

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 September 30, 2023

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
(State or other jurisdiction of
incorporation or organization)

98-1359336
(I.R.S. Employer
Identification Number)

2572 boul. Daniel-Johnson, 2nd Floor
Laval, Québec, Canada H7T 2R3
(Address of principal executive offices, including zip code)

450-686-4555
(Registrant's telephone number, including area code)

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 November 9, 2023, was 9,399,404.

ACASTI PHARMA INC.

QUARTERLY REPORT ON FORM 10-Q

For the Quarter Ended September 30, 2023

Table of Contents

	Page
<u>PART I. FINANCIAL INFORMATION</u>	
Item 1. Financial Statements	4
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3. Quantitative and Qualitative Disclosures About Market Risk	38
Item 4. Controls and Procedures	38
<u>PART II. OTHER INFORMATION</u>	
Item 1. Legal Proceedings	38
Item 1A. Risk Factors	39
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	39
Item 3. Defaults Upon Senior Securities	39
Item 4. Mine Safety Disclosures	39
Item 5. Other Information	39
Item 6. Exhibits	39

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 the present or historical facts.

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 which, 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 U.S. Food and Drug Administration (“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 included in our Annual Report on Form 10-K for the year ended March 31, 2023.

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 “\$” and “U.S.\$” are to U.S. dollars and references to “C\$” or “CAD\$” are to Canadian dollars.

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

PART I. FINANCIAL INFORMATION

Item 1: Financial Information

Unaudited Condensed Consolidated Interim Financial Statements

Condensed Consolidated Interim Balance Sheets	5
Condensed Consolidated Interim Statements of Loss and Comprehensive Loss	6
Condensed Consolidated Interim Statements of Shareholders' Equity	7
Condensed Consolidated Interim Statements of Cash Flows	8
Notes to the Condensed Consolidated Interim Financial Statements	9

ACASTI PHARMA INC.
Condensed Consolidated Interim Balance Sheet
(Unaudited)

		September 30, 2023	March 31, 2023
	Notes	\$	\$
<i>(Expressed in thousands of U.S. dollars except share data)</i>			
Assets			
Current assets:			
Cash and cash equivalents		26,991	27,875
Short-term investments	5	15	15
Receivables	4	837	802
Prepaid expenses		1,044	598
Total current assets		28,887	29,290
Operating lease right of use asset		47	463
Equipment		10	104
Intangible assets		41,128	41,128
Goodwill		8,138	8,138
Total assets		78,210	79,123
Liabilities and Shareholders' equity			
Current liabilities:			
Trade and other payables	6	1,351	3,336
Operating lease liability	7	46	75
Total current liabilities		1,397	3,411
Derivative warrant liabilities	8(b)	3,457	—
Operating lease liability		—	410
Deferred tax liability		6,611	7,347
Total liabilities		11,465	11,168
Shareholders' equity:			
Class A common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 9,399,404 and 7,435,533 shares issued and outstanding as of September 30, 2023 and March 31, 2023	8(a)	261,038	258,294
Class B common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 0 shares issued and outstanding as of September 30, 2023 and March 31, 2023		—	—
Class C common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 0 shares issued and outstanding as of September 30, 2023 and March 31, 2023		—	—
Class D common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 0 shares issued and outstanding as of September 30, 2023 and March 31, 2023		—	—
Class E common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and March 31, 2023; 0 shares issued and outstanding as of September 30, 2023 and March 31, 2023		—	—
Additional paid-in capital		17,307	13,965
Accumulated other comprehensive loss		(6,038)	(6,038)
Accumulated deficit		(205,562)	(198,266)
Total shareholders' equity		66,745	67,955
Commitments and contingencies	13		
Total liabilities and shareholders' equity		78,210	79,123

See accompanying notes to unaudited interim financial statements.

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

		Three months ended		Six months ended	
		September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
<i>(Expressed in thousands of U.S dollars, except share and per share data)</i>	Notes	\$	\$	\$	\$
Operating expenses					
Research and development expenses, net of government assistance		(460)	(3,292)	(1,555)	(5,882)
General and administrative expenses		(1,589)	(1,680)	(3,352)	(3,599)
Sales and marketing		(43)	(136)	(154)	(357)
Restructuring cost	14	—	—	(1,485)	—
Loss from operating activities		(2,092)	(5,108)	(6,546)	(9,838)
Foreign exchange gain (loss)		(13)	(12)	(5)	(90)
Change in fair value of warrant liabilities	8(b)	(1,826)	—	(1,826)	10
Interest income and other expense		212	36	346	68
Total other income (expense), net		(1,627)	24	(1,485)	(12)
Loss before income tax recovery		(3,719)	(5,084)	(8,031)	(9,850)
Income tax recovery		446	155	735	397
Net loss and total comprehensive loss		(3,273)	(4,929)	(7,296)	(9,453)
Basic and diluted loss per share	10	(0.43)	(0.66)	(0.97)	(1.28)
Weighted average number of shares outstanding		7,552,677	7,425,166	7,494,425	7,406,689

See accompanying notes to unaudited interim financial statements

ACASTI PARMA INC.

 Condensed Consolidated Interim Statements of Shareholders' Equity
 (Unaudited)

Common Shares

<i>(Expressed in thousands of U.S. dollars except share data)</i>	Notes	Number	Dollar \$	Additional paid-in capital \$	Accumulated other comprehensive loss \$	Deficit \$	Total \$
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	9	—	—	78	—	—	78
Balance at June 30, 2023		7,435,533	258,294	14,043	(6,038)	(202,289)	64,010

Issuance of common shares and pre-funded warrants through private placement, net of offering costs	8(a)	1,951,371	2,744	2,963	—	—	5,707
Issuance of common shares upon the exercise of stock options		12,500	—	21	—	—	21
Net loss and total comprehensive loss for the period		—	—	—	—	(3,273)	(3,273)
Stock-based compensation	9	—	—	280	—	—	280
Balance at September 30, 2023		9,399,404	261,038	17,307	(6,038)	(205,562)	66,745

Common Shares

<i>(Expressed in thousands of US dollars except for share data)</i>	Notes	Number	Dollar \$	Additional paid-in capital \$	Accumulated other comprehensive loss \$	Deficit \$	Total \$
Balance, March 31, 2022		7,381,425	257,990	12,154	(6,037)	(155,837)	108,270
Net loss and total comprehensive loss for the period		—	—	—	—	(4,524)	(4,524)
Cumulative translation adjustment		—	—	—	(2)	—	(2)
Stock-based compensation	9	—	—	464	—	—	464
Net proceeds from shares issued under the at-the-market (ATM) program		34,335	195	—	—	—	195
Balance at June 30, 2022		7,415,760	258,185	12,618	(6,039)	(160,361)	104,403

Net loss and total comprehensive loss for the period		—	—	—	—	(4,929)	(4,929)
Cumulative translation adjustment		—	—	—	(1)	—	(1)
Net proceeds from shares issued under the at-the-market (ATM) program		19,773	109	—	—	—	109
Stock-based compensation	9	—	—	582	—	—	582
Balance at September 30, 2022		7,435,533	258,294	13,200	(6,040)	(165,290)	100,164

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

		September 30, 2023	Six months ended September 30, 2022
	Notes	\$	\$
<i>(Expressed in thousands of U.S. dollars)</i>			
Cash flows used in operating activities:			
Net loss for the period		(7,296)	(9,453)
Adjustments:			
Depreciation of equipment		9	106
Gain on sale of equipment		(58)	—
Stock-based compensation	9	358	1,046
Change in fair value of warrant liabilities		1,826	(10)
Income tax recovery		(735)	(397)
Unrealized foreign exchange (gain) loss		—	(51)
Write-off of equipment		32	31
Changes in operating assets and liabilities	11	(2,489)	(137)
Net cash used in operating activities		(8,353)	(8,865)
Cash flows from investing activities:			
Acquisition of equipment		—	(9)
Proceeds from sale of equipment		110	—
Acquisition of short-term investments		—	(14)
Maturity of short-term investment		—	13,185
Net cash from investing activities		110	13,162
Cash flows from financing activities:			
Net proceeds from issuance of common shares and warrants from private placement	(8a)	7,338	—
Proceeds from issuance of common shares from exercise of stock options		21	—
Net proceeds from shares issuance under the at-the-market (ATM) program	(8a)	—	304
Net cash from financing activities		7,359	304
Effect of exchange rate fluctuations on cash and cash equivalents		—	(14)
Net (decrease) increase in cash and cash equivalents		(884)	4,587
Cash and cash equivalents, beginning of period		27,875	30,339
Cash and cash equivalents, end of period		26,991	34,926
Cash and cash equivalents are comprised of:			
Cash		10,596	34,926
Cash equivalents		16,395	—

See accompanying notes to unaudited interim financial statements.

ACASTI PHARMA INC.

Notes to Condensed Consolidated Interim Financial Statements

(Unaudited)

(Expressed in thousands of U.S. dollars except share and per share data)

1. Nature of operation

Acasti Pharma Inc. ("Acasti" or the "Corporation") is incorporated under the Business Corporations Act (Québec) (formerly Part 1A of the Companies Act (Québec)). The Corporation is domiciled in Canada and its registered office is located at 2572 boul. Daniel-Johnson, 2nd Floor Laval, Québec, Canada H7T 2R3.

The Corporation's shares are listed on the Nasdaq Capital Market (the "Nasdaq"), and through March 27, 2023 the Corporation's shares were also listed on the TSX Venture Exchange ("TSXV"), in each case, under the symbol "ACST". On March 13, 2023 the Corporation received approval to voluntarily delist from the TSXV. Effective as at the close of trading on March 27, 2023, the Corporation's common shares are no longer listed and posted for trading on the TSXV.

In August 2021, the Corporation completed the acquisition via a share-for-share merger of Grace Therapeutics, Inc. ("Grace"), a privately held emerging biopharmaceutical company focused on developing innovative drug delivery technologies for the treatment of rare and orphan diseases. The post-merger Corporation is focused on building a late-stage specialty pharmaceutical company specializing in rare and orphan diseases and developing and commercializing products that improve clinical outcomes using its novel drug delivery technologies. The Corporation seeks to apply new proprietary formulations to existing pharmaceutical compounds to achieve enhanced efficacy, faster onset of action, reduced side effects, more convenient delivery and increased patient compliance; all of which could result in improved patient outcomes. The active pharmaceutical ingredients chosen by the Corporation for further development may be already approved in the target indication or could be repurposed for use in new indications.

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

In May 2023, the Corporation implemented a strategic realignment plan to enhance shareholder value that resulted in the Corporation engaging a new management team, streamlining its research and development activities to concentrate on its lead product, GTX-104, and greatly reducing its workforce. Moving forward, the Corporation plans to build a smaller, more focused organization in the United States. Further development of GTX-102 and GTX-101 will occur at such time as additional funding is obtained or strategic partnerships are entered into.

On September 24, 2023, the Corporation entered into a securities purchase agreement with certain institutional and accredited investors. Gross proceeds to the Corporation from this private placement were approximately \$7,500, before deducting fees and expenses. The Corporation issued and sold an aggregate of 1,951,371 common shares, no par value per share, pre-funded warrants to purchase up to an aggregate of 2,106,853 common shares, each at a purchase price of \$1.8481 per common share and accompanying common warrants to purchase up to an aggregate of 2,536,391 common shares. The Corporation 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 Corporation believes its cash runway, including net proceeds from this financing, will be sufficient to fund the Corporation's operations into the second calendar quarter of 2026.

The Corporation will require additional capital to fund its daily operating needs beyond that time. The Corporation does not expect to generate revenue from product sales unless and until it successfully completes drug development and obtains regulatory approval, which the Corporation expects will take several years and is subject to significant uncertainty. To date, the Corporation 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 Corporation 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 Corporation to relinquish certain rights related to its technologies or drug product candidates. Adequate additional financing may not be available to the Corporation on acceptable terms, or at all. The Corporation'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 Corporation plans to raise additional capital in order to maintain adequate liquidity. Negative results from studies or trials, if any, and depressed prices of the Corporation's stock could impact the Corporation's ability to raise additional financing. Raising additional equity capital is subject to market conditions not within the Corporation's control. If the Corporation is unable to raise additional funds, the Corporation may not be able to realize its assets and discharge its liabilities in the normal course of business.

The Corporation 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 Corporation's Annual Report on Form 10-K for the year ended March 31, 2023, filed with the SEC on June 23, 2023 (the "Annual Report").

Reverse stock split

On June 29, 2023, the Board of Directors of the Corporation approved an amendment to the Corporation's Articles of Incorporation to implement a reverse stock split of the Corporation's Class A common shares, no par value per share, at a ratio of 1-for-6 (the "Reverse Stock Split"). On July 4, 2023, the Corporation filed Articles of Amendment to its Articles of Incorporation with the *Registraire des entreprises du Québec*, to implement the Reverse Stock Split. All references in these financial statements to number of common shares, warrants and options, price per share and weighted average number of shares outstanding have been adjusted to reflect the Reverse Stock Split, which became effective on July 10, 2023.

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, 2023, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Corporation's consolidated financial position as of September 30, 2023, the consolidated results of its operations for the three and six months ended September 30, 2023 and 2022, its statements of shareholders' equity for the three and six months ended September 30, 2023 and 2022 and its consolidated cash flows for the six months ended September 30, 2023 and 2022.

These unaudited condensed consolidated financial statements should be read in conjunction with the Corporation's audited consolidated financial statements and the accompanying notes for the year ended March 31, 2023 included in the Corporation's Annual Report. The condensed consolidated balance sheet data as of March 31, 2023 presented for comparative purposes was derived from the Corporation's audited consolidated financial statements but does not include all disclosures required by U.S. GAAP. The results for the three and six months ended September 30, 2023 are not necessarily indicative of the operating results to be expected for the full year or for any other subsequent interim period.

The Corporation's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended March 31, 2023 included in the Annual Report. There have been no changes to the Corporation's significant accounting policies since the date of the audited consolidated financial statements for the year ended March 31, 2023 included in the Annual Report.

Use of estimates

The preparation of these 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 Corporation recognizes the tax credits once it has reasonable assurance that they will be realized.

Recent accounting pronouncements

The Corporation has considered recent accounting pronouncements and concluded that they are either not applicable to the Corporation's business or that the effect is not expected to be material to the 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 September 30, 2023 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	16,395	16,395	—	—
Total assets	16,395	16,395	—	—
Liabilities				
Derivative warrant liabilities	3,457	—	—	3,457
Total liabilities	3,457	—	—	3,457

There were no changes in valuation techniques or transfers between Levels 1, 2 or 3 during the six months ended September 30, 2023. The Corporation'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(b) for the valuation techniques and assumptions used in estimating the fair value of the derivative warrant liabilities.

4. Receivables

	September 30, 2023 \$	March 31, 2023 \$
Sales tax receivables	360	338
Government assistance	356	412
Interest receivable	94	52
Other receivables	27	-
Total receivables	837	802

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. For the six months ended September 30, 2022, the Corporation recorded \$81 as a reduction of research and development expenses in the Statement of Loss and Comprehensive Loss.

5. Short-term investments

The Corporation holds various marketable securities, with maturities greater than 3 months at the time of purchase, as follows:

	September 30, 2023 \$	March 31, 2023 \$
Term deposits issued in CAD currency earning interest at 3% and maturing on March 29, 2024	15	15
Total short-term investments	15	15

6. Trade and other payables

	September 30, 2023 \$	March 31, 2023 \$
Trade payables	685	1,242
Accrued liabilities and other payables	460	946
Employee salaries and benefits payable	206	1,148
Total trade and other payables	1,351	3,336

7. Leases

The Corporation has historically entered into lease arrangements for its research and development and quality control laboratory facility located in Sherbrooke, Québec. As of September 30, 2023, the Corporation had one operating lease with required future minimum payments.

On March 14, 2022, the Corporation renewed the lease agreement effective April 1, 2022, resulting in a commitment of \$556 over a 24 months base lease term and 48 months additional lease renewal term. In April 2023, the Corporation elected not to renew the additional 48 months lease renewal term with the lease expected to terminate March 31, 2024. The Corporation accounted for the change in lease term as a lease modification under ASC 842. Due to the modification in lease term, the Corporation remeasured the lease liability and right-of-use asset associated with the lease. As of the effective date of modification, the Corporation recorded an adjustment to the right-of-use asset and lease liability in the amount of \$369 based on the net present value of lease payments discounted using an estimated incremental borrowing rate of 4.3%.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Corporation's operating lease for the six-month period ended September 30, 2023:

Operating cash flows for operating lease	\$	47
Weighted-average remaining lease term (in years)		0.50
Weighted-average discount rate		4.3 %

As the Corporation's lease does not provide an implicit rate, the Corporation utilized its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Corporation could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

Future minimum lease payments under the Corporation's operating lease as of September 30, 2023 were as follows:

	September 30, 2023
	\$
2024	47
2025 and thereafter	-
Total lease payments	47
Less: interest	(1)
Total lease liability	46

On July 19, 2023, the Corporation entered into a new short term lease for its headquarters located at 2572 boul. Daniel-Johnson, 2nd Floor Laval, Québec, Canada H7T 2R3. On July 24, 2023, the Corporation terminated the lease for its office located at 3009 boul. de la Concorde East, Suite 102, Laval, Québec, Canada H7E 2B5.

8. Capital and other components of equity

a. Common Shares

Authorized capital stock

Unlimited number of shares

- Class A shares ("Common Shares"), voting (one vote per share), participating and without par value. As of September 30, 2023, there were 9,399,404 Class A shares issued and outstanding.
- Class B shares, voting (ten votes per share), non-participating, without par value and maximum annual non-cumulative dividend of 5% on the amount paid per share. Class B shares are convertible, at the holder's discretion, into Common Shares, on a one-for-one basis, and Class B shares are redeemable at the holder's discretion for CAD \$4.80 per share, subject to certain conditions. As of September 30, 2023, there were no Class B shares issued and outstanding.
- Class C shares, non-voting, non-participating, without par value and maximum annual non-cumulative dividend of 5% on the amount paid per share. Class C shares are convertible, at the holder's discretion, into Common Shares, on a one-for-one basis, and Class C shares are redeemable at the holder's discretion for CAD \$1.20 per share, subject to certain conditions. As of September 30, 2023, there were no Class C shares issued and outstanding.
- Class D and E shares, non-voting, non-participating, without par value and maximum monthly non-cumulative dividend between 0.5% and 2% on the amount paid per share. Class D and E shares are convertible, at the holder's discretion, into Common Shares, on a one-for-one basis, and Class D and E shares are redeemable at the holder's discretion, subject to certain conditions. As of September 30, 2023, there were no Class D or E shares issued and outstanding.

Private Placement

On September 24, 2023, the Corporation entered into a securities purchase agreement (the "Purchase Agreement") with certain institutional and accredited investors in connection with a private placement of the Corporation's securities (the "Offering"). Pursuant to the Purchase Agreement, the Corporation agreed to offer and sell in the Offering 1,951,371 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 (the "Pre-funded Warrant Shares") at a purchase price equal to the purchase price per Common Share less \$0.0001. Each Pre-funded Warrant is exercisable for one Pre-funded Warrant Share at an exercise price of \$0.0001 per Pre-funded Warrant Share, is immediately exercisable and will expire once exercised in full. Pursuant to the Purchase Agreement, the Corporation also issued to such institutional and accredited investors common warrants (the "Common Warrants" and, together with the Pre-funded Warrants, the "Warrants") to purchase Common Shares, exercisable for an aggregate of 2,536,391 Common Shares (the "Common Warrant Shares" and, together with the Pre-Funded Warrant Shares, the "Warrant 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 Warrant Share at an exercise price of \$3.003 per Common Warrant 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 Corporation's product candidate GTX-104 or (ii) five years from the date of issuance. The Common Warrants were offered and sold at a purchase price of \$0.125 per whole underlying Common Warrant Share, which purchase price was included in the offering price per Common Share and Pre-funded Warrant issued in the Offering.

The Offering closed on September 25, 2023 (the "Closing Date"). The net proceeds to the Corporation from the Offering was approximately \$7,300, after deducting fees and expenses.

At-the-Market ("ATM") Program

On June 29, 2020, the Corporation entered into an amended and restated sales agreement (the "Sales Agreement") with B. Riley FBR, Inc. ("B.Riley"), Oppenheimer & Co. Inc. and H.C. Wainwright & Co., LLC (collectively, the "Agents") to amend the Corporation's existing ATM program. Under the terms of the Sales Agreement, which had a three-year term, the Corporation could issue and sell from time-to-time Common Shares having aggregate gross proceeds of up to \$75,000 through the Agents. Subject to the terms and conditions of the Sales Agreement, the Agents would use their commercially reasonable efforts to sell the Common Shares from time to time, based upon the Corporation's instructions. The Corporation had no obligation to sell any of the Common Shares and could, at any time, suspend sales under the Sales Agreement. The Corporation and the Agents could terminate the Sales Agreement in accordance with its terms. Under the terms of the Sales Agreement, the Corporation provided the Agents with customary indemnification rights and the Agents were entitled to compensation at a commission rate equal to 3.0% of the gross proceeds from each sale of the Common Shares. The Sales Agreement expired pursuant to its terms on June 29, 2023.

During the six months ended September 30, 2023, no Common Shares were sold under the ATM program. During the six months ended September 30, 2022, 54,108 Common Shares were sold for total net proceeds of approximately \$304 with commissions, legal expenses and costs related to the share sale amounting to \$10. The Common Shares were sold at the prevailing market prices, which resulted in an average price of approximately \$5.70 per share.

b. Warrants

During the six-month period ended June 30, 2023, 137,370 of the May 2018 Canadian public offering warrants to acquire one common share at an exercise price of CAD \$62.88 expired on May 9, 2023.

As further discussed above, on September 25, 2023, the Corporation issued an aggregate of 4,643,244 Warrants exercisable for 4,643,244 Warrant Shares in the Offering pursuant to the terms of the Purchase Agreement entered into with certain institutional and accredited investors. Pursuant to the terms of the Purchase Agreement, the Corporation sold Pre-funded Warrants to purchase up to 2,106,853 Pre-funded Warrant Shares. Each Pre-funded Warrant is exercisable for one Pre-funded Warrant Share at an exercise price of \$0.0001 per Pre-funded Warrant Share, is immediately exercisable and will expire once exercised in full. Pursuant to the Purchase Agreement, the Corporation also issued to such institutional and accredited investors Common Warrants to purchase an aggregate of 2,536,391 Common Warrant Shares. Each whole Common Warrant is exercisable for one Common Warrant Share at an exercise price of \$3.003 per Common Warrant 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 Corporation's product candidate GTX-104 or (ii) five years from the date of issuance.

The Common Warrants issued as a part of the Offering are derivative warrant liabilities given the warrant indenture did not meet the fixed-for-fixed criterion and that the Common Warrants are not indexed to the Corporation'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. For the six months ended September 30, 2023, Common Warrants were revalued at fair value through profit and loss.

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:

Balance - March 31, 2023	\$-
Issued during the year	1,631
Change in fair value	1,826
Balance - September 30, 2023	\$3,457

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 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 Corporation's product candidate GTX-104 or (ii) five years from the date on issuance.

	Issue Date September 25, 2023	Reporting date September 30, 2023
Risk-free interest rate	5.00%	4.94%
Share price	\$ 1.78	\$ 2.78
Expected warrant life	2.54	2.53
Dividend yield	0%	0%
Expected volatility	80.90%	84.36%

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 Corporation's product candidate GTX-104 and of it expiring on five years from the date of issuance. The weighted average fair value of the Common Warrants were determined to be \$0.64 and \$1.36 per Common Warrant, as of September 25, 2023 and September 30, 2023, respectively. The risk-free interest rate at the issue date and on the reporting date of September 30, 2023 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.

9. Stock-based compensation

At September 30, 2023, the Corporation had in place a stock option plan for directors, officers, employees, and consultants of the Corporation ("Stock Option Plan").

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 Corporation'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 amended Stock Option Plan shall not exceed 20% of the aggregate number of issued and outstanding shares of the Corporation as of July 28, 2022. The terms and conditions for acquiring and exercising options are set by the Corporation'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 Corporation'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 Corporation (or any subsidiary of the Corporation) conducting investor relations services, cannot exceed in the aggregate 2% of the Corporation'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 six-month period ended September 30, 2023:

	Number of options	Weighted average exercise price	Weighted average grant date fair value
Outstanding, March 31, 2023	740,957	13.60	11.23
Granted	446,502	2.64	2.27
Exercised	(12,500)	1.27	2.27
Forfeited/Cancelled	(613,594)	13.68	1.61
Outstanding, September 30, 2023	561,365	4.14	2.08
Exercisable, September 30, 2023	141,455	6.70	1.56

Forfeited and cancelled options were as a result of the Corporations restructuring that occurred during the six months ended September 30, 2023. On July 14, 2023, the Corporation's Board of Directors approved the grant of 446,502 stock options at an exercise price of \$2.64 under the Corporation's Stock Option Plan.

The weighted average grant date fair value of awards for options granted during the six months ended September 30, 2023 was \$2.27. 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:

	September 30, 2023 Weighted average
Exercise price	\$2.64
Share price	\$2.64
Dividend	0%
Risk-free interest	3.62%
Estimated life (years)	5.78
Expected volatility	118.40%

Compensation expense recognized under the stock option plan is summarized as follows:

	Three months ended		Six months ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
	\$	\$	\$	\$
Research and development expenses	82	184	84	342
General and administrative expenses	198	368	258	650
Sales and marketing expenses	-	30	16	54
	280	582	358	1,046

As of September 30, 2023, there was \$680 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 1.48 years.

Corporation equity incentive plan

The Corporation established an equity incentive plan (the "Equity Incentive Plan") for employees, directors, and consultants. The Equity Incentive Plan provides for the issuance of restricted share units (RSUs), 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 September 30, 2023 and 2022, and no stock-based compensation was recognized for the period ended September 30, 2023 and 2022 under the Equity Incentive Plan.

10. Loss per share

The Corporation 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 Corporation 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:

	September 30, 2023	September 30, 2022
Options outstanding	561,365	740,974
September 2023 US private offering pre-funded warrants	2,106,853	—
September 2023 US private offering warrants	2,536,391	—
May 2018 public offering warrants	—	137,370
December 2017 public offering warrants	—	147,354
December 2017 public offering broker warrants	—	5,399

11. Supplemental cash flow disclosure

Changes in operating assets and liabilities

	September 30, 2023	Six Months ended September 30, 2022
	\$	\$
Receivables	(35)	(359)
Prepaid expenses	(446)	(704)
Trade and other payables	(1,986)	926
Write-off of operating lease right of use asset	(23)	—
Total changes in operating assets and liabilities	(2,489)	(137)

12. Financial instruments

a. Concentration of credit risk

Financial instruments that potentially subject the Corporation to a concentration of credit risk consist primarily of cash and cash equivalents and investments. Cash and cash equivalents and investments are all invested in accordance with the Corporation's Investment Policy with the primary objective being the preservation of capital and the maintenance of liquidity, which risk is managed by dealing only with highly rated Canadian institutions. The carrying amount of financial assets, as disclosed in the consolidated balance sheets, represents the Corporation's credit exposure at the reporting date.

b. Foreign currency risk

The Corporation is exposed to financial risk related to the fluctuation of foreign exchange rates and the degrees of volatility of those rates. Foreign currency risk is limited to the portion of the Corporation's business transactions denominated in currencies other than the Corporation's functional currency of the U.S. dollar. Fluctuations related to foreign exchange rates could cause unforeseen fluctuations in the Corporation's operating results. The Corporation does not use derivative instruments to hedge exposure to foreign exchange risk. The fluctuation of the Canadian dollar in relation to the U.S. dollar and other foreign currencies will consequently have an impact upon the Corporation's net loss.

c. Liquidity risk

Liquidity risk is the risk that the Corporation will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset. The Corporation manages liquidity risk through the management of its capital structure and financial leverage. It also manages liquidity risk by continuously monitoring actual and projected cash flows. The Board of Directors reviews and approves the Corporation's operating budgets, and reviews material transactions outside the normal course of business. The Corporation currently does not have long-term debt nor arranged committed sources of financing and is operating via use of existing cash and short-term investment balances. Refer to Note 1 – Nature of Operations.

The Corporation's financial liabilities obligations include trade and other payables, which fall due within the next 12 months.

13. Commitments and contingencies

Research and development contracts and contract research organizations agreements

The Corporation utilizes contract manufacturing organizations ("CMOs") for the development and production of clinical materials and contract research organizations ("CROs") to perform services related to its clinical trials. Pursuant to the agreements with these CMOs and CROs, the Corporation has either the right to terminate the agreements without penalties or under certain penalty conditions. As of September 30, 2023, the Corporation has no commitments from CMOs and approximately \$8,500 of commitments for the next twelve months to CROs.

Raw krill oil supply contract

On October 25, 2019, the Corporation 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 Corporation'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 Corporation 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 Corporation was therefore required to accept the remaining product commitment. The Corporation 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 Corporation. The dispute remained unresolved as of both March 31, 2023 and 2022. On October 18, 2023, the Corporation entered into a settlement agreement with AKBM to settle any and all potential claims regarding amounts due under the supply 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 Corporation and AKBM agreed to the following: (a) AKBM retained ownership of all raw krill oil product, including amounts previously delivered to the Corporation, (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 related to CaPre owned by the Corporation, including all patents and trademarks. 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 Corporation 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 Corporation, 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. As of September 30, 2023, no liability was recorded by the Corporation.

Legal proceedings and disputes

In the ordinary course of business, the Corporation is at times subject to various legal proceedings and disputes. The Corporation assesses its liabilities and contingencies in connection with outstanding legal proceedings utilizing the latest information available. Where it is probable that the Corporation will incur a loss and the amount of the loss can be reasonably estimated, the Corporation 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 Corporation 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 Corporation'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 Corporation's financial position, results of operations, or cash flows. No reserves or liabilities have been accrued as of September 30, 2023.

14. Restructuring Costs

On May 8, 2023, the Corporation communicated its decision to terminate a substantial amount of its workforce as part of a plan that intended to align the Corporation's organizational and management cost structure to prioritize resources to GTX-104 and reduce losses to improve cash flow and extend available cash resources. The Corporation incurred \$1,485 of costs primarily consisting of employee severance costs and legal fees.

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 as at September 30, 2023. This MD&A also explains the material variations in our results of operations for the three and six months ended September 30, 2023 and 2022, consolidated balance sheets as of September 30, 2023 and March 31, 2023, and cash flows as for the six months ended September 30, 2023 and 2022.

Market data, and certain industry data and forecasts included in this MD&A were obtained from internal Corporation 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 is 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 23, 2023 (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 and six months ended September 30, 2023 and 2022 included elsewhere in this quarterly report. Our interim 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 provides the opportunity for us to utilize the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act 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 and multiple pre-clinical stage assets 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 currently in clinical development 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 infusion (IV) 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. Intravenous delivery of GTX-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTX-104 has the potential to better manage hypotension in aSAH patients. GTX-104 has been administered in over 150 healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine. The pivotal pharmacokinetics (“PK”) bridging study was successfully completed in May 2022.

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, financing 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, and 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 quarter ended March 31, 2023 we booked 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 impairment charge overall amounted to \$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.

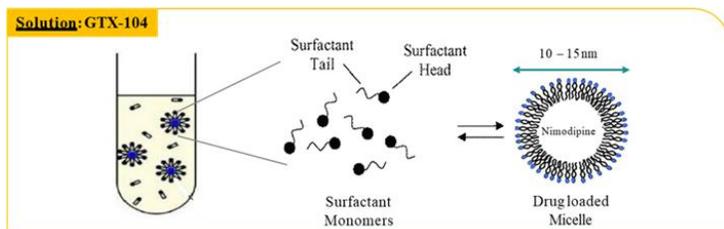
Our management team possesses significant experience in drug formulation and drug delivery research and development, clinical and pharmaceutical development and manufacturing, regulatory affairs, and business development, as well as being well-versed in late-stage drug development and commercialization. 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 a drug candidate for aSAH.

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.

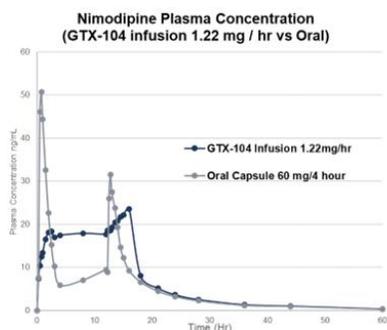


Key Potential Benefits:

- 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

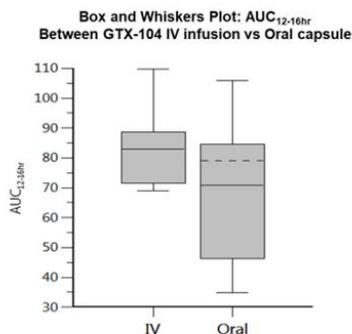
GTX-104 could provide a more convenient mode of administration as compared to generic nimodipine capsules or NYMALIZE™, GTX-104 is administered as an intravenous infusion compared to oral administration via a nasogastric tube in unconscious patients every four hours for both nimodipine capsules and NYMALIZE™. 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 can also reduce the risk of medication errors. In addition, as depicted in the charts below, two PK studies 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. The variability was observed higher following the capsule administration 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.

GTX-104: Novel Aqueous Formulation for IV Infusion



Consistent and predictable plasma concentrations allow for tighter control of hypotension

Sources: GTX-104-001 PK study report



GTX-104 is effective at 1/12th the oral dose

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.

GTX-104: Potentially Strong Value Proposition

Effective hypotension management, ensure compliance, and reduce hospital resources

Clinical Value 	Hospital Value 	Patient Value 
<ul style="list-style-type: none"> ✓ Predictable drug concentration ✓ Effective hypotension management ✓ Therapeutic dose compliance ✓ Reduced drug intake ✓ No food effects and reduced DDI 	<ul style="list-style-type: none"> ✓ Reduce medication errors ✓ Reduce nursing burden ✓ Reduce rescue therapy ✓ Shorter ICU stay ✓ Joint Commission compliance 	<ul style="list-style-type: none"> ✓ Improved outcomes ✓ Convenient dosing ✓ Faster recovery ✓ Safer ✓ Lower disease burden

About aneurysmal Subarachnoid Hemorrhage (aSAH)

aSAH is bleeding over the surface of the brain in the subarachnoid space between the brain and the skull, which contains blood vessels that supply the brain. A primary cause of such bleeding is rupture of an aneurysm. The result is a relatively uncommon type of stroke that accounts for about 5% of all strokes and has an incidence of six per 100,000 person years.

In contrast to more common types of 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 aneurysmal SAH (“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 dependence on family members, and half die within one month 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 SAH 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 based on annual inpatient admissions and the average length-of-stay.

GTX-104 Recent Activities & Near Term Milestones: Conduct Phase 3 Safety Trial

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 on May 18, 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 three 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 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.

Next Step – Phase 3 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 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 of same, will allow us to proceed with the initiation of a Phase 3 safety clinical trial in aSAH patients. On July 5, 2023, we announced the alignment with the U.S. Food and Drug Administration on our GTX-104 pivotal Phase 3 safety 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.

Based on the proposed design of our Phase 3 trial, which we have titled STRIVE-ON (Safety, Tolerability, Randomized, IV and Oral Nimodipine), the clinical trial will be 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.

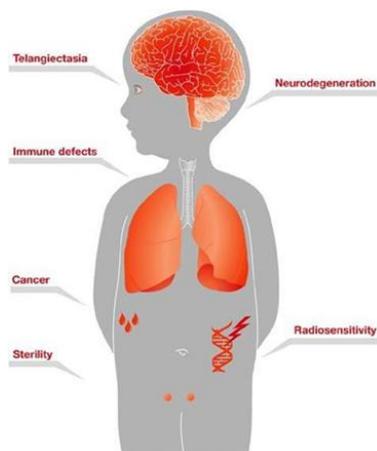
On October 23, 2023, we enrolled our first patient in our STRIVE-ON clinical trial. The trial is expected to take approximately 18 months to complete from the time the first patient is enrolled, and we expect this safety trial to be the final clinical step required to seek FDA approval under the 505(b)(2) regulatory pathway. Before submitting an NDA, we plan to hold a pre-NDA meeting with the FDA.

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 - R&D 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:

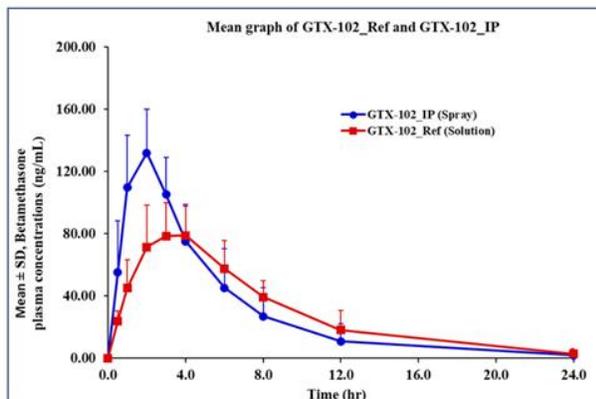
GTX-102 administered as a concentrated oral spray achieves similar blood levels at only 1/70th the volume of an oral solution of betamethasone. This more convenient mode of administration will be important for A-T patients who have difficulties swallowing large volumes of liquids.

Nonclinical PK Comparison of GTX-102 Betamethasone Oral Spray vs. Oral Solution Marketed in Europe

Group/Formulation	Group 1, GTX-102_IP	Group 2, GTX-102_Ref
Lot Number	GTX-102-008	GTX-102-009
Pk	0.292 mg/rabbit, Oral	0.25 mg/rabbit, Oral
Parameters/Dose/ROA	Spray	solution
C _{max} (ng/mL)	158.17 ± 31.30 (20)	82.63 ± 23.06 (26)
T _{max} (hr) [a]	2.0 (1.0 - 3.0)	3.0 (2.0 - 4.0)
AUC _{0-∞} (ng*hr/mL)	851.16 ± 314.19 (37)	709.29 ± 193.51 (27)
AUC _{0-t} (ng*hr/mL)	866.02 ± 336.77 (39)	729.40 ± 217.86 (30)
Kel (1/hr)	0.19 ± 0.04 (23)	0.19 ± 0.06 (29)
t _{1/2} (hr)	3.91 ± 0.92 (23)	3.93 ± 1.21 (31)
CL/F (mL/min)	6.19 ± 1.85 (30)	6.11 ± 1.67 (27)
V _d /F (L)	2.06 ± 0.75 (37)	2.00 ± 0.52 (26)
Relative Bioavailability (% F)	103.70 ± 23.7 (23)	-

Note: Values are mean ± SD (% CV); [a] represents Median (minimum-maximum); ROA=Route of administration; CV=Coefficient of variation

Mean plasma pharmacokinetic parameters of Betamethasone following reference (oral solution) and GTX-102 (oral mucosal spray) administered orally in rabbits show similar characteristics.



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. On December 28, 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 C_{max} (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 C_{max} 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 C_{max} of GTX-102 was within the same range of exposure as the OS, but the C_{max} 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 (AE) were reported, and the most frequent drug-related adverse effect was mild headache (4 cases).

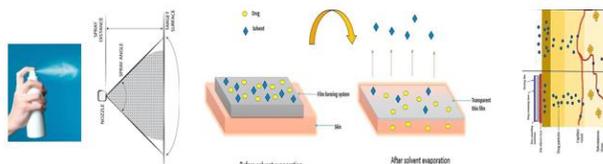
The further development of GTX-102 has been deprioritized in favor of our focus on development of GTX-104. Pending additional funding for GTX-102 or the signing of a strategic partnership, we will work with our clinical experts and the FDA to determine the best final dosing regimen for GTX-102 to incorporate into our Phase 3 trial design. Based on previous discussions with the FDA, we plan to conduct a

confirmatory Phase 3 safety and efficacy trial in A-T patients, and plan to seek guidance from the FDA on the trial design at a Type B meeting if and when development of GTX-102 resumes. It is also possible that we may out-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, 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.

Mechanism of GTX-101 Bioadhesive Film Formation



- Metered-dose of bupivacaine spray forms a thin bio-adhesive topical film:
 - **Touch-free, non-greasy** application
 - **Convenient, portable** 30mL plastic bottles
 - **No skin sensitivity** reported in Phase 1 trial
- **Non-narcotic**, non-addictive pain management
 - Potentially reduces the need for opioids

Source: GTX-101 Phase 1 trial report

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 on 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 we commissioned, 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.

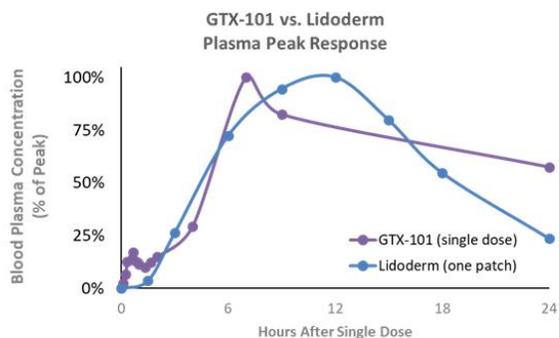
GTX-101 R&D History and Clinical Trials Completed to Date

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.

Phase 1 Single Dose PK Data in Humans



Biphasic drug release profile is expected to provide patients with immediate relief upon first application and continuous relief with consistent use

GTX-101 recent activities:

We believe that the PHN pain market will continue to grow, and non-opioid products like GTX-101 that can relieve PHN pain more quickly and in a sustained manner by means of a more efficient delivery system, will be an attractive therapy option for patients and physicians. GTX-101 is administered by spraying our proprietary bupivacaine formulation over the affected area, which we believe has the potential to provide several advantages over currently marketed products such as the lidocaine patch, including faster onset of action, sustained pain relief, possibly lower dosing requirements and improved dosing convenience, all which could lead to increased patient satisfaction and compliance.

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 on April 18, 2018, 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 on December 23, 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 a multiple ascending dose trial in 2023. 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 out-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 asset. Currently, we have prioritized the development of GTX-104 and de-emphasized the development of GTX-102 and GTX-101. If we receive regulatory approval for GTX-104 in the US, we may look to out-license commercialization or consider self-commercialization including outsourcing sales to ensure efficient commercial management and maximize market penetration and financial returns. We may seek commercial partnerships to fully exploit the market potential of GTX-104 in territories outside the US. It is possible that we may out-license or sell GTX-102 and/or GTX-101 for the US and/or global markets.

Recent Developments

September 2023 Private Placement Offering

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, we agreed to offer and sell in the Offering 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 (the “Pre-funded Warrant Shares”) at a purchase price equal to the purchase price per Common Share less \$0.0001. Each Pre-funded Warrant is exercisable for one Pre-funded Warrant Share at an exercise price of \$0.0001 per Pre-funded Warrant Share, is 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” and, together with the Pre-funded Warrants, the “Warrants”) to purchase Common Shares, exercisable for an aggregate of 2,536,391 Common Shares (the “Common Warrant Shares” and, together with the Pre-Funded Warrant Shares, the “Warrant 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 Warrant Share at an exercise price of \$3.003 per Common Warrant 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 our product candidate GTX-104 or (ii) five years from the date of issuance. The Common Warrants were offered and sold at a purchase price of \$0.125 per whole underlying Common Warrant Share, which purchase price was included in the offering price per Common Share and Pre-funded Warrant issued in the Offering.

The Offering closed on September 25, 2023 (the “Closing Date”). Shore Pharma LLC, an entity controlled by Vimal Kavuru, the Chair of our Board of Directors, and SS Pharma LLC, the beneficial owner of 5.5% of our Common Shares outstanding prior to the Offering, each a related party of ours, participated in the Offering. The net proceeds to us from the Offering was approximately \$7.3 million, after deducting fees and expenses.

Pursuant to the terms of the Purchase Agreement, we agreed to register for resale the Common Shares sold in the Offering and the Warrant Shares. On October 6, 2023, we filed a resale Registration Statement on Form S-3 with the SEC, registering the Common Shares sold in the Offering and the Warrant Shares for resale. The resale Registration Statement on Form S-3 was declared effective on October 16, 2023.

Announcement of compliance with the Nasdaq minimum bid price requirement

On July 24, 2023, we received written notice (the “Notification Letter”) from The Nasdaq Stock Market LLC notifying us that we had regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. The Notification Letter was sent following the implementation of a 1-for-6 reverse split of our Common Shares (the “Reverse Stock Split”), which became effective on July 10, 2023.

Reverse stock split

On June 29, 2023, our Board of Directors approved an amendment to our Articles of Incorporation to implement the Reverse Stock Split. On July 4, 2023, we filed Articles of Amendment to our Articles of Incorporation with the *Registraire des entreprises du Québec*, to implement the Reverse Stock Split. All applicable references in this MD&A to number of common shares, warrants and options, price per share and weighted average number of shares outstanding prior to the Reverse Stock Split have been adjusted to reflect the Reverse Stock Split, which was made effective on July 10, 2023.

Basis of Presentation of the Financial Statements

Our condensed consolidated interim financial statements, which include the accounts of our wholly owned subsidiaries, Acasti Pharma U.S., and Acasti Innovations AG, 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 September 30, 2023, include cash and cash equivalents and short-term investments totaling \$27.0 million and intangible assets and goodwill totaling \$49.3 million. Our current liabilities total \$1.4 million as of September 30, 2023 and are comprised primarily of amounts due to or accrued for creditors.

Results of Operations for the Three and Six months ended September 30, 2023 and 2022

	Three months ended			Six months ended		
	September 30, 2023	September 30, 2022	Increase (Decrease)	September 30, 2023	September 30, 2022	Increase (Decrease)
	\$	\$	\$	\$	\$	\$
Operating expenses						
Research and development expenses, net of government assistance	460	3,292	(2,832)	1,555	5,882	(4,327)
General and administrative expenses	1,589	1,680	(91)	3,352	3,599	(247)
Sales and marketing expenses	43	136	(93)	154	357	(203)
Restructuring costs	—	—	—	1,485	—	1,485
Loss from operating activities	(2,092)	(5,108)	(3,016)	(6,546)	(9,838)	(3,292)
Foreign exchange gain (loss)	(13)	(12)	(1)	(5)	(90)	85
Change in fair value of warrant liabilities	(1,826)	—	(1,826)	(1,826)	10	(1,836)
Interest income and other expense	212	36	176	346	68	278
Income tax recovery	446	155	291	735	397	338
Net loss	(3,273)	(4,929)	(1,656)	(7,296)	(9,453)	(2,157)

Net Loss

The net loss of \$3,273 or \$0.43 per share for the three months ended September 30, 2023 decreased by \$1,656 from the net loss of \$4,929 or \$0.66 per share for the three months ended September 30, 2022.

The net loss of \$7,296 or \$0.97 per share for the six months ended September 30, 2023 decreased by \$2,157 from the net loss of \$9,453 or \$1.28 per share for the six months ended September 30, 2022.

Research and development expenses

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 and six months ended September 30, 2023, was focused primarily on our clinical development programs for our GTX-104 drug candidate. Research and development expenses during the three and six months ended September 30, 2022 were focused primarily on our clinical development programs GTX-104, GTX-102, and GTX-101 drug candidates, which were acquired in the Grace Therapeutics, Inc. ("Grace") merger on August 27, 2021.

The following table summarizes our research and development expenses for the periods presented:

Research and development expenses

	Three months ended			Six months ended		
	September 30, 2023	September 30, 2022	Increase (Decrease)	September 30, 2023	September 30, 2022	Increase (Decrease)
	\$	\$	\$	\$	\$	\$
Total third-party research and development expenses ¹	152	2,561	(2,409)	965	4,573	(3,608)
Government grants & tax credits	4	109	(105)	55	(81)	136
Salaries and benefits	209	472	(263)	435	961	(526)
Research and development expense before stock-based compensation and depreciation	365	3,142	(2,777)	1,455	5,453	(3,998)
Stock-based compensation	83	184	(101)	83	342	(259)
Depreciation and write-off of equipment	12	(34)	46	17	87	(70)
Total	460	3,292	(2,832)	1,555	5,882	(4,327)

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 and six months ended September 30, 2023, totaled \$152 and \$965, respectively, compared to \$2,561 and \$4,573 for the three and six months ended September 30, 2022, respectively. This decrease of \$2,409 and \$3,608 related mostly to the restructuring to align our organizational and management cost structure to prioritize resources to GTX-104 and reduce losses and cash flow. Our clinical development programs for GTX-102, and GTX-101 were de-prioritized in the current year compared to the prior year.

Government grants and tax credits of \$4 and \$55 for the three and six months ended September 30, 2023, respectively, decreased by (\$105) and increased by \$136 compared to \$109 and \$(81) for the three and six months ended September 30, 2022, respectively. The changes within government grants and tax credits are due to adjustments of provisions regarding the estimated realizability of credits receivable after assessments and correspondence from tax authorities.

Salaries and benefits of \$209 and \$435 for the three and six months ended September 30, 2023, respectively, decreased by \$263 and \$526 compared to \$472 and \$961 for the three and six months ended September 30, 2022, respectively. The decrease relates to a reduction in research and development headcount due to the restructuring as we prioritize resources to GTX-104.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related benefits, including share-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			Six months ended		
	September 30, 2023	September 30, 2022	Increase (Decrease)	September 30, 2023	September 30, 2022	Increase (Decrease)
	\$	\$	\$	\$	\$	\$
Salaries and benefits	228	472	(244)	570	1,004	(434)
Professional fees	864	434	430	1,809	1,037	772
Other	297	418	(121)	710	874	(164)
General and administrative expense before stock-based compensation and depreciation ¹	1,389	1,324	65	3,089	2,915	174
Stock-based compensation	199	368	(169)	259	650	(391)
Depreciation	1	(12)	13	4	34	(30)
Total	1,589	1,680	(91)	3,352	3,599	(247)

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 totaled \$1,389 and \$3,089 before stock-based compensation and depreciation expense for the three and six months ended September 30, 2023, respectively, an increase of \$65 and \$174 from \$1,324 and \$2,915 for the three and six months ended September 30, 2022, respectively. The increase was primarily a result of increase legal, tax, accounting and other professional fees related to the restructuring offset by decreased salaries and benefits due to a reduction in general and administrative headcount due to our restructuring and reorganization of our management structure. Stock-based compensation of \$199 and \$259 for the three and six months ended September 30, 2023, respectively, decreased by \$169 and \$391 compared to \$368 and \$650 for the three and six months ended September 30, 2022, respectively. The decrease relates to a reduction in general and administrative headcount due to our restructuring and reorganization of our management structure.

Sales and marketing expenses

Sales and marketing expenses consist primarily of salaries and benefits, including share-based compensation, related to our commercial functions.

Sales and marketing expenses

	Three months ended			Six months ended		
	September 30, 2023	September 30, 2022	Increase (Decrease)	September 30, 2023	September 30, 2022	Increase (Decrease)
	\$	\$	\$	\$	\$	\$
Salaries and benefits	—	99	(99)	15	281	(266)
Professional fees	—	4	(4)	20	9	11
Other	43	3	40	103	13	90
Sales and Marketing expenses before stock-based compensation ¹	43	106	(63)	138	303	(165)
Stock-based compensation	—	30	(30)	16	54	(38)
Total	43	136	(93)	154	357	(203)

¹ Sales and marketing sub-total expenses are calculated before 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.

Sales and marketing expenses before stock-based compensation expense totaled \$43 and \$138 for the three and six months ended September 30, 2023, respectively, compared to \$106 and \$303 for the three and six months ended September 30, 2022, respectively. The decrease of \$63 and \$165, was mostly due to the reduction of headcount due to our restructuring and reorganization of our management structure.

Stock-based compensation of nil and \$16 for the three and six months ended September 30, 2023, decreased by \$30 and \$38, respectively, compared to \$30 and \$54 for the three and six months ended September 30, 2022, respectively. The decrease relates to a reduction in sales and marketing headcount due to our restructuring and reorganization of our management structure.

Restructuring Costs

On May 8, 2023, we announced our decision to terminate a substantial amount of our workforce as part of a plan that intended to align our organizational and management cost structure to prioritize resources to GTX-104 and reduce losses to improve cash flow and extend available cash resources. We incurred \$1,485 of cost primarily consisting of employee severance costs.

Change in fair value of warrant liabilities

Change in fair value of warrant liabilities for the three and six months ended September 30, 2023 increased by \$1,826 mainly attributable to an increase in the fair value of derivative warrant liabilities.

Interest income and other expense

Interest income was \$212 and \$346 for the three and six months ended September 30, 2023, respectively, compared to \$36 and \$68 for the three and six months ended September 30, 2022, respectively. The increase in our interest income was due to higher interest rates earned on average balances of cash, cash equivalents and short-term investments.

Liquidity and Capital Resources

Share capital structure

Our authorized share capital consists of an unlimited number of Class A, Class B, Class C, Class D and Class E common shares, without par value. Issued and outstanding fully paid shares, stock options, and warrants, were as follows for the periods indicated (after giving effect to the Reverse Stock Split, which became effective on July 10, 2023):

	September 30, 2023	March 31, 2023
	Number outstanding	Number outstanding
Class A common shares, voting, participating and without par value	9,399,404	7,435,533
Stock options granted and outstanding	561,365	740,957
September 2023 US private offering pre-funded warrants	2,106,853	—
September 2023 US private offering warrants	2,536,391	—
May 2018 Canadian public offering of warrants exercisable at CAD\$62.88 until May 9, 2023	—	137,370
Total fully diluted shares	14,604,013	8,313,860

Cash flows and financial condition for the six months ended September 30, 2023 and 2022

Summary

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 with 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 we expect to be sourced from a combination of public or private equity offerings or debt financings or other non-dilutive sources, which may include fees, milestone payments and royalties from collaborations with third parties.

As of September 30, 2023, cash and cash equivalents totaled \$26,991, a decrease of \$884 compared to cash and cash equivalents totaling \$27,875 at March 31, 2023 primarily due to ongoing research and development activities, and funding the restructuring expense offset by the proceeds of our September 2023 Offering.

Net cash used in operating activities

Net cash used in operating activities for the six months ended September 30, 2023 was \$8,353, compared to \$8,865 for the six months ended September 30, 2022, a decrease of \$512. Cash used in operating activities during the six months ended September 30, 2023 primarily related to our net loss of \$7,296, adjusted for non-cash items such as stock-based compensation of \$358, change in fair value of warrant liabilities of \$1,826, income tax recovery of \$(735) and changes in our operating assets and liabilities of \$(2,489). Net cash used in operating activities for the six months ended September 30, 2022, was \$8,865. Cash used in operating activities during 2022 primarily related to our net loss of \$9,453, adjusted for non-cash items such as stock-based compensation of \$1,046, income tax recovery of \$397 and changes in our operating assets and liabilities of \$(137).

Net cash provided by investing activities

Net cash provided by investing activities for the six months ended September 30, 2023, was \$110 related to our sale of equipment. For the six months ended September 30, 2022, our investing activities generated cash of \$13,162, which was a function of an increase in proceeds from maturity of short-term investments.

Net cash provided by financing activities

Net cash provided by financing activities for the six months ended September 30, 2023, totaled \$7,359 compared to cash generated of \$304 during the six months ended September 30, 2022 due to net proceeds from our September 2023 Offering of \$7,338.

Private Placement

On September 24, 2023, we entered into the Purchase Agreement with certain institutional and accredited investors in connection with the Offering. Pursuant to the Purchase Agreement, we agreed to offer and sell in the Offering 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 Pre-funded Warrant Shares at a purchase price equal to the purchase price per Common Share less \$0.0001. Each Pre-funded Warrant is exercisable for one Pre-funded Warrant Share at an exercise price of \$0.0001 per Pre-funded Warrant Share, is immediately exercisable and will expire once exercised in full. Pursuant to the Purchase Agreement, we also issued to such institutional and accredited Common Warrants to purchase Common Shares, exercisable for an aggregate of 2,536,391 Common Warrant 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 Warrant Share at an exercise price of \$3.003 per Common Warrant 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 our product candidate GTX-104 or (ii) five years from the date of issuance. The Common Warrants were offered and sold at a purchase price of \$0.125 per whole underlying Common Warrant Share, which purchase price was included in the offering price per Common Share and Pre-funded Warrant issued in the Offering.

The Offering closed on September 25, 2023. The net proceeds to us from the Offering was approximately \$7.3 million, after deducting fees and expenses.

At-the-Market (“ATM”) program

On June 29, 2020, we entered into an amended and restated sales agreement (the “Sales Agreement”) with B. Riley, Oppenheimer & Co. Inc. and H.C. Wainwright & Co., LLC (collectively, the “Agents”). Under the terms of the Sales Agreement, which had a three-year term, we could issue and sell from time-to-time Common Shares having an aggregate offering price of up to \$75 million through the Agents. Subject to the terms and conditions of the Sales Agreement, the Agents would use their commercially reasonable efforts to sell the Common Shares from time to time, based upon our instructions. We had no obligation to sell any of the Common Shares and could, at any time, suspend sales under the Sales Agreement. We and the Agents could terminate the Sales Agreement in accordance with its terms. Under the terms of the Sales Agreement, we provided the Agents with customary indemnification rights and the Agents were entitled to compensation at a commission rate equal to 3.0% of the gross proceeds from each sale of the Common Shares. The Sales Agreement expired pursuant to its terms on June 29, 2023. We intend to examine our financing strategies on a go-forward basis and may consider entering into a new ATM program in the future.

During the six months ended September 30, 2023, no Common Shares were sold under the ATM program. During the six months ended September 30, 2022, 54,108 Common Shares were sold for total net proceeds of approximately \$304 with commissions, legal expenses and costs related to the share sale amounting to \$10. The Common Shares were sold at the prevailing market prices, which resulted in an average price of approximately \$5.70 per share.

Financial position

The following table details the significant changes to our consolidated balance sheets as of September 30, 2023, compared to the prior fiscal year end at March 31, 2023:

Accounts	Increase (Decrease) \$	Comments
Cash and cash equivalents	(884)	See cash flow statement
Receivables	35	Timing of reimbursement of sales taxes
Prepaid expenses	446	Renewal of insurance contract and other prepaid expenses (advances to US vendors)
Right of use asset	(416)	Adjustment to the net present value of lease contract for Sherbrooke due to lease modification
Equipment	(94)	Depreciation of equipment and write off of equipment
Trade and other payables	(1,985)	Timing of payments net of accruals
Lease liability	(439)	Adjustment to the net present value of lease contract for Sherbrooke due to lease modification
Derivative warrant liabilities	3,457	Issuance of warrants in relation to Purchase Agreement and change in fair value of warrant liabilities
Deferred tax liability	(736)	Related to recovery expense

See the consolidated statements of shareholders' equity in our financial statements for details of changes to our equity accounts during the three and six months ended September 30, 2023 and 2022.

Treasury Operations

Our treasury policy is to invest cash that is not required immediately into instruments with an investment strategy based on capital preservation. Cash equivalents and marketable securities are primarily in guaranteed investment certificates, term deposits and high-interest savings accounts, which are issued and held with Canadian chartered banks, highly rated promissory notes issued by government bodies and commercial paper. We hold cash denominated in both U.S. and Canadian dollars. Funds received in U.S. dollars from equity financings are invested as per our treasury policy in U.S. dollar investments and converted to Canadian dollars as appropriate to fulfill operational requirements and funding.

Intangible Assets

On August 27, 2021, we completed the Grace merger.

In connection with the share-for-share noncash transaction, Grace was merged with a new wholly owned subsidiary of Acasti and became a subsidiary of Acasti. As a result, we acquired Grace's entire therapeutic pipeline consisting of three unique clinical stage and multiple pre-clinical stage assets supported by an intellectual property portfolio consisting of various granted and pending patents in various jurisdictions worldwide. Under the terms of the acquisition, each issued and outstanding share of Grace common stock was automatically converted into the right to receive Acasti Common Shares equal to the equity exchange ratio set forth in the merger agreement.

Intangible assets of \$69,810 relate to the value of in-process research and development ("IPR&D"), related to Grace's therapeutic pipeline, consisting of three unique clinical stage programs/assets supported by intellectual property, the value of which has been attributed as follows:

	\$ GTX-104	\$ GTX-102	\$ GTX-101	\$ Total
Intangible assets – in-process research and development				
Balance, April 1, 2022	27,595	31,908	10,307	69,810
Impairment	—	(22,712)	(5,970)	(28,682)
Balance, March 31, 2023	27,595	9,196	4,337	41,128
	\$ GTX-104	\$ GTX-102	\$ GTX-101	\$ Total
Intangible assets – in-process research and development				
Balance, April 1, 2023	27,595	9,196	4,337	41,128
Impairment	—	—	—	—
Balance, September 30, 2023	27,595	9,196	4,337	41,128

In April 2023, we announced the strategic decision to prioritize development of GTX-104 with a goal to advance to commercialization, while conserving resources as much as possible to complete development efficiently. We estimate that the deferral of the GTX-102 and GTX-101 clinical programs 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 triggered a comprehensive impairment review of our intangible assets in March 2023. Given the extended timeline, we increased the discount rates used to value the assets in order to recognize additional risks related to prioritizing one asset over the others, financing 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, and 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, an impairment of intangible assets of \$28,682 resulted in the year ended March 31, 2023. In addition, an impairment of \$4,826 of goodwill resulted in the year ended March 31, 2023. We determined there was no triggering event in the six months ended September 30, 2023 that would have required us to perform a quantitative impairment test.

Contractual Obligations and Commitments

Our contractual obligations and commitments include trade payables, operating lease obligations, 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 September 30, 2023, we have no commitments from CMOs and approximately \$8,500 of commitments for the next twelve months to CROs.

Raw krill oil supply contract

On October 25, 2019, we 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 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 a settlement agreement with AKBM to settle any and all potential claims regarding amounts due under the supply 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 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 related to CaPre owned by us, including all patents and trademarks. 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 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. As of September 30, 2023, no liability was recorded.

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 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 Corporation recognizes the tax credits once it has reasonable assurance that they will be realized.

Critical Accounting Policies

During the six months ended September 30, 2023, there were no material changes to our critical accounting policies from those described in our Annual Report for the year ended March 31, 2023.

Future Accounting Changes

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 Chief 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 September 30, 2023, our existing disclosure controls and procedures were effective. It should be noted that while our Chief Executive Officer and Chief 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 September 30, 2023 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 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.

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

None.

m 3. Defaults upon Senior Securities

None.

m 4. Mine Safety Disclosures

Not applicable.

m 5. Other Information

None.

m 6. Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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)
4.1	Form of Common Warrant, dated September 25, 2023 (incorporated by reference to Exhibit 4.1 from Form 8-K (File No. 001-35776) filed with the Commission on September 26, 2023)
4.2	Form of Pre-Funded Warrant, dated September 25, 2023 (incorporated by reference to Exhibit 4.2 from Form 8-K (File No. 001-35776) filed with the Commission on September 26, 2023)
10.1	Form of Securities Purchase Agreement, dated September 24, 2023, by and between the Company and each of the Purchasers signatory thereto (incorporated by reference to Exhibit 10.1 from Form 8-K (File No. 001-35776) filed with the Commission on September 26, 2023)
10.2	Settlement Agreement, dated October 18, 2023, by and between the Company and Aker BioMarine Antarctic AS. (incorporated by reference to Exhibit 10.1 from Form 8-K (File No. 001-35776) filed with the Commission on October 23, 2023)
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 Chief 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 Chief 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 Document

101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF Inline XBRL Taxonomy Extension Definition Linkbase Document
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: November 13, 2023

ACASTI PHARMA INC.

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

By: /s/ Brian Ford
Name: Brian Ford
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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: November 13, 2023

/s/ Prashant Kohli

Chief Executive Officer

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

I, Brian Ford, 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: November 13, 2023

/s/ Brian Ford

Chief Financial Officer

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 September 30, 2023 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: November 13, 2023

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.

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 September 30, 2023 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/ Brian Ford

Name: Brian Ford
Title: Chief Financial Officer
Date: November 13, 2023

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.
