

August 7, 2023



GT Biopharma Reports Second Quarter 2023 Financial Results

Cash of approximately \$18.0 million as of June 30, 2023, provides ample runway to fund operations into Q3 2024; anticipated to be sufficient to achieve IND clearance for GTB-3650 and initiate clinical trial activities on GTB-3650.

BRISBANE, CALIFORNIA, Aug. 07, 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 second quarter 2023 results for the period ended June 30, 2023.

"We continue to prudently manage expenses while moving pipeline development across our novel portfolio of TriKE[®] nanobody assets forward. We expect to advance GTB-3650, a second generation nanobody TriKE[®] for the treatment of CD33+ leukemia, with GTB-5550 for the treatment of B7H3+ solid tumors to follow. We continue to expect investigational new drug (IND) filing with the U.S. Food and Drug Administration for GTB-3650 to occur in the second half of 2023," said Michael Breen, Executive Chairman and interim Chief Executive Officer. "In conjunction with these efforts, we maintain a cash balance on hand that will provide an operational runway into Q3 2024, anticipated to be sufficient to achieve IND clearance and initiate clinical trial activities for GTB-3650. Additionally, we continue to actively explore potential development partnerships for our programs."

Second Quarter 2023 Financial Summary

Cash Position: The Company had cash, cash equivalents and short-term investments of \$18.0 million as of June 30, 2023, compared to \$16.5 million as of December 31, 2022. We expect ample runway to fund operations into Q3 2024.

Research and Development (R&D) Expenses: R&D expenses for the three months and six months ended June 30, 2023 were \$2.1 million and \$3.7 million, compared to \$1.1 million and \$3.2 million for the same comparable periods of 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 increased over the previous year primarily due to reduction in in-house staff offset with the increase in 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 three months and six

months ended June 30, 2023 were \$1.5 million and \$3.5 million, compared to \$1.9 million and \$5.2 million for the same comparable periods of 2022. The decrease in G&A expenses was primarily attributable to reduction in stock-based compensation to advisory board, investor relations consultants, legal and professional fees, and payroll expenses.

Other (Income) Expenses

The Company recorded a gain of \$1.4 million and \$4.3 million for the three months and six months ended June 30, 2023, compared to a gain of \$5,000 and \$23,000 for the same comparable periods of 2022. The increase in gain resulted due to a change in the fair value of warrants liability during the three months and six months ended June 30, 2023. The Company recorded interest income of \$220,000 and \$384,000 for the three months and six months ended June 30, 2023, compared to \$36,000 and \$44,000, for the same comparable periods in 2022. The increase in interest income was due to higher interest rates offered by financial institutions in the three months and six months ended June 30, 2023 as compared to the same comparable periods of 2022. We recorded interest expense of \$1,000 and \$213,000 for the three months and six months ended June 30, 2023, compared to \$0 and \$0 for the same comparable periods in 2022, respectively. The increase in interest expense was due to the financing costs incurred associated with warrants accounted as warrant liability sold during the current year, with no comparable costs in the prior year. We recorded a gain on extinguishment of debt of \$14,000 and \$547,000 for the three months and six months ended June 30, 2023, compared to \$0 and \$0 for the same comparable periods in 2022. The gain for the six months ended June 30, 2023 was as a result of share settlement of a greater amount of vendor accounts payable than the fair value of the shares on the date of settlement. We recorded unrealized gains on marketable securities of \$9,000 and \$38,000 for the three months and six months ended June 30, 2023, compared to unrealized losses of \$6,000 and \$30,000 for the same comparable periods in 2022, respectively. This resulted from an improved mix of investments combined with higher interest rates for the three months and six months ended June 30, 2023 as compared to comparable periods of 2022.

Net Loss: The Company reported a net loss of \$2.0 million and \$2.2 million for the three months and six months ended June 30, 2023, compared to a net loss of \$3.0 million and \$8.4 million for the same comparable periods 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.

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GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except shares and par value)

	June 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	\$ 2,767	\$ 5,672
Short-term investments	15,206	10,836
Prepaid expenses and other current assets	48	54
Total Current Assets	<u>18,021</u>	<u>16,562</u>
Operating lease right-of-use asset	114	165
Deposits	9	9
TOTAL ASSETS	<u>\$ 18,144</u>	<u>\$ 16,736</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,501	\$ 3,140
Accrued expenses	1,222	1,669
Current operating lease liability	120	110
Total Current Liabilities	<u>4,843</u>	<u>4,919</u>
Non-current operating lease liability	-	64
Warrant liability	1,538	19
Total Liabilities	<u>\$ 6,381</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 June 30, 2023 and December 31, 2022, respectively	1	1
Common stock, par value \$0.001, 250,000,000 shares authorized, 40,639,688 shares and 32,722,452 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	41	33
Additional paid in capital	688,408	686,168
Accumulated deficit	<u>(676,687)</u>	<u>(674,468)</u>
Total Stockholders' Equity	<u>11,763</u>	<u>11,734</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 18,144</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 June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues	\$ -	\$ -	\$ -	\$ -
Operating Expenses:				
Research and development	2,095	1,139	3,745	3,226
Selling, general and administrative (including \$398 and \$463 from stock compensation granted to officers, directors and employees for the three months ended June 30, 2023 and 2022, respectively, and \$905 and \$910 for the six months ended June 30, 2023 and 2022, respectively)	1,526	1,875	3,541	5,230
Loss from Operations	3,621	3,014	7,286	8,456
Other (Income) Expense				
Interest income	(220)	(36)	(384)	(44)
Interest expense	1	-	213	-
Change in fair value of warrant liability	(1,387)	(5)	(4,311)	(23)
Gain on extinguishment of debt	(14)	-	(547)	-
Unrealized (gain) loss on marketable securities	(9)	6	(38)	30
Total Other (Income), net	(1,629)	(35)	(5,067)	(37)
Net Loss	\$ (1,992)	\$ (2,979)	\$ (2,219)	\$ (8,419)
Net Loss Per Share - Basic and Diluted	\$ (0.05)	\$ (0.10)	\$ (0.06)	\$ (0.26)
Weighted Average Common Shares Outstanding - Basic and Diluted	40,172,599	31,237,560	39,632,060	31,865,425

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

	For The Three Months Ended June 30, 2023 (Unaudited)					
	Preferred Shares		Common Shares		Additional Paid in	Accumulated
	Shares	Amount	Shares	Amount	Capital	Deficit
Balance, March 31, 2023	96	\$ 1	36,883	\$ 37	\$ 687,710	\$ (674,695)
Fair value of vested stock options	-	-	-	-	398	-
Issuance of common stock for exercise of Prefunded Warrants	-	-	2,900	3	(3)	-
Issuance of common shares in settlement of vendors payable	-	-	857	1	303	-
Net loss	-	-	-	-	-	(1,992)
Balance, June 30, 2023	96	\$ 1	40,640	\$ 41	\$ 688,408	\$ (676,687)

For The Six Months Ended June 30, 2023 (Unaudited)

	Preferred Shares		Common Shares		Additional Paid in	Accumulated	Total
	Shares	Amount	Shares	Amount	Capital	Deficit	
Balance, December 31, 2022	96	\$ 1	32,723	\$ 33	\$ 686,168	\$ (674,468)	\$ 11,734
Private placement of common stock	-	-	3,600	4	6,264	-	6,268
Initial recognition of fair value of warrant liability	-	-	-	-	(5,831)	-	(5,831)
Fair value of vested stock options	-	-	-	-	905	-	905
Issuance of common shares for services	-	-	73	-	315	-	315
Issuance of common stock for exercise of Prefunded Warrants	-	-	2,900	3	(3)	-	-
Issuance of common shares in settlement of vendors payable	-	-	1,344	1	590	-	591
Net loss	-	-	-	-	-	(2,219)	(2,219)
Balance, June 30, 2023	96	\$ 1	40,640	\$ 41	\$ 688,408	\$ (676,687)	\$ 11,763

For The Three Months Ended June 30, 2022 (Unaudited)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	
Balance, March 31, 2022	96	\$ 1	32,346	\$ 32	-	\$ -	\$ 676,780	\$ (659,024)	\$ 17,789
Cancellation of common stock upon settlement with former officer	-	-	(1,845)	(1)	-	-	(222)	-	(223)
Equity compensation to officers, employees, and board of directors	-	-	79	-	-	-	463	-	463
Issuance of common shares for services	-	-	114	-	-	-	390	-	390
Net loss	-	-	-	-	-	-	-	(2,979)	(2,979)
Balance, June 30, 2022	96	\$ 1	30,694	\$ 31	-	\$ -	\$ 677,411	\$ (662,003)	\$ 15,440

	For The Six Months Ended June 30, 2022 (Unaudited)									
	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in	Accumulated		
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit		Total
Balance, December 31, 2021	96	\$ 1	32,062	\$ 32	327	\$ 1,113	\$ 674,348	\$ (653,584)		\$ 21,910
Cancellation of common stock upon settlement with former officer	-	-	(1,845)	(1)	-	-	(222)	-		(223)
Cancellation of common stock	-	-	(291)	-	-	-	-	-		-
Common shares issued upon conversion of notes payable	-	-	327		(327)	(1,113)	1,113	-		-
Equity compensation to officers, employees, and board of directors	-	-	164	-	-	-	910	-		910
Issuance of common shares for services	-	-	277	-	-	-	1,262	-		1,262
Net loss	-	-	-	-	-	-	-	(8,419)		(8,419)
Balance, June 30, 2022	96	\$ 1	30,694	\$ 31	-	\$ -	\$ 677,411	\$ (662,003)		\$ 15,440

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For The Six Months Ended June 30,	
	2023	2022
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (2,219)	\$ (8,419)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation - services	315	1,262
Stock based compensation - officers, employees and board of directors	905	910
Change in fair value of warrant liability	(4,311)	(23)
Gain on extinguishment in settlement of vendor payable	(547)	-
Change in operating lease right-of-use assets	51	46
Unrealized (gain) loss on marketable securities	(38)	30
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses	5	(32)
Increase in deposits	-	(9)
Increase (decrease) in accounts payable and accrued expenses	1,052	(1,729)
(Decrease) in operating lease liability	(54)	(37)
Net Cash Used in Operating Activities	(4,841)	(8,001)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale (purchase) of investments	(4,332)	4,614
Net Cash Provided by (Used in) Investing Activities	(4,332)	4,614
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and prefunded warrants	6,268	-
Cancellation of common stock upon settlement with former officer	-	(223)
Net Cash Provided by (Used in) Financing Activities	6,268	(223)
Net Decrease in Cash	(2,905)	(3,610)
Cash at Beginning of Period	5,672	8,968
Cash at End of Period	\$ 2,767	\$ 5,358
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 exchanged for lease liabilities	\$ -	\$ 260
Initial recognition of fair value of warrant liability	\$ 5,831	\$ -
Fair value of common stock issued to a vendor to settle accounts payable	\$ 591	\$ -



Source: GT Biopharma, Inc.