Company had in place a stock option plan for directors, officers, employees, and consultants of the Company (“Stock Option Plan”). As of June 30, 2024, there were 540,595 awards available under the plan for issuance.

The Stock Option Plan provides for the granting of options to purchase Common Shares. Under the terms of the Stock Option Plan, the exercise price of the stock options granted under the Stock Option Plan may not be lower than the closing price of the Company’s Common Shares on the Nasdaq Capital Market at the close of such market the day preceding the grant. The maximum number of Common Shares that may be issued upon exercise of options granted under the Stock Option Plan shall not exceed 20% of the aggregate number of issued and outstanding shares of the Company as of July 28, 2022. The terms and conditions for acquiring and exercising options are set by the Company’s Board of Directors, subject to, among others, the following limitations: the term of the options cannot exceed ten years and (i) all options granted to a director will be vested evenly on a monthly basis over a period of at least twelve (12) months, and (ii) all options granted to an employee will be vested evenly on a quarterly basis over a period of at least thirty-six (36) months.

The total number of options issued to any one consultant within any twelve-month period cannot exceed 2% of the Company’s total issued and outstanding Common Shares (on a non-diluted basis). The total number of options issued within any twelve-month period to all directors, employees and/or consultants of the Company (or any subsidiary of the Company) conducting investor relations services, cannot exceed in the aggregate 2% of the Company’s issued and outstanding Common Shares (on a non-diluted basis), calculated at the date an option is granted to any such person.

The following table summarizes information about activities within the Stock Option Plan for the three-month period ended June 30, 2024:

	Number of options	Weighted-average exercise price $	Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, March 31, 2024	721,793	3.68	9.08	527
Granted	198,130	2.96		
Outstanding, June 30, 2024	919,923	3.53	9.05	241
Exercisable, June 30, 2024	378,174	4.41	8.65	115

The weighted-average grant date fair value of awards for options granted during the three months ended June 30, 2024 was $2.52. The fair value of options granted was estimated using the Black-Scholes option pricing model, resulting in the following weighted-average assumptions for the options granted:

	June 30, 2024 Weighted-average	June 30, 2023 Weighted-average
Exercise price	$2.96	—
Share price	$2.96	—
Dividend	—	—
Risk-free interest	4.43%	—
Estimated life (years)	5.81	—
Expected volatility	114.37%	—

Compensation expense recognized under the Stock Option Plan is summarized as follows:

	Three months ended	
	June 30, 2024 $	June 30, 2023 $
Research and development expenses	65	2
General and administrative expenses	173	76
	238	78

As of June 30, 2024, there was $689 of total unrecognized compensation cost, related to non-vested stock options, which is expected to be recognized over a remaining weighted-average vesting period of 1.39 years.

Equity incentive plan

The Company established an equity incentive plan (the “Equity Incentive Plan”) for employees, directors, and consultants. The Equity Incentive Plan provides for the issuance of 1,483,140 restricted share units, performance share units, restricted shares, deferred share units and other stock-based awards, subject to restricted conditions as may be determined by the Board of Directors. There were no such awards outstanding as of June 30, 2024, and no stock-based compensation was recognized for the three months ended June 30, 2024.

10. Loss per share

The Company has generated a net loss for all periods presented. Therefore diluted loss per share is the same as basic loss per share since the inclusion of potentially dilutive securities would have had an anti-dilutive effect. All currently outstanding options and warrants could potentially be dilutive in the future.

The Company excluded the following potential Common Shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

	June 30, 2024	June 30, 2023
Options outstanding	919,923	473,178
September 2023 Common Warrants	2,536,391	—

Basic and diluted net loss per share is calculated based upon the weighted-average number of Common Shares outstanding during the period. Common Shares underlying the Pre-funded Warrants are included in the calculation of basic and diluted earnings per share.

11. Commitments and contingencies

Research and development contracts and contract research organizations agreements

The Company utilizes CMOs for the development and production of clinical materials and CROs to perform services related to its clinical trials. Pursuant to the agreements with these CMOs and CROs, the Company has either the right to terminate the agreements without penalties or under certain penalty conditions. As of June 30, 2024, the Company has no commitments due to CMOs and $5,876 of commitments for the next twelve months to CROs.

Raw krill oil supply contract

On October 25, 2019, the Company signed a supply agreement with Aker BioMarine Antarctic AS. ("AKBM") to purchase raw krill oil product for a committed volume of commercial starting material for CaPre, one of the Company's former drug candidates, for a total fixed value of $3,100 based on the value of krill oil at that time. As of March 31, 2022, the remaining balance of commitment amounted to $2,800. 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. 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. The dispute remained unresolved as of both March 31, 2023 and 2022. On October 18, 2023, the Company entered into an agreement with AKBM to settle any and all potential claims regarding amounts due under the supply agreement ("Settlement Agreement"). 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 retained ownership of all raw krill oil product, including amounts previously delivered to the Company, (b) AKBM acquired and took ownership of all production equipment related to the production of CaPre, (c) AKBM acquired and took ownership of all data from research, clinical trials and pre-clinical studies with respect to CaPre, and (d) AKBM acquired and took ownership over all rights, title and interest in and to all intellectual property rights, including all patents and trademarks, related to CaPre owned by the Company. Pursuant to the terms of the Settlement Agreement, AKBM acknowledged that the CaPre assets were 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 value of the raw krill oil previously delivered to the Company, the production equipment, and the intellectual property rights related to CaPre were fully impaired in prior reporting periods and had a carrying value of nil as of March 31, 2023. For the three months ended June 30, 2024, there was $193 in expenses recorded by the Company in relation to shipping cost to transport the Company's production equipment related to the production of CaPre.

Legal proceedings and disputes

In the ordinary course of business, the Company is at times subject to various legal proceedings and disputes. The Company assesses its liabilities and contingencies in connection with outstanding legal proceedings utilizing the latest information available. Where it is probable that the Company will incur a loss and the amount of the loss can be reasonably estimated, the Company records a liability in its consolidated financial statements. These legal contingencies may be adjusted to reflect any relevant developments. Where a loss is not probable or the amount of loss is not estimable, the Company does not accrue legal contingencies. While the outcome of legal proceedings is inherently uncertain, based on information currently available, management believes that it has established appropriate legal reserves. Any incremental liabilities arising from pending legal proceedings are not expected to have a material adverse effect on the Company's financial position, results of operations, or cash flows. However, it is possible that the ultimate resolution of these matters, if unfavorable, may be material to the Company's financial position, results of operations, or cash flows. No reserves or liabilities have been accrued as of June 30, 2024.

12. Restructuring costs

On May 8, 2023, the Company communicated its decision to terminate a substantial amount of its workforce as part of a plan that intended to align the Company's organizational and management cost structure to prioritize resources to GTX-104, thereby reducing losses to improve cash flow and extend available cash resources. During the three months ended, June 30, 2023, the Company incurred $1,485 of costs primarily consisting of employee severance costs and legal fees. There were no restructuring cost incurred during the three months ended June 30, 2024.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation

This management's discussion and analysis ("MD&A") is presented in order to provide the reader with an overview of the financial results and changes to our consolidated balance sheet at June 30, 2024. This MD&A also explains the material variations in our results of operations for the three months ended June 30, 2024 and 2023, consolidated balance sheets as of June 30, 2024 and March 31, 2024, and cash flows for the three months ended June 30, 2024 and 2023.

Market data, and certain industry data and forecasts included in this MD&A were obtained from internal Company surveys and market research conducted by third parties hired by us, publicly available information, reports of governmental agencies and industry publications, and independent third-party surveys. We have relied upon industry publications as our primary sources for third-party industry data and forecasts. Industry surveys, publications and forecasts generally state that the information they contain has been obtained from sources believed to be reliable, but that the accuracy and completeness of that information are not guaranteed. We have not independently verified any of the data from third-party sources or the underlying economic assumptions they have made. Similarly, internal surveys, industry forecasts and market research, which we believe to be reliable based upon our management's or contracted third parties' knowledge of our industry, have not been independently verified. Our estimates involve risks and uncertainties, including assumptions that may prove not to be accurate, and these estimates and certain industry data are subject to change based on various factors, including those discussed in this quarterly report and in our most recently filed Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on June 21, 2024 (the "Annual Report"). This MD&A contains forward-looking information. You should review our Special Note Regarding Forward-Looking Statements presented at the beginning of this quarterly report.

This MD&A should be read in conjunction with our unaudited condensed consolidated interim financial statements for the three months ended June 30, 2024 and 2023 included elsewhere in this quarterly report. Our unaudited condensed consolidated financial statements were prepared in accordance with U.S. GAAP.

All amounts appearing in this MD&A for the period-by-period discussions are in thousands of U.S. dollars, except share and per share amounts or unless otherwise indicated.

Business Overview

We are focused on developing and commercializing products for rare and orphan diseases that have the potential to improve clinical outcomes by using our novel drug delivery technologies. We seek to apply new proprietary formulations to approved and marketed pharmaceutical compounds to achieve enhanced efficacy, faster onset of action, reduced side effects, more convenient drug delivery and increased patient compliance; all of which could result in improved patient outcomes. The active pharmaceutical ingredients used in the drug candidates under development by Acasti may be already approved in a target indication or could be repurposed for use in new indications.

The existing well understood efficacy and safety profiles of these marketed compounds provide the opportunity for us to utilize the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act ("FDCA") for the development of our reformulated versions of these drugs, and therefore may provide a potentially shorter path to regulatory approval. Under Section 505(b)(2), if sufficient support of a product's safety and efficacy either through previous U.S. Food and Drug Administration ("FDA") experience or sufficiently within the existing and accepted scientific literature, can be established, it may eliminate the need to conduct some of the pre-clinical studies and clinical trials that new drug candidates might otherwise require.

Our therapeutic pipeline consists of three unique clinical-stage drug candidates supported by an intellectual property portfolio of more than 40 granted and pending patents in various jurisdictions worldwide. These drug candidates aim to improve clinical outcomes in the treatment of rare and orphan diseases by applying proprietary formulation and drug delivery technologies to existing pharmaceutical compounds to achieve improvements over the current standard of care, or to provide treatment for diseases with no currently approved therapies.

We believe that rare disorders represent an attractive area for drug development, and there remains an opportunity for us to utilize already approved drugs that have established safety profiles and clinical experience to potentially address significant unmet medical needs. A key advantage of pursuing therapies for rare disorders is the potential to receive orphan drug designation ("ODD") from the FDA. Our three drug candidates have received ODD status, provided certain conditions are met at new drug application ("NDA") approval. ODD provides for seven years of marketing exclusivity in the United States post-launch, provided certain conditions are met, and the potential for faster regulatory review. ODD status can also result in tax credits of up to 50% of clinical development costs conducted in the United States upon marketing approval and a waiver of the NDA fees, which we estimate can translate into savings of approximately $3.2 million for our lead drug candidate, GTX-104. Developing drugs for rare diseases can often allow for clinical trials that are more manageably scaled and may require a smaller, more targeted commercial infrastructure.

The specific diseases targeted for drug development by us are well understood, although the patient populations suffering from such diseases may remain poorly served by available therapies or, in some cases, approved therapies do not yet exist. We aim to effectively treat debilitating symptoms that result from these underlying diseases.

Our lead drug candidate:

- GTX-104 is a clinical-stage, novel, injectable formulation of nimodipine being developed for intravenous ("IV") infusion in aneurysmal subarachnoid hemorrhage ("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 eliminating the need for nasogastric tube administration in unconscious or dysphagic patients. IV 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 ("PK") variability compared to oral nimodipine. On October 23, 2023, we enrolled our first patient in our pivotal Phase 3 safety trial to evaluate GTX-104 in patients hospitalized for aSAH. Patient enrollment in the STRIVE-ON Phase 3 trial is continuing, and potential NDA submission with the FDA is anticipated to occur in the first half of calendar 2025.
- On June 27, 2024, we announced that our pivotal Phase 3 STRIVE-ON safety trial had exceeded the 50% patient enrollment milestone.

Other pipeline drug candidates:

- GTX-102, an oral-mucosal betamethasone spray for the treatment of Ataxia Telangiectasia (“A-T”), a complex orphan pediatric genetic neurodegenerative disorder usually diagnosed in young children, for which no FDA approved treatment currently exists.

- GTX-101, a topical bioadhesive film-forming bupivacaine spray for Postherpetic Neuralgia (“PHN”), which can be persistent and often causes debilitating pain following infection by the shingles virus. We believe that GTX-101 could be administered to patients with PHN to treat pain associated with the disease.

In May 2023, we announced the strategic decision to prioritize development of GTX-104 with a goal to advance the product candidate to commercialization, while conserving resources as much as possible to complete development efficiently. We estimate that the deferral of GTX-102 and GTX-101 clinical development could be at least three years given the timeline to complete the development and potential commercial launch of GTX-104. Further development of GTX-102 and GTX-101 will occur at such time as we obtain additional funding, or enter into strategic partnerships for license or sale with third parties.

The decision to defer further development of GTX-102 and GTX-101 triggered a comprehensive impairment review of our intangible assets as of March 31, 2023. Given the extended timeline, we increased the discount rates used to value the related assets in order to recognize additional risks related to prioritizing one asset over the others, the financing for the projects given limited available resources and the need to preserve cash to advance GTX-104 as far as possible, potential competitor advances that could arise over three years, the general market depression affecting small cap development companies like us, and the prohibitively high dilution and expense of available funding in the capital markets. Increasing the discount rates significantly reduced the discounted cash flow values for each of the programs deferred. Accordingly, in the year ended March 31, 2023, we recorded impairment charges related to GTX-102 and GTX-101 of $22.7 million and $6.0 million respectively, together with further adjustments made to deferred taxes and goodwill directly related to those assets. The aggregate impairment charge was $33.5 million. We continue to believe that GTX-102 and GTX-101 may eventually provide significant value when development resumes and, if approved, commercialized successfully.

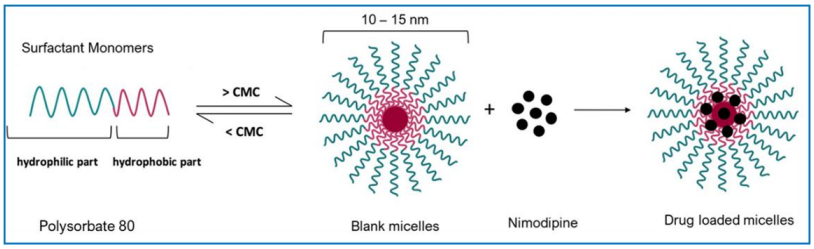
Our management team possesses significant experience in drug formulation and drug delivery research and development, clinical and pharmaceutical development and manufacturing, regulatory affairs, and business development, as well as being well-versed in late-stage drug development and commercialization. Importantly, our team is comprised of industry professionals with deep expertise and knowledge, including a world-renowned practicing neurosurgeon-scientist and respected authority in aSAH, as well as product development, chemistry, manufacturing and controls (“CMC”), planning, implementation, management, and execution of global Phase 2 and Phase 3 trials for GTX-104, and drug commercialization.

GTX-104 Overview

Nimodipine was granted FDA approval in 1988, and is the only approved drug that has been clinically shown to improve neurological outcomes in aSAH patients. It is only available in the United States as a generic oral capsule and as a branded oral liquid solution called NYMALIZE™, which is manufactured and sold by Arbor Pharmaceuticals (acquired in September 2021 by Azurity Pharmaceuticals). Nimodipine has poor water solubility and high permeability characteristics as a result of its high lipophilicity. Additionally, orally administered nimodipine has dose-limiting side-effects such as hypotension, poor absorption and low bioavailability resulting from high first-pass metabolism, and a narrow administration window as food effects lower bioavailability significantly. Due to these issues, blood levels of orally administered nimodipine can be highly variable, making it difficult to manage blood pressure in aSAH patients. Nimodipine capsules are also difficult to administer, particularly to unconscious patients or those with impaired ability to swallow. Concomitant use with CYP3A inhibitors is contraindicated (NIMODIPINE Capsule PI).

NIMOTOP™ is an injectable form of nimodipine that is manufactured by Bayer Healthcare. It is approved in Europe and in other regulated markets (but not in the United States). It has limited utility for aSAH patients because of its high organic solvent content, namely 23.7% ethanol and 17% polyethylene glycol 400 (NIMOTOP SmPC).

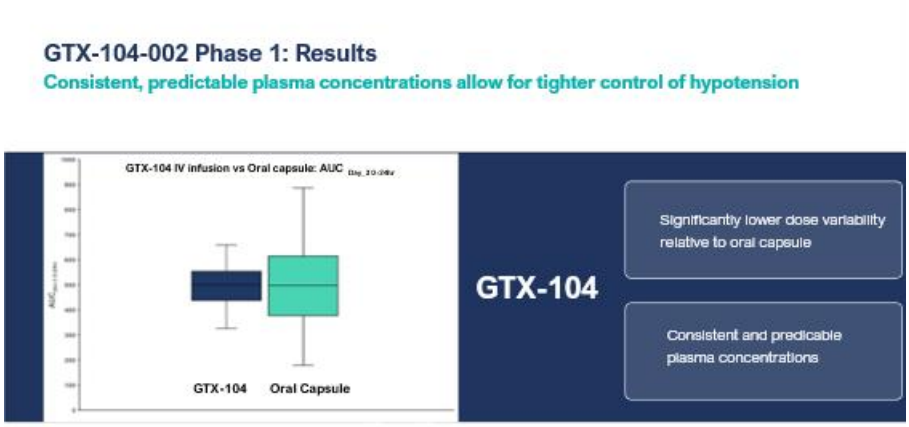
- GTX-104 is a clinical-stage, novel formulation of nimodipine for IV infusion in aSAH patients. It uses surfactant micelles as the drug carrier to solubilize nimodipine. This unique nimodipine injectable formulation is composed of a nimodipine base, an effective amount of polysorbate 80, a non-ionic hydrophilic surfactant, and a pharmaceutically acceptable carrier for injection. GTX-104 is supplied as an aqueous concentrate that upon dilution with saline, dextrose or lactated ringer, is a ready-to-use infusion solution, which is stable and clear.



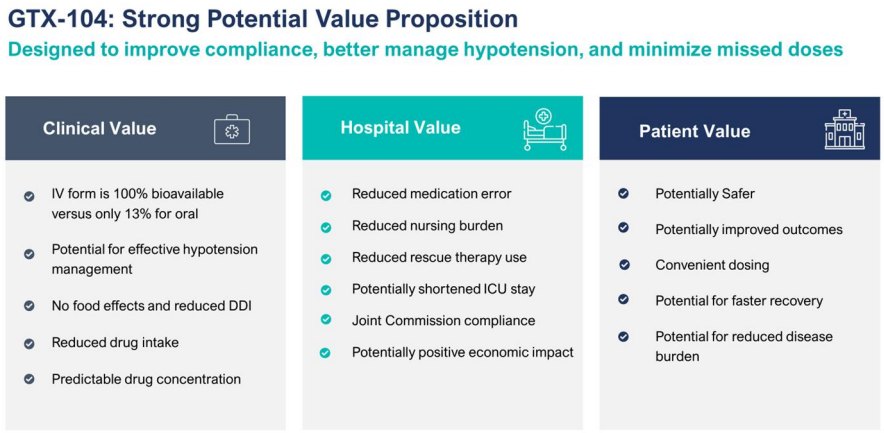
Key potential benefits of GTX-104 include:

- Novel nanoparticle technology facilitates aqueous formulation of insoluble nimodipine for a safe, standard peripheral IV infusion
- Better control of blood pressure and improved management of hypotension
- 100% bioavailability
- Eliminates food effects that impact the absorption of the oral form of nimodipine
- Lower inter and intra-subject variability as compared to oral nimodipine

GTX-104 could provide a more convenient mode of administration as compared to generic nimodipine capsules or NYMALIZE™. GTX-104 is administered as an IV infusion compared to oral administration via a nasogastric tube in unconscious patients every four hours for both nimodipine capsules and NYMALIZE™. Therefore, GTX-104 could make a major contribution to patient care by potentially reducing the dosing associated nursing burden. More convenient, continuous, and consistent dosing may also reduce the risk of medication errors. In addition, as depicted in the charts below, two PK studies conducted by us have shown that GTX-104 has the potential to provide improved bioavailability and show reduced inter- and intra-subject variability compared to oral nimodipine, which is hypothesized to limit the risk of hypotension and to better achieve a desired therapeutic concentration. Following the capsule administration, the variability was observed higher as compared to IV infusion administration (nimodipine exposure variability at steady state observed 37.5% following oral capsule administration versus 15.5%, following GTX-104 IV infusion). Because of its IV formulation, we also expect GTX-104 to reduce certain drug-drug interactions and food effects.



Despite the positive impact it has on recovery, physicians often must discontinue their patients from oral nimodipine, primarily as a result of hypotensive episodes that cannot be controlled by titrating the oral form of drug. Such discontinuation could potentially be avoided by administering GTX-104, which because of its IV administration, may reduce the complexity associated with the need for careful attention to the timing of nimodipine administration at least one hour before or two hours after a meal. Also, unconscious patients will likely receive more consistent concentrations of nimodipine when delivered via the IV route as compared to oral gavage or a nasogastric tube. More consistent dosing is expected to result in a reduction of vasospasm and a better, more consistent management of hypotension. As summarized in the table below, we also anticipate reduced use of rescue therapies, such as vasopressors, and expensive hospital resources, such as the angiography suite, are possible by more effectively managing blood pressure with GTX-104. Reduced incidences of vasospasm could result in shorter length of stay and better outcomes.



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 (aSAH) that accounts for about 5% of all strokes and has an incidence of six per 100,000 person years.

In contrast to more common types of ischemic stroke in elderly individuals, aSAH often occurs at a relatively young age, with approximately half the affected patients younger than 60 years old. Approximately 10% to 15% of aSAH patients die before reaching the hospital, and those who survive the initial hours post hemorrhage are admitted or transferred to tertiary care centers with high risk of complications, including rebleeding and delayed cerebral ischemia ("DCI"). Systemic manifestations affecting cardiovascular, pulmonary, and renal function are common and often complicate management of DCI. Approximately 70% of aSAH patients experience death or a permanent disability, and the mortality rate is about 8.7% at one week, 18.4% at three months, 22.9% at one year, and 29% at five years after the hemorrhage. Of those who survive the initial month, half remain permanently dependent on a caregiver to maintain daily living.

We estimate that approximately 50,000 individuals experience aSAH each year in the U.S. based on third-party market research, and that total addressable market for aSAH is approximately $300 million in the U.S. There are an estimated 150,000 aSAH patients each year in China and approximately 55,000 patients in the European Union. The unmet needs in the treatment of aSAH and the potential of GTX-104 to address the limitations of the current standard of care were the subject of a Key Opinion Leader event we hosted on October 4, 2023. In an independent market research survey we conducted of hospital administrators, critical and neuro intensive care physicians at institutions with Comprehensive or Advanced Stroke Center certification who are involved in purchasing decisions for their institutions/units, respondents reported 80% likelihood of adopting an IV formulation of nimodipine (GTX-104), assuming 100% bioavailability, better safety, no food effects, effective hypotension management, potential hospital value and patient value.

GTX-104 Development Milestones

In September 2021, we initiated our pivotal PK bridging trial to evaluate the relative bioavailability of GTX-104 compared to currently marketed oral nimodipine capsules in approximately 50 healthy subjects. The PK trial was the next required step in our proposed 505(b)(2) regulatory pathway for GTX-104.

Final results from this pivotal PK trial were reported in May 2022, and showed that the bioavailability of GTX-104 compared favorably with the oral formulation of nimodipine in all subjects, and no serious adverse events were observed for GTX-104.

All endpoints indicated that statistically there was no difference in exposures between GTX-104 and oral nimodipine over the defined time periods for both maximum exposure and total exposure. Plasma concentrations obtained following IV administration showed significantly less variability between subjects as compared to oral administration of capsules, since IV administration is not as sensitive to some of the physiological processes that affect oral administration, such as taking the drug with and without meals, variable gastrointestinal transit time, variable drug uptake from the gastrointestinal tract into the systemic circulation, and variable hepatic blood flow and hepatic first pass metabolism. Previous studies have shown these processes significantly affect the oral bioavailability of nimodipine, and therefore cause oral administration to be prone to larger inter- and intra-subject variability.

The bioavailability of oral nimodipine capsules observed was only approximately 8% compared to 100% for GTX-104. Consequently, about one-twelfth the amount of nimodipine is delivered with GTX-104 to achieve the same blood levels as with the oral capsules.

No serious adverse events and no adverse events leading to withdrawal were reported during the trial.

Phase 3 STRIVE-ON Randomized Safety Trial for GTX-104

In April 2023, we received a Type C written meeting response and clarifying feedback from the FDA on our proposed pivotal Phase 3 safety trial for GTX-104. The FDA provided additional comments on our development plan that, pending submission of the final clinical protocol and FDA approval, would allow us to proceed with a pivotal Phase 3 safety clinical trial in aSAH patients. On July 5, 2023, we announced the alignment with the FDA on our GTX-104 pivotal Phase 3 safety clinical trial protocol.

The FDA concurred with the suitability of the 505(b)(2) regulatory pathway with the selected Reference Listed Drug NIMOTOP oral capsules ("NDA 018869"), and that our GTX-104-002 PK trial may have met the criteria for a scientific bridge.

The design of our Phase 3 safety clinical trial, which we have titled STRIVE-ON (Safety, Tolerability, Randomized, IV and Oral Nimodipine), is a prospective, open-label, randomized (1:1 ratio), parallel group trial of GTX-104 compared with oral nimodipine, in patients hospitalized for aSAH. Key trial design features include:

- Approximately 100 patients will be enrolled at an estimated 25 hospitals in the U.S.
- The primary endpoint is safety and will be measured as comparative adverse events, including hypotension, between the two groups.
- GTX-104 will be administered as a continuous IV infusion of 0.15 mg/hour, and a 30-minute IV bolus of 4 mg every 4 hours. Oral nimodipine will be administered as 60 mg (two 30 mg capsules) every 4 hours.
- Both groups will receive their assigned GTX-104 or oral nimodipine for up to 21 consecutive days and will be evaluated from commencement of patient treatment through a 90-day follow-up period.

On October 23, 2023, we enrolled our first patient in our STRIVE-ON clinical trial. Patient enrollment in the STRIVE-ON Phase 3 trial is continuing, and potential NDA submission with the FDA is anticipated to occur in the first half of calendar 2025. We expect this safety trial to be the final clinical step required to seek FDA approval under the 505(b)(2) regulatory pathway.

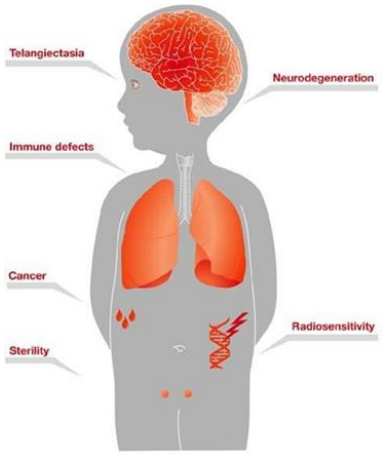
On June 27, 2024, we announced that our pivotal Phase 3 STRIVE-ON safety trial had exceeded the 50% enrollment milestone.

GTX-102 Overview

GTX-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of A-T for which there are currently no FDA-approved therapies. GTX-102 is a stable, concentrated oral spray formulation comprised of the gluco-corticosteroid betamethasone that, together with other excipients can be sprayed conveniently over the tongue of the A-T patient and is rapidly absorbed.

About Ataxia Telangiectasia

A-T is a rare genetic progressive autosomal recessive neurodegenerative disorder that affects children, with the hallmark symptoms of cerebellar ataxia and other motor dysfunction, and dilated blood vessels (telangiectasia) that occur in the sclera of the eyes. A-T is caused by mutations in the ataxia telangiectasia gene, which is responsible for modulating cellular response to stress, including breaks in the double strands of DNA.



Children with A-T begin to experience balance and coordination problems when they begin to walk (toddler age), and ultimately become wheelchair-bound in their second decade of life. In pre-adolescence (between ages 5 and 8), patients experience oculomotor apraxia, dysarthria, and dysphagia. They also often develop compromised immune systems and are at increased risk of developing respiratory tract infections and cancer (typically lymphomas and leukemia).

A-T is diagnosed through a combination of clinical assessment (especially neurologic and oculomotor deficits), laboratory analysis, and genetic testing. There is no known treatment to slow disease progression, and treatments that are used are strictly aimed at controlling the symptoms (e.g., physical, occupational or speech therapy for neurologic issues), or conditions secondary to the disease (e.g., antibiotics for lung infections, chemotherapy for cancer, etc.). There are no FDA-approved therapeutic options currently available. Patients typically die by age 25 from complications of lung disease or cancer. According to a third-party report we commissioned, A-T affects approximately 4,300 patients per year in the United States and has a potential total addressable market of $150 million, based on the number of treatable patients in the United States.

GTX-102 - Research & Development and Clinical Trials to Date

We have licensed the data from the multicenter, double-blinded, randomized, placebo-controlled crossover trial from Azienda Ospedaliera Universitaria Senese, Siena, Italy, where Dr. Zannolli et. al. studied the effect of oral liquid solution of betamethasone to reduce ataxia symptoms in patients with A-T. This oral liquid solution is not marketed in the United States, and therefore is not available for clinical use. Currently, betamethasone is only available in the United States as an injectable or as a topical cream. This license gives us the right to reference the trial's data in our NDA filing. On November 12, 2015, we submitted the data from the Zannolli trial to the FDA's Division of Neurology at a pre-Investigational New Drug ("IND") meeting and received guidance from the agency on the regulatory requirements to seek approval.

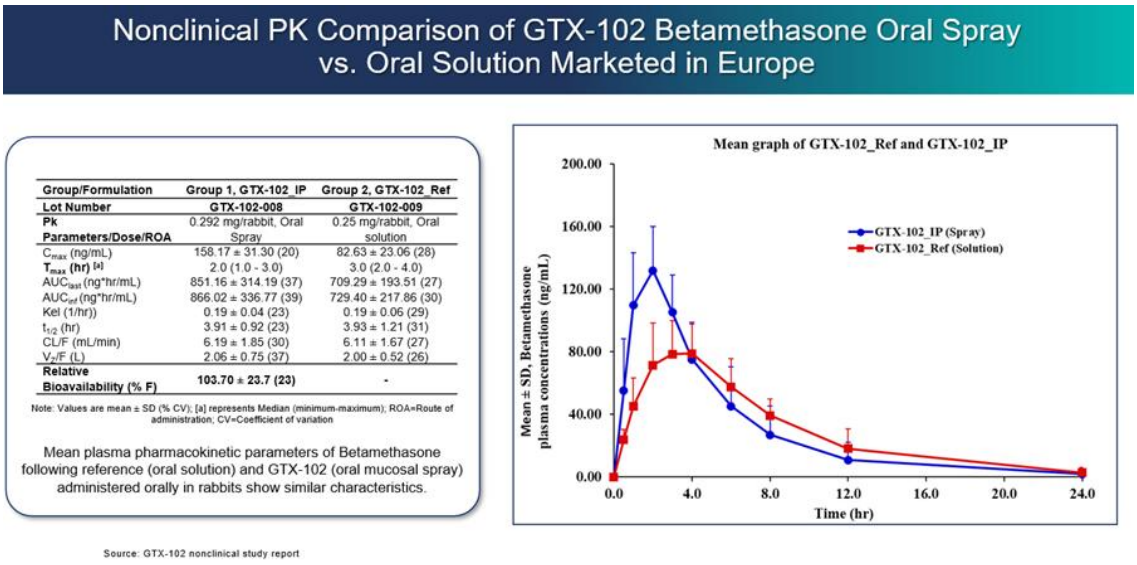
In a multicenter, double-blind, randomized, placebo-controlled crossover trial conducted in Italy, Dr. Zannolli et al. studied the effect of an oral liquid solution of betamethasone on the reduction of ataxia symptoms in 13 children (between ages 2 to 8 years) with A-T. The primary outcome measure was the reduction in ataxia symptoms as assessed by the International Cooperative Ataxia Rating Scale ("ICARS").

In the trial, oral liquid betamethasone reduced the ICARS total score by a median of 13 points in the intent-to-treat population and 16 points in the per-protocol population (the median percent decreases of ataxia symptoms of 28% and 31%, respectively). Adverse events in the trial were minimal, with no compulsory withdrawals and only minor side effects that did not require medical intervention. Clinical trial results in A-T patients administered oral betamethasone indicated that betamethasone significantly reduced ICARS total score relative to placebo ($P = 0.01$). The median ICARS change score (change in score with betamethasone minus change in score with placebo) was -13 points (95% confidence interval for the difference in medians was -19 to -5.5 points).

Based on the Zannolli data, we believe that our GTX-102 concentrated oral spray has the potential to provide clinical benefits in decreasing A-T symptoms, including assessments of posture and gait disturbance and kinetic, speech and oculomotor functions. In addition, GTX-102 may ease drug administration for patients experiencing A-T given its application of 1-3x/day of 140µL of concentrated betamethasone liquid sprayed onto the tongue using a more convenient metered dose delivery system, as these A-T patients typically have difficulty swallowing.

GTX-102 PK Data to Date:

GTX-102 administered as a concentrated oral spray achieves similar blood levels at only 1/70th the volume of an oral solution of betamethasone. This more convenient mode of administration will be important for A-T patients who have difficulties swallowing large volumes of liquids.



Source: GTX-102 nonclinical study report

We initiated a PK bridging trial of GTX-102 as compared to the oral liquid solution of betamethasone used in the Zannolli trial and against the injectable form of betamethasone that is approved in the U.S. in the third calendar quarter of 2022. The primary objectives of the PK bridging trial were to evaluate the bioavailability, pharmacokinetics and safety of GTX-102. In December 2022, we reported that the topline results of this trial met all primary outcome measures.

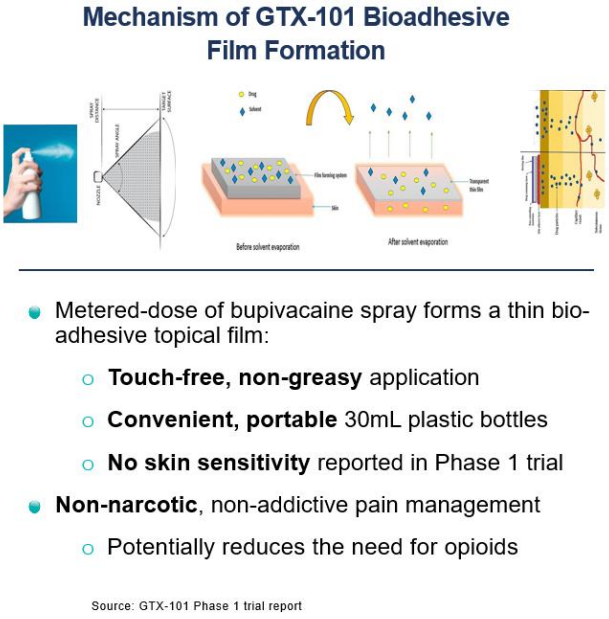
Results showed that GTX-102 betamethasone blood concentrations were highly predictable and consistent based on AUC (the area under the concentration time curve up to 72 hours post-dose, extrapolated to infinity) and Cmax (the maximum concentration occurring between 0 hour to 72 hours after trial drug administration), indicating good linearity and dose-proportionality. GTX-102 betamethasone blood concentrations were within the same range of exposure as IM betamethasone, based on AUC. This IM formulation will serve as a bridge for GTX-102 in the context of the proposed 505(b)(2) regulatory pathway. GTX-102 betamethasone blood concentrations were also within the same range of exposure as Oral Solution ("OS"), based on AUC. This OS formulation was used by Zannolli and may serve as a clinical comparator for further clinical development. Furthermore, statistically there was no significant difference ($p>0.05$) between GTX-102 administered at a fast rate (each spray immediately following the preceding one) vs. a slow rate (1 spray/minute), as indicated by Cmax and AUC. We believe this result is important because being able to use the fast or the slow rate of administration may provide greater flexibility for patients and caregivers. The Cmax of GTX-102 was within the same range of exposure as the OS, but the Cmax for the IM formulation was lower than both GTX-102 and the OS, as well as what has been reported previously for the IM in industry publications. It is important to note that achieving bioequivalence with the IM was not an objective of this trial, nor was it expected. Finally, of the 48 healthy adult subjects, no serious adverse events were reported, and the most frequent drug-related adverse effect was mild headache (4 cases).

The further clinical development of GTX-102 has been deprioritized in favor of our focus on development of GTX-104. However, we plan to collaborate with clinical experts to design the Phase 3 safety and efficacy protocol for GTX-102 and gain alignment with the FDA on the

development path forward. Further clinical development work will be contingent on additional funding for GTX-102 or the signing of a strategic partnership. It is also possible that we may license or sell our GTX-102 drug candidate.

GTX-101 Overview

GTX-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to ease the symptoms of patients suffering with postherpetic neuralgia ("PHN"). GTX-101 is administered via a metered-dose of bupivacaine spray and forms a thin bio-adhesive topical film on the surface of the patient's skin, which enables a touch-free, non-greasy application. It also comes in convenient, portable 30 ml plastic bottles. Unlike oral gabapentin and lidocaine patches which are used for the treatment of PHN, we believe that the biphasic delivery mechanism of GTX-101 has the potential for rapid onset of action and continuous pain relief for up to eight hours. No skin sensitivity was reported in a Phase 1 trial.



About Postherpetic Neuralgia (PHN)

PHN is neuropathic pain due to damage caused by the varicella zoster virus ("VZV"). Infection with VZV causes two distinct clinical conditions. Primary VZV infection causes varicella (i.e., chickenpox), a contagious rash illness that typically occurs among young children. Secondary VZV can reactivate clinically, decades after initial infection, to cause herpes zoster ("HZ"), otherwise known as shingles. Acute HZ arises when dormant virus particles, persisting within an affected sensory ganglion from the earlier, primary infection with VZV become reactivated when cellular immunity to varicella decreases. Viral particles replicate and may spread to the dorsal root, into the dorsal horn of the spinal cord, and through peripheral sensory nerve fibers down to the level of the skin. Viral particles also may circulate in the blood. This reactivation is accompanied by inflammation of the skin, immune response, hemorrhage, and destruction of peripheral and central neurons and their fibers. Following such neural degeneration, distinct types of pathophysiological mechanisms involving both the central and peripheral nervous systems may give rise to the severe nerve pain associated with PHN.

While the rash associated with HZ typically heals within two to four weeks, the pain may persist for months or even years, and this PHN manifestation is the most common and debilitating complication of HZ. There is currently no consensus definition for PHN, but it has been suggested by the Centers for Disease Control and Prevention ("CDC") that PHN is best defined as pain lasting at least three months after resolution of the rash.

PHN is associated with significant loss of function and reduced quality of life, particularly in the elderly. It has a detrimental effect on all aspects of a patient's quality of life. The nature of PHN pain varies from mild to severe, constant, intermittent, or triggered by trivial stimuli. Approximately half of patients with PHN describe their pain as "horrible" or "excruciating," ranging in duration from a few minutes to

constant on a daily or almost daily basis. The pain can disrupt sleep, mood, work, and activities of daily living, adversely impacting the quality of life and leading to social withdrawal and depression. PHN is the number-one cause of intractable, debilitating pain in the elderly, and has been cited as the leading cause of suicide in chronic pain patients over the age of 70.

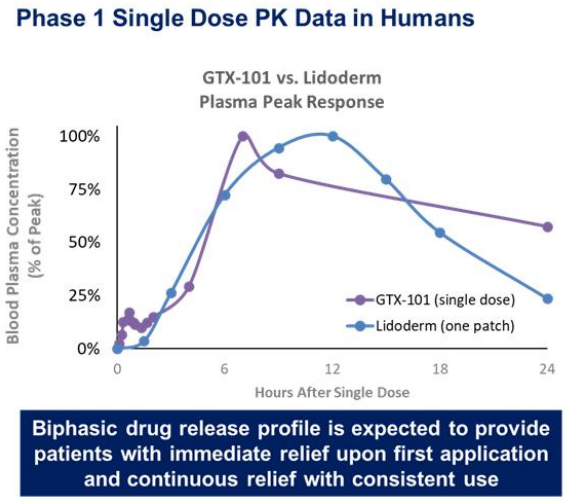
Current treatment of PHN most often consists of oral gabapentin (first line) and prescription lidocaine patches or antidepressants (second line), and refractory cases may be prescribed opioids to address persistent pain. Gabapentin and opioid abuse have continued to proliferate, and lidocaine patches are suboptimal for many reasons. An independent third-party market research firm we commissioned interviewed more than 250 physicians who regularly treat PHN patients and found that approximately 40% of patients using lidocaine patches experience insufficient pain relief. Lidocaine patches are difficult to use, fall off, and look unsightly with possible skin sensitivity and irritation. Additionally, lidocaine patches can only be used for 12 hours and then need to be removed for 12 hours before being reapplied. Prescription lidocaine patches are only approved for PHN, and the market is currently made up of both branded and generic offerings. It is estimated that PHN affects approximately 120,000 patients per year in the United States. According to a third-party report, the total addressable market for GTX-101 could be as large as $2.5 billion, consisting of approximately $200 million for PHN pain and $2.3 billion for non-PHN pain indications.

GTX-101 Research & Development History and Clinical Trials Completed to Date

To date, we have conducted four Phase I trials in healthy volunteers to assess the PK, safety and tolerability of GTX-101 and to determine the plasma levels of bupivacaine HCl administered as a single dose in various concentrations between 30 mg (three sprays) and 2100 mg (twenty sprays).

These trials confirmed that bupivacaine delivered as a topical spray (GTX-101) is well absorbed through the skin, as demonstrated in the graph below, while very little is absorbed systemically.

In all four trials, the administration of GTX-101 to healthy volunteers was safe and well tolerated. In addition, no evidence of skin irritation was observed at the application site following the spray administrations. The data below is from two separate trials of GTX-101 and the Lidoderm patch superimposed on each other.



GTX-101 activities:

The data from the single dose Phase 1 clinical trial for GTX-101 was submitted to the FDA's Division of Anesthesiology and feedback was received at a pre-IND meeting that informed the design of pre-clinical toxicology studies and a clinical and regulatory pathway to approval under section 505(b)(2). We completed a minipig skin sensitivity study in the second calendar quarter of 2022, and we initiated a single dose PK trial in healthy human volunteers in July 2022. Topline results from this single dose PK trial were reported in December 2022, and the results met all primary outcome measures.

The median Tmax (the time of maximum concentration between 0 hour and 240 hours after study drug administration) of bupivacaine in plasma following GTX-101 single-dose topical applications ranged between 18 to 24 hours depending on dose, while the median Tmax following the subcutaneous injection of 10 mg of bupivacaine was only 23 minutes. This result suggests that bupivacaine delivered by

GTX-101 remains in the skin for a long period of time, potentially inducing prolonged analgesic effect in the sprayed area. The exposure to bupivacaine based on Cmax (the maximum concentration occurring at Tmax between 0 hour and 240 hours after study drug administration) and AUC (the area under the concentration time curve, extrapolated to infinity) following GTX-101 topical application as a single-dose increased with increasing dose.

The systemic exposure to bupivacaine following a 200mg dose of GTX-101 was approximately 29-fold less than a single subcutaneous dose of 10mg of bupivacaine based on Cmax and approximately 6-fold less than a single subcutaneous dose of 10mg of bupivacaine based on AUC. We predict these lower blood levels will correspond to an increased safety margin for GTX-101 with regards to toxicity risk. Mean half-life ("T half") following GTX-101 single-dose topical applications ranged between 24 to 37 hours depending on dose, suggesting a slow elimination and potentially long duration of effect, while mean Tmax following the subcutaneous injection of 10 mg of bupivacaine was only 8 hours.

There were only two adverse events judged as related to the study drug by the investigator for each of GTX-101 and the bupivacaine subcutaneous injection. Following GTX-101 topical application: headache (1 event = 3%) and numbness (1 event = 3%) at the sprayed area following bupivacaine subcutaneous injection: dizziness (1 event = 8%) and nausea (1 event = 8%).

The further development of GTX-101 has been deprioritized in favor of our focus on development of GTX-104. Pending additional funding for GTX-101 or the signing of a strategic partnership, we plan to follow this successful PK trial with the next step of the clinical development plan including a multiple ascending dose trial. Results from these non-clinical studies and clinical trials are required before the initiation of our Phase 2 program in PHN patients. It is also possible that we may license or sell our GTX-101 drug candidate.

Overall Commercialization Strategy

We have worldwide commercialization rights for all our pipeline drug candidates and plan to maximize the value of each of our drug candidates over time. Currently, we have prioritized the development of GTX-104 over that of GTX-102 and GTX-101. If we receive regulatory approval for GTX-104 in the US, we may look to out-license its commercialization or consider self-commercialization including outsourcing sales to ensure efficient commercial management and maximize market penetration and financial returns. We may further seek commercial partnerships to fully exploit the market potential of GTX-104 in territories outside the US. It is possible that we out-license or sell GTX-102 and/or GTX-101 for the US and/or global markets.

Basis of Presentation of the Financial Statements

Our unaudited condensed consolidated financial statements, which include the accounts of our wholly owned subsidiaries, have been prepared in accordance with U.S. GAAP and the rules and regulations of the SEC related to quarterly reports filed on Form 10-Q. All intercompany transactions and balances are eliminated on consolidation.

Our assets as of June 30, 2024, include cash, cash equivalents, and short-term investments totaling $19.4 million and intangible assets and goodwill totaling $49.3 million. Our current liabilities total $2.3 million as of June 30, 2024 and are comprised primarily of amounts due to or accrued for creditors. The Company believes its cash runway will be sufficient to fund the Company’s operations into the second calendar quarter of 2026.

Results of Operations for the three months ended June 30, 2024 and 2023

	Three months ended		
	June 30, 2024 $	June 30, 2023 $	Increase (Decrease) $
Operating expenses			
Research and development expenses, net of government assistance	2,708	1,095	1,613
General and administrative expenses	2,255	1,874	381
Restructuring costs	—	1,485	(1,485)
Loss from operating activities	**(4,963)**	**(4,454)**	**509**
Foreign exchange (loss) gain	(8)	8	(16)
Change in fair value of derivative warrant liabilities	1,395	—	1,395
Interest income and other expense, net	235	134	101
Income tax benefit	724	289	435
Net loss	**(2,617)**	**(4,023)**	**(1,406)**

Net loss

The net loss of $2.6 million, or $0.24 per share, for the three months ended June 30, 2024 decreased by $1.4 million from the net loss of $4.0 million, or $0.54 per share, for the three months ended June 30, 2023. The decrease in net loss was primarily due to restructuring costs of $1.5 million during the three months ended June 30, 2023 and a $1.4 million decrease to the fair value of our derivative warrant liabilities, offset in part by a $1.6 million increase in research and development expenses.

Research and development expenses, net of government assistance

Research and development expenses consist primarily of:

- fees paid to external service providers such as contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") related to clinical trials, including contractual obligations for clinical development, clinical sites, manufacturing and scale-up, and formulation of clinical drug supplies;
- fees paid to contract service providers related to drug discovery efforts including chemistry and biology services; and
- salaries and related expenses for research and development personnel, including expenses related to stock options.

We record research and development expenses as incurred.

Our research and development during the three months ended June 30, 2024 and 2023 were focused primarily on our clinical development program for our GTX-104 drug candidate.

The following table summarizes our research and development expenses:

Research and development expenses			
	Three months ended		
	June 30, 2024 $	June 30, 2023 $	Increase (Decrease) $
Total third-party research and development expenses[1]	2,435	800	1,635
Government grants & tax credits	—	51	(51)
Salaries and benefits	207	225	(18)
Research and development expense before stock-based compensation and depreciation	2,642	1,076	1,566
Stock-based compensation	66	2	64
Depreciation and loss on disposal of equipment	—	17	(17)
Total	2,708	1,095	1,613

[1] Total third-party research and development expenses are calculated before salaries and benefits, depreciation, write-off of equipment and stock-based compensation. Because there is no standard method endorsed by U.S. GAAP, the results may not be comparable to similar measurements presented by other public companies.

Total third-party research and development expenses for the three months ended June 30, 2024, were $2.4 million, compared to $0.8 million for the three months ended June 30, 2023. This increase of $1.6 million was primarily due to the increase in our research activities for our GTX-104 pivotal Phase 3 safety clinical trial.

Government grants and tax credits were nil and $51 thousand for the three months ended June 30, 2024 and 2023, respectively. The changes within government grants and tax credits were due to adjustments of provisions regarding the estimated realizability of credits receivable after assessments and correspondence from tax authorities.

Stock-based compensation of $66 thousand for the three months ended June 30, 2024, increased by $64 thousand compared to $2 thousand for the three months ended June 30, 2023. The increase was primarily due to the issuance of new grants.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal, and support functions, including professional fees for auditing, tax, consulting, rent and utilities and insurance.

General and administrative expenses

	Three months ended		
	June 30, 2024 $	June 30, 2023 $	Increase (Decrease) $
Salaries and benefits	395	357	38
Professional fees	1,454	965	489
Other	233	473	(240)
General and administrative expense before stock-based compensation and depreciation[1]	2,082	1,795	287
Stock-based compensation	172	76	96
Depreciation and loss on disposal of equipment	1	3	(2)
Total	2,255	1,874	381

[1] General and administrative sub-total expenses are calculated before stock-based compensation and depreciation. Because there is no standard method endorsed by U.S. GAAP, the results may not be comparable to similar measurements presented by other public companies.

General and administrative expenses were $2.1 million before stock-based compensation and depreciation expense for the three months ended June 30, 2024, an increase of $0.3 million from $1.8 million for the three months ended June 30, 2023. The increase was primarily a result of increased legal, tax, accounting and other professional fees related to the proposed change in the jurisdiction of incorporation of Acasti from the Province of Québec in Canada to the State of Delaware in the United States. Stock-based compensation of $172 thousand for the three months ended June 30, 2024, increased by $96 thousand compared to $76 thousand for the three months ended June 30, 2023. The increase was primarily due to the issuance of new grants.

Restructuring Costs

On May 8, 2023, we announced our decision to terminate a substantial amount of our workforce as part of a plan intended to align our organizational and management cost structure to prioritize resources to GTX-104, thereby reducing losses to improve cash flow and

extend available cash resources. We incurred $1.5 million of related costs primarily consisting of employee severance costs. There were no restructuring costs during the three months ended June 30, 2024.

Change in fair value of warrant liabilities

The decrease in fair value of derivative warrant liabilities for the three months ended June 30, 2024 of $1.4 million was mainly attributable to a decrease in our stock price.

Interest income

Interest income was $235 thousand for the three months ended June 30, 2024, compared to $134 thousand for the three months ended June 30, 2023. The $101 thousand increase in our interest income was due to higher interest rates earned on average balances of cash and cash equivalents.

Liquidity and Capital Resources

Cash flows and financial condition for the three months ended June 30, 2024 and 2023

Summary

As of June 30, 2024, cash and cash equivalents were $19.4 million, a net decrease of $3.6 million compared to cash and cash equivalents of $23.0 million at March 31, 2024. We believe our existing cash and cash equivalents, will be sufficient to fund our operations into the second calendar quarter of 2026.

We will require additional capital to fund our daily operating needs beyond that time. We do not expect to generate revenue from product sales unless and until we successfully complete drug development and obtain regulatory approval, which we expect will take several years and is subject to significant uncertainty. To date, we have financed our operations primarily through public offerings and private placements of our Common Shares, warrants and convertible debt and the proceeds from research tax credits. Until such time that we can generate significant revenue from drug product sales, if ever, we will require additional financing, which is expected to be sourced from a combination of public or private equity or debt financing or other non-dilutive sources, which may include fees, milestone payments and royalties from collaborations with third parties. Arrangements with collaborators or others may require us to relinquish certain rights related to our technologies or drug product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategy. We plan to raise additional capital in order to maintain adequate liquidity. Negative results from studies or trials, if any, or depressed prices of our Common Shares could impact our ability to raise additional financing. Raising additional equity capital is subject to market conditions that are not within our control. If we are unable to raise additional funds, we may not be able to realize our assets and discharge our liabilities in the normal course of business.

Net cash used in operating activities

Net cash used in operating activities for the three months ended June 30, 2024 was $3.6 million, compared to $6.2 million for the three months ended June 30, 2023, a decrease of $2.6 million. The reduction in cash used in operating activities during 2025 was primarily due to our increased research and development activities for our GTX-104 pivotal Phase 3 safety clinical trial protocol, which resulted in higher third-party research and development expenses of $1.5 million. In addition, our general and administrative fees were higher due to the increase in professional fees of $0.3 million as a result of increased legal, tax, accounting and other professional fees related to the proposed change in our jurisdiction of incorporation from the Province of Québec in Canada to the State of Delaware in the United States. Cash used in operating activities during the three months ended June 30, 2023 primarily related to cash used in operating activities due to our May 2023 restructuring, which resulted in lower third-party research and development expenses of $1.0 million, and lower salaries and benefits expenses of $0.3 million. These amounts were offset in part by additional cash used of $2.0 million to fund operating assets and liabilities and restructuring costs of $1.5 million.

Net cash used in investing activities

Net cash used in investing activities for the three months ended June 30, 2024, was from our purchase of short-term investments of $15 thousand. For the three months ended June 30, 2023, we had no investing activities.

Private Placement

On September 24, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") with certain institutional and accredited investors in connection with a private placement offering of our securities (the "Offering"). Pursuant to the Purchase Agreement, sold 1,951,371 Class A common shares, no par value per share (the "Common Shares"), at a purchase price of $1.848 per Common Share and pre-funded warrants (the "Pre-funded Warrants") to purchase up to 2,106,853 Common Shares at a purchase price equal to the purchase price per Common Share less $0.0001. Each Pre-funded Warrant is exercisable for one Common Share at an exercise price of $0.0001 per

Common Share, was immediately exercisable, and will expire once exercised in full. Pursuant to the Purchase Agreement, we also issued to such institutional and accredited investors common warrants (the "Common Warrants") to purchase Common Shares, exercisable for an aggregate of 2,536,391 Common Shares. Under the terms of the Purchase Agreement, for each Common Share and each Pre-funded Warrant issued in the Offering, an accompanying five-eighths (0.625) of a Common Warrant was issued to the purchaser thereof. Each whole Common Warrant is exercisable for one Common Share at an exercise price of $3.003 per Common Share, was immediately exercisable, and will expire on the earlier of (i) the 60th day after the date of the acceptance by the FDA of a New Drug Application for our product candidate GTX-104 or (ii) five years from the date of issuance. The Offering closed on September 25, 2023. The net proceeds to us from the Offering were approximately $7.3 million, after deducting fees and expenses.

Contractual Obligations and Commitments

Our contractual obligations and commitments include trade payables, CMO and CRO agreements, and the raw krill oil supply agreement, as described below.

Research and development contracts and contract research organizations agreements:

We utilize CMOs, for the development and production of clinical materials and CROs to perform services related to our clinical trials. Pursuant to the agreements with CMOs and CROs, we have either the right to terminate the agreements without penalties or under certain penalty conditions. As of June 30, 2024, we have no commitments due to CMOs and $5.9 million of commitments for the next twelve months to CROs.

Raw krill oil supply contract

On October 25, 2019, we entered into a supply agreement with Aker BioMarine Antarctic AS. ("AKBM") to purchase raw krill oil product for a committed volume of commercial starting material for CaPre, one of our former drug candidates, for a total fixed value of $3.1 million based on the value of krill oil at that time. As of March 31, 2022, the remaining balance of commitment amounted to $2.8 million. During the second calendar quarter of 2022, AKBM informed us 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 we were therefore required to accept the remaining product commitment. We 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 us. The dispute remained unresolved as of both March 31, 2023 and 2022. On October 18, 2023, we entered into an agreement with AKBM to settle any and all potential claims regarding amounts due under the supply agreement (the "Settlement Agreement"). 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, we agreed to the following: (a) AKBM retained ownership of all raw krill oil product, including amounts previously delivered to us; (b) AKBM acquired and took ownership of all of our production equipment related to the production of CaPre; (c) AKBM acquired and took ownership of all of our data from research, clinical trials and pre-clinical studies with respect to CaPre; and (d) AKBM acquired and took ownership over all of our rights, title and interest in and to all intellectual property rights, including all patents and trademarks, related to CaPre owned by us. Further, AKBM acknowledged that the CaPre assets were transferred on an "as is" basis, and in connection therewith we disclaimed all representations and warranties in connection with the CaPre assets, including any representations with respect to performance or sufficiency. The value of the raw krill oil previously delivered to us, the production equipment, and the intellectual property rights related to CaPre were fully impaired in prior reporting periods and had a carrying value of nil as of March 31, 2023. For the three months ended June 30, 2024, there was $0.2 million in expenses recorded by us in relation to shipping cost to transport our production equipment related to the production of CaPre.

Contingencies

We evaluate contingencies on an ongoing basis and establish loss provisions for matters in which losses are probable and the amount of the loss can be reasonably estimated.

Use of Estimates and Measurement of Uncertainty

The preparation of these unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, income, and expenses. Actual results may differ from these estimates.

Estimates are based on management's best knowledge of current events and actions that management may undertake in the future. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Estimates and assumptions include the measurement of stock-based compensation, derivative warrant liabilities, accruals for research and development contracts and contract organization agreements, and valuation of intangibles and goodwill. Estimates and assumptions are also involved in determining which research and development expenses qualify for research and development tax credits and in what amounts. The Company recognizes the tax credits once it has reasonable assurance that they will be realized.

Critical Accounting Policies

During the three months ended June 30, 2024, there were no material changes to our critical accounting policies from those described in our Annual Report for the year ended March 31, 2024.

Recent Accounting Pronouncements

We have considered recent accounting pronouncements and concluded that they are either not applicable to our business or that the effect is not expected to be material to our consolidated financial statements as a result of future adoption.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

A smaller reporting company is not required to provide the information required by this Item.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

As of the end of the period covered by this quarterly report, our management, with the participation of our Chief Executive Officer and Principal Financial Officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures within the meaning of Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based upon this evaluation, our management has concluded that, as of June 30, 2024, our existing disclosure controls and procedures were effective. It should be noted that while our Chief Executive Officer and Principal Financial Officer believe that our disclosure controls and procedures provide a reasonable level of assurance that they are effective, they do not expect the disclosure controls and procedures to be capable of preventing all errors and fraud. A control system, no matter how well conceived or operated, can provide only reasonable, but not absolute, assurance that the objectives of the control system are met.

Changes in Internal Control over Financial Reporting

No changes were made to our internal controls over financial reporting that occurred during the quarter ended June 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are at times subject to various legal proceedings and disputes. We assess our liabilities and contingencies in connection with outstanding legal proceedings utilizing the latest information available. Where it is probable that we will incur a loss and the amount of the loss can be reasonably estimated, we record a liability in our unaudited condensed consolidated financial statements. These legal reserves may be increased or decreased to reflect any relevant developments on a quarterly basis. Where a loss is not probable or the amount of loss is not estimable, we do not accrue legal reserves. While the outcome of legal proceedings is inherently uncertain, based on information currently available and available insurance coverage, our management believes that it has established appropriate legal reserves. Any incremental liabilities arising from pending legal proceedings are not expected to have a material adverse effect on our financial position, results of operations, or cash flows. However, it is possible that the ultimate resolution of these matters, if unfavorable, may be material to our financial position, results of operations, or cash flows. We are not currently a party to any legal proceedings that, in the opinion of management, are likely to have a material adverse effect on our business.

Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in our Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended June 30, 2024, no director or officer of the Company adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit No.	Description

3.1	Articles of Incorporation, as amended (incorporated by reference to Exhibit 4.1 from Form S-3 (File No. 333-274899) filed with the Commission on October 6, 2023)
3.2	Amended and Restated General By-Law (incorporated by reference to Exhibit 3.4 from Form 10-Q (File No. 001-35776) filed with the Commission on August 11, 2023)
3.3	Advance Notice bylaw No. 2013-1 (incorporated by reference to Exhibit 4.3 from Form S-8 (File No. 333-191383) filed with the Commission on September 25, 2013)
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
32.1*	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed or furnished herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Dated: August 9, 2024

ACASTI PHARMA INC.

By: /s/ Prashant Kohli
Name: Prashant Kohli
Title: Chief Executive Officer
(Principal Executive Officer)

By: /s/ Robert DelAversano
Name: Robert DelAversano
Title: Principal Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Prashant Kohli, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acasti Pharma Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2024

/s/ Prashant Kohli
Chief Executive Officer

Exhibit 31.2

CERTIFICATION
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert DelAversano, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acasti Pharma Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2024

/s/ Robert DelAversano
Principal Financial Officer

Exhibit 32.1

SECTION 906 CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code) in connection with the quarterly report on Form 10-Q of Acasti Pharma Inc. for the quarterly period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer hereby certifies, to such officer's knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Acasti Pharma Inc.

/s/ Prashant Kohli

Name: Prashant Kohli
Title: Chief Executive Officer
Date: August 9, 2024

This certification accompanies the Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed "filed" by Acasti Pharma Inc. for purposes of §18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section.

Exhibit 32.2

SECTION 906 CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code) in connection with the quarterly report on Form 10-Q of Acasti Pharma Inc. for the quarterly period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer hereby certifies, to such officer's knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Acasti Pharma Inc.

/s/ Robert DelAversano

Name: Robert DelAversano
Title: Principal Financial Officer
Date: August 9, 2024

This certification accompanies the Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed "filed" by Acasti Pharma Inc. for purposes of §18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section.