

May 15, 2023



GT Biopharma Reports First Quarter 2023 Financial Results and Provides Corporate Update

- *Cash of approximately \$19.9 million as of March 31, 2023, provides ample runway to fund operations into Q2 2024; anticipated to be sufficient to achieve IND clearance for GTB-3650 and GTB-5550, and initiate clinical trial activities on GTB-3650.*

BRISBANE, CALIFORNIA, May 15, 2023 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. (the "Company") (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary natural killer (NK) cell engager, TriKE[®] platform, today announced first quarter 2023 results for the period ended March 31, 2023.

"Pipeline development progress continues to move forward in the advancement of GTB-3650, a second generation nanobody TriKE[®] for the treatment of CD33+ leukemia, followed by GTB-5550 for the treatment of B7H3+ solid tumors. Operationally, our development timeline remains aligned, and we expect to submit an investigational new drug (IND) filing with the U.S. Food and Drug Administration for GTB-3650 in the 2H 2023," said Michael Breen, Executive Chairman and interim Chief Executive Officer. "Additionally, we reaffirm our current cash on hand, coupled with significant recent cost reduction efforts, is sufficient to provide ample runway to fund operations into Q2 2024, anticipated to be sufficient to achieve IND clearance for GTB-3650 and GTB-5550, and initiate clinical trial activities for GTB-3650. Concurrently, we continue to investigate and develop the Company's TriKE[®] nanobody platform for multiple additional targets and indications, while actively exploring potential development partnerships for our programs."

Highlights and Recent Updates

- The Company was recently informed of a certain unforeseen complication at our contract manufacturing organization (CMO) which has since been resolved, and which was not specific to the work related to our products. The issue was not central to the manufacturing processes for any GT Biopharma-related molecules, and the specific processes remain unaffected. However, it has resulted in operational challenges at the CMO that will affect the anticipated IND submission timing for GTB-3650, which is now expected in the 2H of 2023. The Company anticipates that the IND submission of

GTB-5550 will follow after GTB-3650.

- In May, Charles J. Casamento was named to the board of directors to fill the seat vacated by Alan Urban.
- Jeffrey Miller, MD, Consulting CMO & CSO, presented at the H.C. Wainwright Cell Therapy Virtual Conference in February.

Upcoming Events

- Dr. Jeff Miller will present at PEGS Boston Conference in Boston, MA on Tuesday, May 16, 2023 at 9:00 AM ET with a talk entitled: “NK Cell Therapy for Cancer, from Individual to Off-the-Shelf CAR-Targeted NK Cells.”
- Dr. Jeffrey Miller will present at the 2nd Joint ASTCT (American Society for Transplantation and Cellular Therapy)-EBMT (European Society for Blood and Marrow Transplantation) Basic and Translational Scientific Meeting in Sitges, Spain on Thursday, May 25, 2023 with a talk entitled, “Off-The-Shelf Targeted NK Cell Therapies to Treat Leukemia.”

First Quarter 2023 Financial Summary

Cash Position: The Company had cash, cash equivalents and short-term investments of \$19.9 million as of March 31, 2023, compared to \$16.5 million as of December 31, 2022. This is expected to provide ample runway to fund operations into Q2 2024.

Research and Development (R&D) Expenses: R&D expenses for the first quarter of 2023 were \$1.7 million compared to \$2.1 million for the same quarter in 2022. Research and development expenses are related to our continued development and production of our most advanced TriKE[®] product candidates GTB-3650 and GTB-5550 along with the progression of other promising product candidates. R&D expenses decreased over the previous year primarily due to reduction in in-house staff and compensation to consultants as we prepare to advance our next generation GTB-3650 camelid nanobody product into the clinic.

General and Administrative (G&A) Expenses: G&A expenses for the first quarter of 2023 were \$2.0 million compared to \$3.4 million for the same quarter a year ago. The decrease in G&A expenses was primarily attributable to reduction in stock-based compensation to advisory board, investor relations consultants, and legal and professional fees for the quarter ended March 31, 2023 as compared to the same quarter in 2022.

Other (Income) Expenses

The Company recorded a gain of \$2.9 million due to a change in fair value of warrant liability for the three months ended March 31, 2023, compared to a gain of \$18,000 for the three months ending March 31, 2022. The increase in gain resulted due to a reduction in the fair value of warrants issued during the three months ended March 31, 2023.

Net Loss: The Company reported a net loss of \$227,000 for the first quarter of 2023, compared to a net loss of \$5.4 million for the same quarter in 2022.

About Camelid Antibodies

[Camelid antibodies](#) are single domain antibodies (sdAbs) from the Camelidae family of mammals that include llamas, camels, and alpacas. These animals produce two main types of antibodies. One type of antibody camelids produce is the conventional antibody that is made up of two heavy chains and two light chains. They also produce another type of antibody that is made up of only two heavy chains and no light chain. This is known as heavy chain IgG (hclgG). While these antibodies do not contain the CH1 region, they retain an antigen binding domain called the VHH region. VHH antibodies, also known as single domain antibodies, contain only the VHH region from the camelid antibody. Camelid antibodies have key characteristics, which include high affinity and specificity (equivalent to conventional antibodies), high thermostability, good solubility and strictly monomeric behavior, small size, relatively low production cost, ease of genetic engineering, format flexibility or modularity, low immunogenicity, and a higher penetration rate into tissues.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology therapeutic products based on our proprietary TriKE[®] NK cell engager platform. Our TriKE[®] platform is designed to harness and enhance the cancer killing abilities of a patient's immune system's natural killer cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE[®] technology. For more information, please visit gtbiopharma.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" regarding future events and our future results. All statements other than statements of historical facts are statements that could be deemed to be forward-looking statements. These statements are based on current expectations, estimates, forecasts, and projections about the markets in which we operate and the beliefs and assumptions of our management. Words such as "expects," "anticipates," "targets," "goals," "projects", "intends," "plans," "believes," "seeks," "estimates," "endeavors," "strives," "may," or variations of such words, and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements are subject to a number of risks, uncertainties and assumptions that are difficult to predict, estimate or verify. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Such risks and uncertainties include those factors described in our most recent annual report on Form 10-K, as such may be amended or supplemented by subsequent quarterly reports on Form 10-Q, or other reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements are made only as of the date hereof, and we undertake no obligation to publicly release the result of any revisions to these forward-looking statements. For more information, please refer to our filings with the Securities and Exchange Commission.

TriKE[®] is a registered trademark owned by GT Biopharma, Inc.

Investor Relations Contact:

LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com
212-915-2577

GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(in thousands, except shares and par value)

	March 31, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 2,045	\$ 5,672
Short-term investments	17,854	10,836
Prepaid expenses and other current assets	38	54
Total Current Assets	<u>19,937</u>	<u>16,562</u>
Operating lease right-of-use asset	140	165
Deposits	9	9
TOTAL ASSETS	<u>\$ 20,086</u>	<u>\$ 16,736</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,131	\$ 3,140
Accrued expenses	829	1,669
Current operating lease liability	116	110
Total Current Liabilities	<u>4,076</u>	<u>4,919</u>
Non-current operating lease liability	31	64
Warrant liability	2,926	19
Total Liabilities	<u>\$ 7,033</u>	<u>\$ 5,002</u>
Stockholders' Equity		
Convertible Preferred stock, par value \$0.01, 15,000,000 shares authorized Series C - 96,230 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	1	1
Common stock, par value \$0.001, 250,000,000 shares authorized, 36,882,724 shares and 32,722,452 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	37	33
Additional paid in capital	687,710	686,168
Accumulated deficit	(674,695)	(674,468)
Total Stockholders' Equity	<u>13,053</u>	<u>11,734</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 20,086</u>	<u>\$ 16,736</u>

GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	For The Three Months Ended	
	March 31,	
	2023	2022
	(unaudited)	(unaudited)
Revenues	\$ -	\$ -
Operating Expenses:		
Research and development	1,650	2,087
Selling, general and administrative (including \$718 and \$447 from stock compensation granted to officers, directors and employees during the three months ended March 31, 2023 and 2022, respectively)	2,015	3,355
Loss from Operations	3,665	5,442
Other (Income) Expense		
Interest income	(164)	(8)
Interest expense	212	-
Change in fair value of derivative liability	(2,924)	(18)
Gain on extinguishment of debt	(533)	-
Unrealized (gain) loss on marketable securities	(29)	24
Total Other (Income) Expense	(3,438)	(2)
Net Loss	\$ (227)	\$ (5,440)
Net Loss Per Share - Basic and Diluted	\$ (0.01)	\$ (0.17)
Weighted average common shares outstanding - basic and diluted	39,085,515	32,486,116

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)

For The Three Months Ended March 31, 2023 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2022	96	\$ 1	32,723	\$ 33	-	\$ -	\$ 686,168	\$ (674,468)	\$11,734
Private placement of common stock	-	-	3,600	4	-	-	433	-	437
Equity compensation to officers, employees, and board of directors	-	-	27	-	-	-	646	-	646
Issuance of common shares for services	-	-	46	-	-	-	176	-	176
Issuance of common shares in settlement of vendors payable	-	-	487	-	-	-	287	-	287
Net loss	-	-	-	-	-	-	-	(227)	(227)
Balance, March 31, 2023	96	\$ 1	36,883	\$ 37	-	\$ -	\$ 687,710	\$ (674,695)	\$13,053

For The Three Months Ended March 31, 2022 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2021	96	\$ 1	32,062	\$ 32	327	\$ 1,113	\$ 674,348	\$ (653,584)	\$21,910
Cancellation of common stock previously issued for services	-	-	(291)	-	-	-	-	-	-
Common shares issued upon conversion of notes payable	-	-	327	-	(327)	(1,113)	1,113	-	-
Equity compensation to officers, employees, and board of directors	-	-	85	-	-	-	447	-	447
Issuance of common shares for services	-	-	163	-	-	-	872	-	872
Net loss	-	-	-	-	-	-	-	(5,440)	(5,440)
Balance, March 31, 2022	96	\$ 1	32,346	\$ 32	-	\$ -	\$ 676,780	\$ (659,024)	\$17,789

GT BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(in thousands)

	For The Three Months Ended	
	March 31,	
	2023	2022
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (227)	\$ (5,440)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation - services	176	872
Stock based compensation - officers, employees and board of directors	646	447
Change in fair value of derivative liability	(2,924)	(18)
Gain on extinguishment of shares settled debt	(533)	-
Change in operating lease right-of-use assets	25	23
Unrealized (gain) loss on marketable securities	(29)	24
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses	16	(263)
(Increase) in deposits	-	(9)
Decrease in accounts payable and accrued expenses	(29)	(838)
Decrease in operating lease liability	(27)	(13)
Net Cash Used in Operating Activities	(2,906)	(5,215)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(6,989)	-
Sale of investments	-	3,533
Net Cash Used in Investing Activities	(6,989)	3,533
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and prefunded warrants	6,268	-
Net Cash Provided by Financing Activities	6,268	-
Net (Decrease) Increase in Cash	(3,627)	(1,682)
Cash at Beginning of Period	5,672	8,968
Cash at End of Period	\$ 2,045	\$ 7,286
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the year for:		
Interest	\$ -	\$ -
Income taxes paid	\$ -	\$ -
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Right-of-use assets and lease liabilities recognized pursuant to lease agreement	\$ -	\$ 260
Initial recognition of fair value of warrant liability	\$ 5,831	\$ -
Fair value of common stock issued to a vendor to settle accounts payable	\$ 287	\$ -



Source: GT Biopharma, Inc.