

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

**FORM 10-Q**

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2021.

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 001-40023

**GT BIOPHARMA, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

94-1620407

(I.R.S. Employer  
Identification Number)

9350 Wilshire Blvd. Suite 203  
Beverly Hills, CA 90212

(Address of principal executive offices and zip code)

(800) 304-9888

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of exchange on which registered</u>
Common Stock, \$0.001 par value per share	GTBP	Nasdaq

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 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

As of November 12, 2021, the issuer had 30,582,354 shares of common stock outstanding.

**GT Biopharma, Inc. and Subsidiaries**  
**FORM 10-Q**  
**For the Quarter Ended September 30, 2021**  
**Table of Contents**

PART I FINANCIAL INFORMATION

	<u>Page</u>
Item 1. Financial Statements	
<a href="#">Condensed Consolidated Balance Sheets as of September 30, 2021 (unaudited) and December 31, 2020</a>	3
<a href="#">Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2021 and 2020 (unaudited)</a>	4
<a href="#">Condensed Consolidated Statements of Stockholders' Equity (Deficit) (unaudited)</a>	5
<a href="#">Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2021 and 2020 (unaudited)</a>	7
<a href="#">Condensed Notes to Consolidated Financial Statements</a>	8
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	20
Item 3. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	25
Item 4. <a href="#">Controls and Procedures</a>	25

PART II OTHER INFORMATION

Item 1. <a href="#">Legal Proceedings</a>	26
Item 1A. <a href="#">Risk Factors</a>	26
Item 2. <a href="#">Unregistered Sales of Securities and Use of Proceeds</a>	26
Item 3. <a href="#">Defaults Upon Senior Securities</a>	26
Item 4. <a href="#">Mine Safety Disclosures</a>	26
Item 5. <a href="#">Other Information</a>	26
Item 6. <a href="#">Exhibits</a>	27
<a href="#">SIGNATURES</a>	28

**GT BIOPHARMA, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**

	<b>September 30,</b>	<b>December 31,</b>
	<b>2021</b>	<b>2020</b>
	(unaudited)	
<b>ASSETS:</b>		
Current assets		
Cash and cash equivalents	\$ 9,682,000	\$ 5,297,000
Short-term investments	26,031,000	-
Prepaid expenses and other current assets	85,000	364,000
Total Current Assets	<u>\$ 35,798,000</u>	<u>\$ 5,661,000</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities		
Accounts payable	\$ 2,802,000	\$ 2,243,000
Accrued expenses	749,000	1,296,000
Accrued interest	-	4,838,000
Convertible notes payable (net of discount of \$4,519,000 at December 31, 2020)	-	26,303,000
Line of Credit	31,000	31,000
Derivative liability	340,000	383,000
Total current liabilities	<u>3,922,000</u>	<u>35,094,000</u>
Stockholders' Equity (Deficit):		
Convertible Preferred stock, par value \$0.01, 15,000,000 shares authorized:		
Series C - 96,230 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1,000	1,000
Series J - 0 and 2,353,548 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	-	2,000
Series K- none issued and outstanding at September 30, 2021 and December 31, 2020, respectively	-	-
Common stock, par value \$0.001, 2,000,000,000 shares authorized, 30,508,260 and 5,218,122 shares issued and outstanding as of September 30, 2021 and December 31, 2020 , respectively	30,000	5,000
Common stock issuable, 1,004,495 shares at September 30, 2021	3,416,000	-
Additional paid in capital	663,991,000	566,356,000
Accumulated deficit	(635,393,000)	(595,628,000)
Non-Controlling Interest	(169,000)	(169,000)
Total stockholders' equity (deficit)	<u>31,876,000</u>	<u>(29,433,000)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<u><b>\$ 35,798,000</b></u>	<u><b>\$ 5,661,000</b></u>

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

**GT BIOPHARMA, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Operations (Unaudited)**

	For the Three Months ended September 30,		For the Nine Months ended September 30,	
	2021 (unaudited)	2020 (unaudited)	2021 (unaudited)	2020 (unaudited)
<b>Revenues</b>	\$ -	\$ -	\$ -	\$ -
<b>Operating Expenses:</b>				
Research and development	1,008,000	(84,000)	3,287,000	252,000
Selling, general and administrative (including \$577,000 and \$15,450,000 of stock compensation to officers and directors in 2021 during the three and nine months ended September 30, 2021, respectively)	4,946,000	2,029,000	36,050,000	4,321,000
Loss from Operations	5,954,000	1,945,000	39,337,000	4,573,000
<b>Other (Income) Expense</b>				
Interest income	(32,000)		(32,000)	
Unrealized loss on marketable securities	33,000		33,000	
Change in fair value of derivative liability	(502,000)	-	(43,000)	-
Settlement expense	-	-	-	11,206,000
Interest expense	-	931,000	696,000	6,227,000
<b>Total Other Expense, net</b>	(501,000)	931,000	654,000	17,433,000
<b>Net Loss</b>	\$ (5,453,000)	\$ (2,876,000)	\$ (39,991,000)	\$ (22,006,000)
Net loss per share				
Basic and diluted	\$ (0.17)	\$ (0.64)	\$ (1.54)	\$ (5.13)
Weighted average common shares outstanding				
Basic and diluted	31,381,282	4,513,534	25,945,827	4,288,808

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

**GT BIOPHARMA, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Stockholders' Equity (Deficit) (unaudited)**  
**For the three and nine months ended September 30, 2021 and 2020**

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in Capital	Accumulated Deficit	Non Controlling Interest	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2020	2,449,778	\$ 3,000	5,218,122	\$ 5,000	-	\$ -	\$ 566,356,000	\$ (595,628,000)	\$ (169,000)	\$ (29,433,000)
Extinguishment of debt discount upon adoption of ASU 2020-06	-	-	-	-	-	-	(4,745,000)	226,000	-	(4,519,000)
Conversion of Preferred Series J-1 to common stock	(2,353,548)	(2,000)	692,220	1,000	-	-	1,000	-	-	-
Common shares issued upon mandatory conversion of notes payable and accrued interest	-	-	10,408,827	10,000	1,004,495	3,416,000	35,373,000	-	-	38,799,000
Common shares issued upon exercise of warrants	-	-	3,073,818	3,000	-	-	16,430,000	-	-	16,433,000
Issuance of common stock in public offering, net of cost	-	-	4,945,000	5,000	-	-	24,674,000	-	-	24,679,000
Issuance of common stock for research and development agreement	-	-	189,753	-	-	-	1,355,000	-	-	1,355,000
Issuance of common stock for services	-	-	2,142,746	2,000	-	-	9,101,000	-	-	9,103,000
Equity compensation to officers and board of directors	-	-	3,837,774	4,000	-	-	15,446,000	-	-	15,450,000
Net loss								(39,991,000)		(39,991,000)
<b>Balance, September 30, 2021</b>	<b>96,230</b>	<b>\$ 1,000</b>	<b>30,508,260</b>	<b>\$ 30,000</b>	<b>1,004,495</b>	<b>\$ 3,416,000</b>	<b>\$ 663,991,000</b>	<b>\$ (635,393,000)</b>	<b>\$ (169,000)</b>	<b>\$ 31,876,000</b>
Balance, June 30, 2021	96,230	\$ 1,000	28,144,077	\$ 28,000	3,152,000	\$ 10,716,000.00	\$ 655,655,000	\$ (629,940,000)	\$ (169,000)	\$ 36,291,000
Common shares issued upon conversion of notes payable	-	-	2,147,018	2,000	(2,147,505)	(7,300,000)	7,294,000	-	-	(4,000)
Common shares issued upon exercise of warrants	-	-	26,000	-	-	-	138,000	-	-	138,000

Issuance of common stock for services	-	-	92,686	-	-	-	327,000	-	-	327,000
Equity compensation to officers and board of directors	-	-	98,479	-	-	-	577,000	-	-	577,000
Net loss								(5,453,000)		(5,453,000)
<b>Balance, September 30, 2021</b>	<u>96,230</u>	<u>\$ 1,000</u>	<u>30,508,260</u>	<u>\$ 30,000</u>	<u>1,004,495</u>	<u>\$ 3,416,000</u>	<u>\$ 663,991,000</u>	<u>\$ (635,393,000)</u>	<u>\$ (169,000)</u>	<u>\$ 31,876,000</u>

*Table of Contents*

Balance, December 31, 2019	2,449,778	\$ 3,000	4,104,982	\$ 4,000	-	\$ -	\$ 548,184,000	\$ (567,332,000)	\$ (169,000)	\$ (19,310,000)
Beneficial conversion feature of convertible notes	-	-	-	-	-	-	27,000	-	-	27,000
Issuance of common stock for settlement of litigation	-	-	205,882	-	-	-	1,909,000	-	-	1,909,000
Common shares issued upon conversion of notes payable	-	-	185,118	-	-	-	9,277,000	-	-	9,277,000
Equity compensation	-	-	63,882	-	-	-	146,000	-	-	146,000
Issuance of warrants for services	-	-	-	-	-	-	180,000	-	-	180,000
Net loss	-	-	-	-	-	-	-	(22,006,000)	-	(22,006,000)
<b>Balance, September 30, 2020</b>	<b><u>2,449,778</u></b>	<b><u>\$ 3,000</u></b>	<b><u>4,559,865</u></b>	<b><u>\$ 4,000</u></b>	<b><u>-</u></b>	<b><u>\$ -</u></b>	<b><u>\$ 559,723,000</u></b>	<b><u>\$ (589,338,000)</u></b>	<b><u>\$ (169,000)</u></b>	<b><u>\$ (29,777,000)</u></b>
Balance, June 30, 2020	2,449,778	\$ 3,000	4,559,865	\$ 4,000	-	\$ -	\$ 559,723,000	\$ (586,462,000)	\$ (169,000)	\$ (26,901,000)
Net loss	-	-	-	-	-	-	-	(2,876,000)	-	(2,876,000)
<b>Balance, September 30, 2020</b>	<b><u>2,449,778</u></b>	<b><u>\$ 3,000</u></b>	<b><u>4,559,865</u></b>	<b><u>\$ 4,000</u></b>	<b><u>-</u></b>	<b><u>\$ -</u></b>	<b><u>\$ 559,723,000</u></b>	<b><u>\$ (589,338,000)</u></b>	<b><u>\$ (169,000)</u></b>	<b><u>\$ (29,777,000)</u></b>

*The accompanying notes are an integral part of these condensed consolidated financial statements.*

**GT BIOPHARMA, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Cash Flows**

	<b>For the Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2021</b>	<b>2020</b>
	(unaudited)	(unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (39,991,000)	\$ (22,006,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liability	(43,000)	-
Stock based compensation - consultants and research and development	10,458,000	-
Stock based compensation - officers and board of directors	15,450,000	327,000
Convertible notes payable issued for consulting services	720,000	-
Amortization of debt discount	-	-
Non-cash interest expense	-	3,970,000
Settlement expense	-	11,206,000
Effect of changes in assets and liabilities:		
Prepaid expenses and other current assets	279,000	3,000
Accounts payable and accrued expenses	537,000	1,165,000
Accrued interest	689,000	-
Net Cash Used in Operating Activities	<u>(11,901,000)</u>	<u>(5,335,000)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of investments	(26,031,000)	-
Net Cash Used by Investing Activities	<u>(26,031,000)</u>	<u>-</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of warrants	16,433,000	-
Proceeds from issuance of common stock	24,679,000	-
Proceeds from issuance of notes payable	1,205,000	5,657,000
Net Cash Provided by Financing Activities	<u>42,317,000</u>	<u>5,657,000</u>
Net Increase in Cash	4,385,000	322,000
Cash at Beginning of Period	5,297,000	28,000
Cash at End of Period	<u>\$ 9,682,000</u>	<u>\$ 350,000</u>
Cash paid during the year for:		
Interest	\$ -	\$ 69,000
Income taxes paid	\$ -	\$ -
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Common stock issued upon conversion of notes payable and accrued interest	\$ 38,799,000	\$ 630,000
Extinguishment of unamortized debt discount and adjustment to accumulated deficit upon adoption of ASU 2020-06	\$ 4,745,000	-

*The accompanying notes are an integral part of these condensed consolidated financial statements.*



**GT BIOPHARMA, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**  
**As of and For the Nine Months Ended September 30, 2021 and 2020**

**Note 1 – Organization and Operations**

In 1965, the corporate predecessor of GT Biopharma Inc. (Company), Diagnostic Data, Inc. was incorporated in the State of California. Diagnostic Data changed its incorporation to the State of Delaware in 1972 and changed its name to DDI Pharmaceuticals, Inc. in 1985. In 1994, DDI Pharmaceuticals merged with International BioClinical, Inc. and Bioxytech S.A. and changed its name to OXIS International, Inc. In July 2017, the Company changed its name to GT Biopharma, Inc.

The Company is a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE™), Tetra-specific Killer Engager (Dual Targeting TriKEDual Targeting TriKE) platforms. The Company's TriKE and Dual Targeting TriKE platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells, or NK cells.

**Note 2 –Going Concern**

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying consolidated financial statements, for the nine months ended September 30, 2021, the Company incurred a net loss of \$40.0 million and used cash in operating activities of \$11.9 million. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year of the date that these financial statements are issued. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

During the nine months ended September 30, 2021, the Company received net cash of \$24.7 million from the sale of 4,945,000 shares of its common stock pursuant to a public offering, issuance of notes payable for cash of \$1.2 million and \$16.4 million in cash from exercise of warrants for a total cash received of \$42.3 million. At September 30, 2021, the Company had cash on hand and short-term investments in the amount of \$35.7 million. The Company's current operations have focused on business planning, raising capital, establishing an intellectual property portfolio, hiring, and conducting preclinical studies and clinical trials. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: public offerings of equity and/or debt securities, payments from potential strategic research and development, and licensing and/or marketing arrangements with pharmaceutical companies. If the Company is unable to secure adequate additional funding, its business, operating results, financial condition and cash flows may be materially and adversely affected. Management estimates that the current funds on hand will be sufficient to continue operations through the next six months. The Company's ability to continue as a going concern is dependent upon its ability to continue to implement its business plan.

**Note 3 – Summary of Significant Accounting Policies**

*Basis of Presentation and Principles of Consolidation*

The accompanying condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC on April 16, 2021 (the "2020 Annual Report"). The consolidated balance sheet as of December 31, 2020 included herein was derived from the audited consolidated financial statements as of that date.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments necessary to fairly present the Company's financial position and results of operations for the interim periods reflected. Except as noted, all adjustments contained herein are of a normal recurring nature. Results of operations for the fiscal periods presented herein are not necessarily indicative of fiscal year-end results.

## Table of Contents

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Oxis Biotech, Inc. and Georgetown Translational Pharmaceuticals, Inc. Intercompany transactions and balances have been eliminated in consolidation.

### Reverse Stock Split

On February 10, 2021, the Company completed a 1:17 reverse stock split of the Company's issued and outstanding shares of common stock and all fractional shares were rounded up. All share and per share amounts in the accompanying financial statements have been adjusted retroactively to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented.

### COVID-19

In March 2020, the World Health Organization declared coronavirus COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, has adversely affected workforces, customers, economies, and financial markets globally. It has also disrupted the normal operations of many businesses. This outbreak could decrease spending, adversely affect demand for the Company's products, and harm the Company's business and results of operations.

During the nine months ended September 30, 2021, the Company believes the COVID-19 pandemic did impact its operating results. However, the Company has not observed any impairments of its assets or a significant change in the fair value of its assets due to the COVID-19 pandemic. At this time, it is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on the Company's business or results of operations, financial condition, or liquidity.

The Company has been following the recommendations of health authorities to minimize exposure risk for its team members, including the temporary closure of its corporate office and having team members work remotely. Most vendors have transitioned to electronic submission of invoices and payments.

### Accounting Estimates

The preparation of financial statements in conformity with Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include accruals for potential liabilities, valuation of notes payable, assumptions used in deriving the fair value of derivative liabilities, valuation of equity instruments issued for services and realization of deferred tax assets. Actual results could differ from those estimates.

### Cash Equivalents and Short-Term Investments

The Company considers highly liquid investments with maturities of three months or less at the date of acquisition as cash equivalents in the accompanying consolidated financial statements. As of September 30, 2021, total cash equivalents, which consists of money market funds, amounted to approximately \$3.9 million.

The Company also invested its excess cash in commercial paper and corporate notes and bonds. Management generally determines the appropriate classification of its investments at the time of purchase. We classify these investments as short-term investments, as part of current assets, based upon our ability and intent to use any and all of these investments as necessary to satisfy liquidity requirements that may arise from our businesses. Investments are carried at fair value with the unrealized holding gains and losses reported in the accompanying consolidated statements of operations. As of September 30, 2021, total short-term investments amounted to approximately \$26 million.

### Stock-Based Compensation

The Company accounts for share-based awards to employees and nonemployees and consultants in accordance with the provisions of ASC 718, Compensation-Stock Compensation. Stock-based compensation cost is measured at fair value on the grant date and that fair value is recognized as expense over the requisite service, or vesting, period.

### Fair Value of Financial Instruments

FASB Accounting Standards Codification ("ASC") 820-10 requires entities to disclose the fair value of financial instruments, both assets and liabilities recognized and not recognized on the balance sheet for which it is practicable to estimate fair value. ASC 820-10 defines the fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties.

## Table of Contents

The three levels of the fair value hierarchy are as follows:

- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the entity has the ability to access.
- Level 2 Valuations based on quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.
- Level 3 Valuations based on inputs that are unobservable, supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amount of the Company's derivative liability of \$340,000 at September 30, 2021 and \$383,000 at December 31, 2020 was based on Level 2 measurements.

The carrying amounts of the Company's other financial assets and liabilities, such as cash, short-term investments, prepaid expense, accounts payable and accrued expenses approximate their fair values because of the short maturity of these instruments.

### Derivative Financial Instruments

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date. The fair value of the embedded derivatives are determined using a Binomial valuation method at inception and on subsequent valuation dates.

### Net Loss Per Share

Basic earnings (loss) per share is computed using the weighted-average number of common shares outstanding during the period. Common stock issuable is included in our calculation as of the date of the underlying agreement. Diluted earnings (loss) per share is computed using the weighted-average number of common shares and the dilutive effect of contingent shares outstanding during the period. Potentially dilutive contingent shares, which primarily consist of convertible notes, stock issuable to the exercise of stock options and warrants have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

These following common stock equivalents were excluded in the computation of the net loss per share because their effect is anti-dilutive.

	September 30, 2021	September 30, 2020
A. Options to purchase common stock	-	3
B. Warrants to purchase common stock	2,337,274	106,650
C. Convertible notes payable	-	4,678,823
D. Convertible Series J Preferred stock	-	692,220
E. Convertible Series C Preferred stock	7	7
	<u>2,337,281</u>	<u>5,477,703</u>

### Segments

The Company determined its reporting units in accordance with ASC 280, "Segment Reporting" ("ASC 280"). Management evaluates a reporting unit by first identifying its operating segments under ASC 280. The Company then evaluates each operating segment to determine if it includes one or more components that constitute a business. If there are components within an operating segment that meet the definition of a business, the Company evaluates those components to determine if they must be aggregated into one or more reporting units. If applicable, when determining if it is appropriate to aggregate different operating segments, the Company determines if the segments are economically similar and, if so, the operating segments are aggregated.

[Table of Contents](#)

Management has determined that the Company has one consolidated operating segment. The Company's reporting segment reflects the manner in which its chief operating decision maker reviews results and allocates resources. The Company's reporting segment meets the definition of an operating segment and does not include the aggregation of multiple operating segments.

Recent Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. Under ASU 2020-06, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, or that do not result in substantial premiums accounted for as paid-in capital. Consequently, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance also requires the if-converted method to be applied for all convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted. Adoption of the standard requires using either a modified retrospective or a full retrospective approach. Effective January 1, 2021, we early adopted ASU 2020-06 using the modified retrospective approach. Adoption of the new standard resulted in a decrease to additional paid-in capital of \$4,519,000 (see Note 4).

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. ASU 2021-04 provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. An issuer measures the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange. ASU 2021-04 introduces a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. Early adoption is permitted for all entities, including adoption in an interim period. If an entity elects to early adopt ASU 2021-04 in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The adoption of ASU 2021-04 is not expected to have a material impact on the Company's financial statements or disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission (the "SEC") did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

**Note 4 - Fair Value of Financial Instruments**

The estimated fair values of financial instruments outstanding were:

	Sept. 30, 2021			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and cash equivalents	\$ 9,682,000	\$ —	\$ —	\$ 9,682,000
Short-term investments	26,064,000	—	(33,000)	26,031,000
	<u>\$ 35,746,000</u>	<u>\$ —</u>	<u>\$ (33,000)</u>	<u>\$ 35,713,000</u>

  

	December 31, 2020			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and cash equivalents	\$ 5,297,000	\$ —	\$ —	\$ 5,297,000

[Table of Contents](#)

The following table represents the Company's fair value hierarchy for its financial assets (cash equivalents and investments):

	Sept. 30, 2021			
	Fair Value	Level 1	Level 2	Level 3
Money market funds	\$ 3,936,000	\$ 3,936,000	\$ —	\$ —
Corporate notes and commercial paper	26,031,000	—	26,031,000	—
	<u>\$ 29,967,000</u>	<u>\$ 3,936,000</u>	<u>\$ 26,031,000</u>	<u>\$ —</u>

**Note 5 – Convertible Notes Payable**

Convertible notes payable consisted of the following:

	September 30, 2021	December 31, 2020
A. Notes payable issued for cash	\$ -	\$ 24,085,000
B. Notes payable issued for settlement agreements	-	2,528,000
C. Notes payable issued for forbearance agreements	-	3,849,000
D. Notes payable issued for consulting services	-	360,000
	-	<u>30,822,000</u>
Less unamortized debt discount	-	(4,519,000)
Convertible notes, net of discount	<u>\$ -</u>	<u>\$ 26,303,000</u>

**A. Notes Payable Issued for Cash**

As part of the Company's financing activities, the Company issued convertible notes payable in exchange for cash. These notes payable were unsecured, bear interest at a rate of 10% per annum, mature in nine months up to one year from the date of issuance, and are convertible to common stock at an average conversion rate of \$3.40 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%) and standard anti-dilution provisions. As of December 31, 2020, the outstanding balance of these notes amounted to \$24,085,000.

In January 2021, the Company issued similar notes payable in exchange for cash of \$1,205,000. On February 16, 2021 in accordance with the note agreements upon completion of the equity offering discussed in Note 7, these notes were mandatorily converted at a conversion rate of \$3.40 per share into 7,438,235 shares of the Company's common stock.

**B. Notes Payable Issued for Settlement Agreements**

In fiscal 2019 and 2020, the Company issued its convertible notes payable to resolve claims and disputes pertaining to certain debt and equity instruments issued by the Company in prior years. The notes were unsecured, bear interest at a rate of 10%, mature in nine months up to one year from the date of issuance, and are convertible to common stock at a conversion rate of \$3.40 per share, as adjusted, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%) and standard anti-dilution provisions. As of December 31, 2020, outstanding balance of these notes payable for settlement agreements amounted to \$2,528,000.

## Table of Contents

On February 16, 2021 in accordance with the note agreements upon completion of the equity offering discussed in Note 7, these notes were mandatorily converted at a conversion rate of \$3.40 per share into 743,529 shares of the Company's common stock.

### C. Notes Payable Issued for Forbearance Agreements

On June 23, 2020, the Company entered into Standstill and Forbearance Agreements (collectively, the "Forbearance Agreements") with the holders of \$13.2 million aggregate principal amount of the Convertible Notes (the "Default Notes"), which were in default. Pursuant to the Forbearance Agreements, the holders of the Default Notes agreed to forbear from exercising their rights and remedies under the Default Notes (including declaring such Default Notes (together with any default amounts and accrued and unpaid interest) immediately due and payable) until the earlier of (i) the date that the Company completes a future financing in the amount of \$15 million and, in connection therewith, commences listing on NASDAQ (collectively, the "New Financing") or (ii) January 31, 2021 (the "Termination Date"). As of December 31, 2020, outstanding balance of the notes payable amounted to \$3,849,000.

On February 16, 2021 in accordance with the note agreements upon completion of the equity offering discussed in Note 7, these notes were mandatorily converted at a conversion rate of \$3.40 per share into 1,132,059 shares of the Company's common stock.

### D. Notes Payable issued for Consulting Agreements

In prior years, the Company issued its convertible notes payable in exchange for consulting services. These notes payable are unsecured, bear interest at a rate of 0% per annum, mature in nine months up to one year from the date of issuance, and are convertible to common stock at an average conversion rate of \$3.40 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%) and standard anti-dilution provisions. As of December 31, 2020, outstanding balance of these notes payable amounted to \$360,000.

In January 2021, the Company issued similar notes payable of \$720,000 in exchange for consulting services. In addition, the Company also issued a note payable of \$25,000 in exchange for the cancellation of unpaid consulting fees that was recorded as part of accrued expenses as of December 31, 2020.

On February 16, 2021 in accordance with the note agreements upon completion of the equity offering discussed in Note 7, these notes in the aggregate amount of \$605,000 were mandatorily converted at a conversion rate of \$3.40 per share into 472,059 shares of the Company's common stock.

As of December 31, 2020, the Company accrued interest of \$4,838,000 related to these convertible notes payable. During the period ended September 30, 2021, the Company accrued interest of \$696,000. As a result of the mandatory conversion of the Company's notes payable, on February 16, 2021, total accrued interest amounted to \$5,527,000 were converted to 1,627,647 shares of common stock.

As a result, total notes payable of \$3,272,000 and accrued interest of \$5,527,000 for a total of \$8,799,000 were mandatorily converted to 11,413,322 shares of common stock.

### Adoption of ASU 2020-06

In fiscal 2020, the Company recorded a note/debt discount of \$4,745,000 to account for the beneficial conversion feature that existed on the date of issuance for the above convertible notes payable. The debt discount is being amortized to interest expense over the term of the corresponding convertible notes payable. At December 31, 2020, the Company had recorded an unamortized note/debt discount of \$4,519,000.

On January 1, 2021 the Company chose to adopt Accounting Standards Update ("ASU") 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. Under ASU 2020-06, the embedded conversion features are no longer required to be separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, or that do not result in substantial premiums accounted for as paid-in capital.

As a result of the adoption of ASU 2020-06, the Company extinguished the previously recorded debt discount of \$4,745,000 by charging the opening additional paid in capital at January 1, 2021. In addition, the Company also adjusted accumulated deficit to account for the derecognition of the \$226,000 interest expense due to the amortization of the debt discount that was recorded in fiscal 2020. As a result of these adjustments, the unamortized debt discount of \$4,519,000 was extinguished.

**Note 6 – Line of Credit**

On November 8, 2010, the Company entered into a financing arrangement with Gemini Pharmaceuticals, Inc., a product development and manufacturing partner of the Company, pursuant to which Gemini Pharmaceuticals made a \$250,000 strategic equity investment in the Company and agreed to make a \$750,000 purchase order line of credit facility available to the Company. The outstanding principal of all advances under the line of credit will bear interest at the rate of interest of prime plus 2% per annum.

As of September 30, 2021 and December 31, 2020, the outstanding balance of this credit line amounted to \$1,000 respectively.

**Note 7 – Derivative Liability**

During the year ended December 31, 2020, the Company issued certain warrants that contained a fundamental transaction provision that could give rise to an obligation to pay cash to the warrant holder upon occurrence of certain change in control type events.

In accordance with ASC 480, the fair value of these warrants are classified as a liability in the Consolidated Balance Sheet and will be re-measured at the end of every reporting period with the change in value reported in the statement of operations.

The derivative liabilities were valued using a Binomial pricing model with the following average assumptions:

	September 30, 2021	December 31, 2020
Stock Price	\$ 6.68	\$ 7.21
Risk-free interest rate	0.98%	0.36%
Expected volatility	132%	135%
Expected life (in years)	3.83 years	4.60 years
Expected dividend yield	-	-
Fair Value:		
Warrants	<u>\$ 340,000</u>	<u>\$ 383,000</u>

The risk-free interest rate was based on rates established by the Federal Reserve Bank. The Company uses the historical volatility of its common stock to estimate the future volatility for its common stock. The expected life of the derivative securities was determined by the remaining contractual life of the derivative instrument. For derivative instruments that already matured, the Company used the estimated life. The expected dividend yield was based on the fact that the Company has not paid dividends to its common stockholders in the past and does not expect to pay dividends to its common stockholders in the future.

During the nine months ended September 30, 2021, the Company recognized a gain of \$43,000 to account for the change in fair value of the derivative liability in accordance with ASC 842.

**Note 8 – Stockholders' Equity (Deficit)**

Common Stock Issuable

As a result of the mandatory conversion of the notes payable and accrued interest in the aggregate of \$8,799,000 on February 16, 2021, the Company is obligated to issue a total of 11,413,322 shares of common stock to the respective noteholders.

As of September 30, 2021, the Company was only able to issue 10,408,827 shares of common stock or approximately 91% or \$5,383,000 of the converted notes payable and accrued interest to the respective noteholders. With regards to the remaining 1,004,495 unissued shares of common stock or \$3,416,000 of the converted notes payable and accrued interest, the Company is in the process of obtaining the necessary supporting documentation from the respective noteholders which will then be provided to the Company's stock transfer agent as a requirement for the issuance of the common stock certificate.

## Table of Contents

For financial reporting purposes, the Company reported \$3,416,000 as common stock issuable in the accompanying statements of stockholders' equity to account for the estimated balance of the converted notes payable and accrued interest that the Company has not yet issued the corresponding common stock.

Subsequent to September 30, 2021, the Company issued a total of 74,094 shares of common stock to these noteholders upon submission of the required documentation to the Company's stock transfer agent.

The following were transactions during the nine months ended September 30, 2021:

### Issuance of Common Stock in public offering

On February 16, 2021, the Company completed a public offering of 4,945,000 shares of common stock for net proceeds of \$24,679,000, after deducting underwriting discounts, commissions and other direct offering expenses. As part of the offering, the Company also granted these investors, warrants to purchase 5,192,250 shares of common stock. The warrants are fully vested, exercisable at \$5.50 per share and will expire in five years.

As a result of the completion of the public offering and the successful listing of its shares of common stock on the Nasdaq Capital Markets, convertible notes with an aggregate principal amount of \$33,272,000 and accrued interest of \$5,527,000 mandatorily converted at its stated conversion rate of \$3.40 per share into 11,413,322 shares of the Company's common stock (see Note 4).

### Issuance of Common Stock for services - consultants

As part of consulting agreements with certain consultants, the Company agreed to grant these consultants common stock equal to 1% and 3% of the fully diluted shares of common stock of the Company upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing).

On February 16, 2021, the Company completed its equity offering and listed its shares of common stock on the Nasdaq Capital Markets (see Note 7). As a result of this offering, the Company agreed to issue to these consultants 2,502,518 shares of common stock with a fair value of \$9,679,000, of which 1,829,620 shares of common stock are fully vested while the remaining 672,898, shares of common stock will vest over two years. Pursuant to current accounting guidelines, as the grant of the common stock is subject to milestone or performance conditions, the Company measured the fair value of the common stock on the respective date of the agreement, and then such award is being recorded as compensation expense based upon the vesting term of the grant.

During the period ended September 30, 2021, pursuant to the vesting terms of the agreements, the Company issued 1,992,746 shares of common stock that vested to these consultants and recorded the corresponding stock compensation expense of \$7,890,000. In addition, the Company also issued 150,000 shares of common stock with a fair value of \$1,213,000 to other consultants for service rendered. As a result, the Company recognized an aggregate of \$9,103,000 in stock compensation expense based upon the vesting of common stock granted to consultants.

As of September 30, 2021, there are 509,772 unvested shares of common stock with a fair value of \$1,789,000 which will be recognized as stock compensation in future periods.

### Issuance of Common Stock for research and development agreement

During the nine months ended September 30, 2021, the Company issued 189,753 shares of common stock for a research and development agreement valued at \$1,355,000. The common shares were valued on the market price at the date of grant.

### Issuance of Common Stock upon exercise of warrants

During the nine months ended September 30, 2021, the Company issued 3,073,818 shares of common stock upon the exercise of warrants resulting in cash proceeds of \$16,433,000.



*Preferred Stock*

A. Series J Preferred Stock

On September 1, 2017, the Board designated 2,000,000 shares of Series J preferred stock (the “Series J Preferred Stock”). On the same day, the Board issued 1,513,548 shares of Series J Preferred Stock in exchange for the cancellation of certain indebtedness.

In the first quarter of 2019, it was discovered that a certificate of designation with respect to the Series J Preferred Stock had never been filed with the Office of the Secretary of State for the State of Delaware. Despite the fact the Company had issued shares of Series J Preferred Stock, the issuance of those shares was not valid and was of no legal effect.

To remedy the situation, on April 4, 2019, the Company filed a certificate of designation with the Office of the Secretary State for the State of Delaware designating a series of preferred stock as the Series J-1 preferred stock, par value \$0.01 per share (the “Series J-1 Preferred Stock”). On April 19, 2019, the Company issued 840,000 shares of Series J-1 Preferred Stock. The issuance was in lieu of the Series J Preferred Stock that should have been issued on September 1, 2017, and in settlement for not receiving preferred stock until 20 months after the debt for which the stock was issued was cancelled.

Shares of the Series J-1 Preferred Stock are convertible at any time, at the option of the holders, into shares of the Company’s common stock at an effective conversion price of \$3.40 per share, subject to adjustment for, among other things, stock dividends, stock splits, combinations, reclassifications of our capital stock and mergers or consolidations, and subject to a beneficial ownership limitation which prohibits conversion if such conversion would result in the holder (together with its affiliates) being the beneficial owner of in excess of 9.99% of the Company’s common stock or 692,220 shares of common stock. Shares of the Series J-1 Preferred Stock have the same voting rights a shares of the Company’s common stock, with the holders of the Series J-1 Preferred Stock entitled to vote on an as-converted-to-common stock basis, subject to the beneficial ownership limitation described above, together with the holders of the Company’s common stock on all matters presented to the Company’s stockholders. The Series J-1 Preferred Stock are not entitled to any dividends (unless specifically declared by the Board), but will participate on an as-converted-to-common-stock basis in any dividends to the holders of the Company’s common stock. In the event of the Company’s dissolution, liquidation or winding up, the holders of the Series J-1 Preferred Stock will be on parity with the holders of the Company’s common stock and will participate, on a on an as-converted-to-common stock basis, in any distribution to holders of the Company’s common stock.

On February 16, 2021, as a result of the completion of the public offering and the successful listing of its shares of common stock on the Nasdaq Capital Markets, 2,353,548 shares of Series J-1 Preferred stock mandatorily converted at a conversion rate of \$3.40 per share into 692,220 shares of the Company’s common stock.

B. Series C Preferred Stock

During Fiscal 2017, the Company issued 96,230 shares of Series C Preferred Stock. The 96,230 shares of Series C preferred stock, par value \$0.01 per share (the “Series C Preferred Stock”), are convertible into 7 shares of the Company’s common stock at the option of the holders at any time. The conversion ratio is based on the average closing bid price of the common stock for the fifteen consecutive trading days ending on the date immediately preceding the date notice of conversion is given, but cannot be less than \$3.40 or more than \$4.9113 for each share of Series C Preferred Stock. The conversion ratio may be adjusted under certain circumstances such as stock splits or stock dividends. The Company has the right to automatically convert the Series C Preferred Stock into common stock if the Company lists its shares of common stock on the Nasdaq National Market and the average closing bid price of the Company’s common stock on the Nasdaq National Market for 15 consecutive trading days exceeds \$3,000.00. Each share of Series C Preferred Stock is entitled to the number of votes equal to 0.26 divided by the average closing bid price of the Company’s common stock during the fifteen consecutive trading days immediately prior to the date such shares of Series C Preferred Stock were purchased. In the event of liquidation, the holders of the Series C Preferred Stock shall participate on an equal basis with the holders of the common stock (as if the Series C Preferred Stock had converted into common stock) in any distribution of any of the assets or surplus funds of the Company. The holders of Series C Preferred Stock are entitled to noncumulative dividends if and when declared by the Company’s board of directors (the “Board”). No dividends to holders of the Series C Preferred Stock were issued or unpaid through September 30, 2021.

C. Series K Preferred Stock

On February 16, 2021, the Board designated 115,000 shares of Series K preferred stock, par value \$.01. (the “Series K Preferred Stock”).

Shares of the Series K Preferred Stock are convertible at any time, at the option of the holders, into shares of the Company’s common stock at an effective conversion rate of 100 shares of common stock for each share of Series K Preferred. Shares of the Series K Preferred Stock have the same voting rights a shares of the Company’s common stock, with the holders of the Series K Preferred Stock entitled to vote on an as-converted-to-common stock basis, subject to the beneficial ownership limitation, together with the holders of the Company’s common stock on all matters presented to the Company’s stockholders. The Series K Preferred Stock are not entitled to any dividends (unless specifically declared by the Board), but will participate on an as-converted-to-common-stock basis in any dividends to the holders of the Company’s common stock. In the event of the Company’s dissolution, liquidation or winding up, the holders of the Series K Preferred Stock will be on parity with the holders of the Company’s common stock and will participate, on a on an as-converted-to-common stock basis, in any distribution to holders of the Company’s common stock.

[Table of Contents](#)

As of September 30, 2021, there were no Series K Preferred stock issued and outstanding.

Stock Warrants

Stock warrant transactions for the nine months ended September 30, 2021:

	Number of Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2020:	221,041	\$ 3.40
Granted	5,192,250	5.50
Forfeited/canceled	-	-
Exercised	(3,076,017)	5.50
Outstanding at September 30, 2021	<u>2,337,274</u>	<u>\$ 5.38</u>
Exercisable at September 30, 2021	<u>2,337,274</u>	<u>\$ 5.38</u>

As of September 30, 2021, all issued and outstanding warrants are fully vested and the intrinsic value of these warrants amounted to \$,180,000.

The following were transactions during the nine months ended September 30, 2021:

On February 16, 2021, as part of the Company's public offering, the Company issued warrants to investors to purchase up to an aggregate of 5,192,250 shares of common stock. The warrants have an exercise price of \$5.50 per share, subject to adjustment in certain circumstances and will expire in five years.

During the nine months ended September 30, 2021, the Company issued 3,076,017 shares of common stock upon exercise of warrants which also resulted cash proceeds of \$16,433,000.

**Note 9 – Related Party**

During the period ended September 30, 2021, the Company recorded consulting expense of \$350,000 for services rendered by a consultant who is also an owner of approximately 10% of the Company's issued and outstanding common stock. In addition, the Company also issued a note payable to this consultant of \$25,000 in exchange for the cancellation of unpaid consulting fees of \$525,000 that was recorded as part of accrued expenses at December 31, 2020. There was no similar consulting expense incurred during the period ended September 30, 2020.

**Note 10 – Equity Compensation to Officers and Board of Directors**

As part of employment agreements with its former CEO and its CFO, these officers were to receive a fully vested stock grants equal to aggregate of 10% and 1.5% of the fully diluted shares of common stock of the Company (calculated with the inclusion of the current stock holdings of Mr. Cataldo) upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). In addition, the Company also granted similar equity compensation to members of the Company's Board of Directors wherein these directors were to receive stock grants equal to 1% and 1.25%, as applicable, of the fully diluted shares of common stock of the Company, of which, 1/3<sup>rd</sup> was vested when issued following the qualified financing, and of which 1/3<sup>rd</sup> will vest on each of the first and second anniversaries of the date on which the director was elected to the Company's Board of Directors.

On February 16, 2021, the Company completed its equity offering and listed its shares of common stock on the Nasdaq Capital Markets (see Note 7). As a result of this offering, 3,197,662 shares of fully vested common stock with a fair value of \$1,701,000 were granted and issued to these officers. In addition, the Company also granted 1,181,745 shares of common stock to members of the Company's Board of Directors with a fair value of \$6,920,000, of which, 393,915 shares of common stock are fully vested upon grant while the remaining 787,830 shares of common stock will vest over two years. During the period ended September 30, 2021, the Company recognized stock compensation expense of \$3,748,000 to account for the 640,112 shares of common stock granted to the Board of Directors that vested.

Pursuant to current accounting guidelines, as the grant of the common stock is subject to milestone or performance condition, the Company measured the fair value of the common stock on the respective date of the agreement, and then such award was recorded as compensation expense as the milestone or performance condition is met and in accordance with its vesting term of the grant.

As of September 30, 2021, there are 541,633 unvested shares of common stock with a fair value of \$1,172,000 that will be recognized as compensation in future periods.

## **Note 11 – Commitments and Contingencies**

### **1. Litigation**

We are involved in certain legal proceedings that arise from time to time in the ordinary course of our business. Except for income tax contingencies, we record accruals for contingencies to the extent that our management concludes that the occurrence is probable and that the related amounts of loss can be reasonably estimated. Legal expenses associated with the contingency are expensed as incurred. There is no current or pending litigation of any significance with the exception of the matters that have arisen under, and are being handled in, the normal course of business.

a. On August 28, 2019, a complaint was filed in the Superior Court of California, County of Los Angeles, West Judicial District, Santa Monica Courthouse, Unlimited Civil Division by Jeffrey Lion, an individual (“Lion”), and by Daniel Vallera, an individual (“Vallera”). Lion and Vallera are referred to jointly as the “Plaintiffs”. The complaint was filed against GT Biopharma, Inc. and its subsidiary Oxis Biotech, Inc. (either of them or jointly, the “Company”). The Plaintiffs allege breach of a license agreement between the Plaintiffs and the Company entered into on or about September 3, 2015. Lion alleges breach of a consulting agreement between Lion and the Company entered into on or about September 1, 2015. Vallera alleges breach of a consulting agreement between Vallera and the Company entered into in or around October, 2018. The Complaint seeks actual damages of \$1,670,000, for the fair market value of the number of shares of GT Biopharma, Inc. that at the time of judgment represent 882,353 shares of such stock as of September 1, 2015, and that GT Biopharma, Inc. issue Lion the number of common shares of GT Biopharma, Inc. that at the time of judgment represent 882,353 such shares as of September 1, 2015. The Company filed an answer to the complaint denying many allegations and asserting affirmative defenses. Discovery has commenced and trial is scheduled for May, 2022. The Company believes the case is without merit and will defend it vigorously.

b. On March 3, 2021 a complaint was filed by Sheffield Properties in the superior Court of California. County of Ventura. The litigation arose from a commercial lease entered into by GT Biopharma for office space in Westlake Village. In July, 2021 we entered into settlement agreement with Sheffield Properties in the amount of \$100,000.

### **2. Research and Development Agreement:**

We are party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, to further develop and commercialize cancer therapies using TriKE technology developed by researchers at the university to target NK cells to cancer. Under the terms of the agreement, we receive exclusive rights to conduct research and to develop, make, use, sell, and import TriKE technology worldwide for the treatment of any disease, state or condition in humans. We are responsible for obtaining all permits, licenses, authorizations, registrations and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as the TriKE technology, including without limitation the FDA in the United States and the European Agency for the Evaluation of Medicinal Products in the European Union. Under the agreement, the University of Minnesota will receive an upfront license fee, royalty fees ranging from 5% to 6%, minimum annual royalty payments of \$0.25 million beginning in the year after the first commercial sale of the licensed product and \$2.0 million beginning in the 5<sup>th</sup> year after the first commercial sale of licensed product and every year thereafter throughout the remainder of the term, and certain milestone payments totaling \$3.1 million.

During the period ended September 30, 2021, the Company recorded research and development expenses of \$50,000 pursuant to this agreement.

### 3. Employee Compensation

The following table summarizes the Company's future financial commitment to certain employees pursuant to their respective employment agreements:

<b>Year ending</b>	<b>Amount</b>
2021 remaining (remaining 3 months)	\$ 527,000
2022	2,085,000
2023	2,085,000
2024	2,085,000
2025 and thereafter	761,000
Total	<u>\$ 7,543,000</u>

#### **Note 12- Subsequent Events**

Subsequent to September 30, 2021, the Company issued a total of 74,094 shares of common stock to noteholders whose notes payable and accrued interest were mandatorily converted to common stock on February 16, 2021 (see Note 4). On November 5, 2021 the Company terminated the employment of Anthony Cataldo as Chief Executive Officer and Michael Handelman as Chief Financial Officer. On November 8, the Board appointed Dr. Greg Berk as Interim Chief Executive Officer, and Dr. Gavin Choy as Acting Chief Financial Officer. On November 8, 2021, the Board also appointed Michael Breen as Executive Chairman of the Board. Compensation for Dr. Berk shall be an annual salary of \$500,000, annual target bonus of up to 50% of salary, and a stock grant of 0.25% of the fully diluted stock as of the date of his appointment. Compensation for Michael Breen shall be an annual salary of \$425,000, annual target bonus of up to 75% of salary, and a stock grant of 1% of the fully diluted stock.

Dr. Berk previously served as a private consultant in the field of drug development and was the Chief Medical Officer of Celularity, a privately owned company. Previously, he served as Chief Medical Officer at Verastem and as President, Chief Medical Officer and Board Member of Sideris Pharmaceuticals. From May 2012 until January 2014, Dr. Berk was Chief Medical Officer of BIND Therapeutics. Prior to this, he was Chief Medical Officer at Intellikine, a privately held biotechnology company focused on the discovery and development of novel PI3 Kinase and mTOR inhibitors. Intellikine was acquired by Takeda/Millennium in January 2012. He also served as Senior Vice President of Global Clinical Development at Abraxis BioScience, where he was responsible for the company's overall clinical strategy, including efforts to expand the indications for their lead clinical program (Abraxane®). Dr. Berk obtained his medical degree from Case Western Reserve University, and completed his internship, residency and fellowship in internal medicine, hematology and medical oncology, at the Weill Medical College of Cornell University and New York Presbyterian Hospital, where he also served as a faculty member from 1989-2004. During this time Dr. Berk served as an investigator on several industry-sponsored and cooperative group oncology clinical trials, including the pivotal trials for Gleevec® and Avastin®.

Dr. Choy received his Doctor of Pharmacy from the University of Southern California and completed residency training at the U.S. Department of Veteran Affairs. Dr. Choy also holds a Master of Business Administration focused on Health Care from the University of California, Irvine, Paul Merage School of Business. Dr. Choy has more than 20 years in the pharmaceutical and biotechnology industry with various executive leadership roles, including serving as a Chief Operating Officer at Apollomics, Inc. as well as President, CG Pharmaceuticals, Inc.

**Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

**CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS**

Some of the statements in this Quarterly Report on Form 10-Q are “forward-looking statements” within the meaning of the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our current beliefs, goals and expectations about matters such as our expected financial position and operating results, our business strategy and our financing plans. The forward-looking statements in this report are not based on historical facts, but rather reflect the current expectations of our management concerning future results and events. The forward-looking statements generally can be identified by the use of terms such as “believe,” “expect,” “anticipate,” “intend,” “plan,” “foresee,” “may,” “guidance,” “estimate,” “potential,” “outlook,” “target,” “forecast,” “likely” or other similar words or phrases. Similarly, statements that describe our objectives, plans or goals are, or may be, forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be different from any future results, performance and achievements expressed or implied by these statements. We cannot guarantee that our forward-looking statements will turn out to be correct or that our beliefs and goals will not change. Our actual results could be very different from and worse than our expectations for various reasons. You should review carefully all information, including the discussion of risk factors under “Part I. Item 1A: Risk Factors” and “Part II. Item 7: Management’s Discussion and Analysis of Financial Condition and Results of Operations” of the Form 10-K for the year ended December 31, 2020. Any forward-looking statements in the Form 10-Q are made only as of the date hereof and, except as may be required by law, we do not have any obligation to publicly update any forward-looking statements contained in this Form 10-Q to reflect subsequent events or circumstances.

Throughout this Quarterly Report on Form 10-Q, the terms “GTBP,” “we,” “us,” “our,” “the company” and “our company” refer to GT Biopharma, Inc., a Delaware corporation formerly known as Oxis International, Inc., DDI Pharmaceuticals, Inc. and Diagnostic Data, Inc. together with our subsidiaries.

**Overview**

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE™) fusion protein immune cell engager technology platform. Our TriKE platform generates proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient’s own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically-targeted proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in the targeted cell’s death. TriKE can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization.

We are using our TriKE platform with the intent to bring to market immuno-oncology products that can treat a range of hematologic malignancies, sarcoma and solid tumors. The platform is scalable, and we are putting processes in place to be able to produce IND-ready moieties in a timely manner after a specific TriKE conceptual design. After conducting market and competitive research, specific moieties can then be advanced into the clinic on our own or through potential collaborations with larger companies. We are also evaluating, in conjunction with our Scientific Advisory Board, additional moieties designed to target different tumor antigens. We believe our TriKE may have the ability, if approved for marketing, to be used as a monotherapy, augment the current monoclonal antibody therapeutics, be used in conjunction with more traditional cancer therapy and potentially overcome certain limitations of current chimeric antigen receptor, or CAR-T, therapy.

We are also using our TriKE platform to develop therapeutics useful for the treatment of infectious disease such as for the treatment of patients infected by the human immunodeficiency virus (HIV). While the use of anti-retroviral drugs has substantially improved the health and increased the longevity of individuals infected with HIV, these drugs are designed to suppress virus replication to help modulate progression to AIDS and to limit further transmission of the virus. Despite the use of anti-retroviral drugs, infected individuals retain reservoirs of latent HIV-infected cells that, upon cessation of anti-retroviral drug therapy, can reactivate and re-establish an active HIV infection. For a curative therapy, destruction of these latent HIV infected cells must take place. The HIV-TriKE contains the antigen binding fragment (Fab) from a broadly-neutralizing antibody targeting the HIV-Env protein. The HIV-TriKE is designed to target HIV while redirecting NK cell killing specifically to actively replicating HIV infected cells. The HIV-TriKE induced NK cell proliferation, and demonstrated the ability in vitro to reactivate and kill HIV-infected T-cells. These findings indicate a potential role for the HIV-TriKE in the reactivation and elimination of the latently infected HIV reservoir cells by harnessing the NK cell’s ability to mediate the antibody-directed cellular cytotoxicity (ADCC).

Our initial work has been conducted in collaboration with the Masonic Cancer Center at the University of Minnesota under a program led by Dr. Jeffrey Miller, the Deputy Director. Dr. Miller is a recognized leader in the field of NK cell and IL-15 biology and their therapeutic potential. We have exclusive rights to the TriKE platform and are generating additional intellectual property.

## Recent Developments

On February 16, 2021, we completed a public offering of 4,945,000 shares of common stock for net proceeds of \$24,679,000, after deducting underwriting discounts, commissions and other direct offering expenses. As part of the offering, we also granted these investors warrants to purchase 5,192,250 shares of common stock. The warrants are fully vested, exercisable at \$5.50 per share and will expire in five years.

As a result of the completion of the public offering and the successful listing of our shares of common stock on the Nasdaq Capital Markets, convertible notes with an aggregate principal amount of \$33,272,000 and accrued interest of \$5,527,000 mandatorily converted at its stated conversion rate of \$3.40 per share into 11,413,322 shares of our common stock (see Note 4 of the Financial Statements).

As part of consulting agreements with certain consultants, we agreed to grant these consultants shares of common stock equal to 1% and 3% of the fully diluted shares of our common stock upon completion of a qualified financing and listing on a national market as consideration for entering into such consulting agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing).

On February 16, 2021, we completed a qualified equity offering and listing. As a result, we granted these consultants 2,502,518 shares of common stock. During the period ended September 30, 2021, pursuant to the vesting terms of the consulting agreements, we issued 1,992,746 shares of common stock to these consultants and recorded the corresponding stock compensation expense of \$7,890,000. In addition, we also issued 150,000 shares of common stock with a fair value of \$1,213,000 to other consultants for services rendered.

On February 16, 2021, as a result of the completion of the public offering and the successful listing of our shares of common stock on the Nasdaq Capital Markets, 2,353,548 shares of Series J-1 Preferred Stock mandatorily converted at a conversion rate of \$3.40 per share into 692,220 shares of our common stock. (See Note 7 of our Financial Statements)

On February 16, 2021, as part of our public offering of common stock and warrants, we issued warrants to investors to purchase up to an aggregate of 5,192,250 shares of common stock. The warrants have an exercise price of \$5.50 per share, subject to adjustment in certain circumstances and will expire in five years. (See Note 7 of our Financial Statements)

As part of employment agreements with our CEO and CFO, these officers were to receive a fully vested stock grant of shares of common stock equal to aggregate of 10% and 1.5% of the fully diluted shares of our common stock (calculated with the inclusion of the current stock holdings of Mr. Cataldo, our CEO, and Mr. Handelman, our CFO) upon conversion of options, warrants and convertible notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). In addition, we also granted similar equity compensation to members of our Board of Directors wherein these directors were to receive stock grant equal to 1% and 1.25% of the fully diluted shares of our common stock. Pursuant to these agreements, the common stock to be issued will vest over a period of two years. On February 16, 2021, we completed a qualified equity offering and listing. As a result, we granted these employees 4,379,407 shares of common stock.

On April 23, 2021, our Compensation Committee approved amendments to the compensation terms of Anthony Cataldo, the Chief Executive Officer and Michael Handelman, the Chief Financial Officer to increase their base salary and bonus compensation. (See Part II, Item 5 of this report)

On April 23, 2021, Dr. Gregory Berk resigned as a director and accepted employment as our Chief Medical Officer. In connection with his appointment as Chief Medical Officer, the Compensation Committee approved a four-year employment agreement for Dr. Berk.

## Table of Contents

On August 23, 2021, Dr. Gregory Berk was promoted to the position of President of Research & Development and Chief Medical Officer. Dr. Berk assume additional responsibilities including discovery, non-clinical development, clinical development and manufacturing.

### Issuance of Common Stock in public offering

On February 16, 2021, the Company completed a public offering of 4,945,000 shares of common stock for net proceeds of \$24,679,000, after deducting underwriting discounts, commissions and other direct offering expenses. As part of the offering, the Company also granted these investors, warrants to purchase 5,192,250 shares of common stock. The warrants are fully vested, exercisable at \$5.50 per share and will expire in five years.

As a result of the completion of the public offering and the listing of its shares of common stock on the Nasdaq Capital Markets, convertible notes payable and accrued interest with an aggregate amount of \$38,799,000 were mandatorily converted at its stated conversion rate of \$3.40 per share into 11,413,322 shares of the Company's common stock (see Note 4).

### Issuance of Common Stock for services - consultants

As part of consulting agreements with certain consultants, the Company agreed to grant these consultants common stock equal to 1% and 3% of the fully diluted shares of common stock of the Company upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing).

On February 16, 2021, the Company completed its equity offering and listed its shares of common stock on the Nasdaq Capital Markets. As such, 2,502,518 shares of common stock were granted to these consultants with a fair value of \$9,679,000, of which, 1,829,620 shares of common stock are fully vested while the remaining 672,898 shares of common stock will vest over two years. Pursuant to current accounting guidelines, as the grant of the common stock is subject to milestone or performance conditions, the Company measured the fair value of the common stock on the respective date of the agreement, and then such award was recorded as compensation expense as the milestone or performance condition was met and in accordance with its vesting term of the grant.

During the period ended September 30, 2021, pursuant to the vesting terms of the agreements, the Company issued 1,992,746 shares of common stock to these consultants. In addition, the Company also issued 150,000 shares of fully vested common stock with a fair value of \$1,213,000 to other consultants for service rendered. As a result, the Company issued a total of 2,142,746 shares of common stock and recognized stock compensation expense of \$9,105,000 to account the fair value of common stock that vested.

As of September 30, 2021, the unvested and unissued common stock totaled 509,772 shares of common stock with an estimated fair value of \$1,789,000 that will be recognized as stock compensation in future periods based upon the remaining vesting term of the grant.

### Issuance of Common Stock for research and development agreement

During the nine months ended September 30, 2021, the Company issued 189,753 shares of common stock for a research and development agreement valued at \$1,355,000. The common shares were valued on the market price at the date of grant.

### Issuance of Common Stock upon exercise of warrants

During the nine months ended September 30, 2021, the Company issued 3,073,818 shares of common stock upon the exercise of warrants resulting in cash proceeds of \$16,433,000.

## Results of Operations

### Comparison of the Three Months Ended September 30, 2021 and 2020

#### *Research and Development Expenses*

During the three months ended September 30, 2021 and 2020, we incurred \$1,008,000 and \$(84,000) research and development expenses, an increase of \$1,092,000. Research and development costs increased due primarily to the admittance of additional patients into the phase one/two clinical trial. We anticipate our research and development costs to increase in the remainder of 2021 due to the continued development of our most advanced TriKe product candidate, OXS-3650 and other research and development.

#### *Selling, general and administrative expenses*

During the three months ended September, 2021 and 2020, we incurred \$4,946,000 and \$2,029,000 of selling, general and administrative expenses. The increase of \$2,917,000 in selling, general and administrative expenses is primarily attributable the increase in stock-based compensation. In the period ended September 30, 2021 we incurred \$902,000 of stock-based compensation, we incurred \$147,000 in stock-based compensation expense during 2020. In addition, with the addition of new personnel to support our planned growth and new public company compliance initiatives in fiscal year 2021 we have incurred an increase in expenses that consist primarily of personnel costs from our executive, legal, finance, human resources and information technology organizations and related expenditures, as well as third party professional fees and insurance.

#### *Change in fair value of derivative liability*

Change in fair value of derivative liability was income of \$502,000 for the three months ended September 30, 2021 and we had no such gain or loss for the same period in 2020.

#### *Interest Expense*

Interest expense was \$0 and \$931,000 for the three months ended September 30, 2021 and 2020 respectively. The decrease is primarily due to the decrease in the amount of outstanding convertible notes, as these convertible notes were converted on February 16, 2021.

### Comparison of the Nine Months Ended September 30, 2021 and 2020

#### *Research and Development Expenses*

During the nine months ended September 30, 2021 and 2020, we incurred \$3,287,000 and \$252,000 research and development expenses, an increase of \$3,035,000. Research and development costs increased due primarily to the issuance of 190,000 shares of common stock as payment of a fee valued at \$1,943,000 and the admittance of additional patients into the phase one/two clinical trial. We anticipate our research and development costs to increase in the remainder of 2021 due to the continued development of our most advanced TriKe product candidate, OXS-3650 and other research and development.

#### *Selling, general and administrative expenses*

During the nine months ended September 30, 2021 and 2020, we incurred \$36,050,000 and \$4,321,000 of selling, general and administrative expenses. The increase of \$31,729,000 in selling, general and administrative expenses is primarily attributable the increase in stock-based compensation. In the period ended September 30, 2021 we incurred \$24,553,000 of stock-based compensation. We incurred no such expenses during 2020. In addition, with the addition of new personnel to support our planned growth and new public company compliance initiatives in fiscal year 2021 we have incurred an increase in expenses that consist primarily of personnel costs from our executive, legal, finance, human resources and information technology organizations and related expenditures, as well as third party professional fees and insurance.

#### *Change in fair value of derivative liability*

Change in fair value of derivative liability was income of \$43,000 for the nine months ended September 30, 2021 and we had no such gain or loss for the same period in 2020.



## Table of Contents

### *Settlement expense*

Settlement expense was an expense of \$11,206,000 for the nine months ended September 30, 2020 and we had no such gain or loss for the same period in 2021.

### *Interest Expense*

Interest expense was \$696,000 and \$6,227,000 for the nine months ended September 30, 2021 and 2020 respectively. The decrease is primarily due to the decrease in the amount of outstanding convertible notes, as the entire balances of convertible notes were converted on February 16, 2021.

### **Liquidity and Capital Resources**

The Company's current operations have focused on business planning, raising capital, establishing an intellectual property portfolio, hiring, and conducting preclinical studies and clinical trials. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future. During the nine months ended September 30, 2021, the Company raised the net amount of \$24.7 million through issuance of common stock, raised \$16.4 million through the exercise of warrants and raised \$1.2 million from a series of issuances of convertible notes as compared to a total of \$5.7 million raised through issuance of convertible notes payable during the same period in 2020. We anticipate that cash utilized for selling, general and administrative expenses will range between \$2 and \$3 million in the coming quarters, while research and development expenses will vary depending on clinical activities.

The financial statements of the Company have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should the Company be unable to continue in existence.

The Company has incurred substantial losses and has cash and short-term investments of \$35.7 million as of September 30, 2021. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales or revenue from out-licensing of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: public offerings of equity and/or debt securities, payments from potential strategic research and development partners, and licensing and/or marketing arrangements with pharmaceutical companies. Management believes that these ongoing and planned financing endeavors, if successful, will provide adequate financial resources to continue as a going concern for at least the next nine months from the date the financial statements are issued; however, there can be no assurance in this regard. If the Company is unable to secure adequate additional funding, its business, operating results, financial condition and cash flows may be materially and adversely affected.

### **Critical Accounting Policies**

We consider the following accounting policies to be critical given they involve estimates and judgments made by management and are important for our investors' understanding of our operating results and financial condition.

#### Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Oxix Biotech, Inc. and Georgetown Translational Pharmaceuticals, Inc. Intercompany transactions and balances have been eliminated in consolidation.

#### Reverse Stock Split

On February 10, 2021, the Company completed a 1:17 reverse stock split of the Company's issued and outstanding shares of common stock and all fractional shares were rounded up. All share and per share amounts in the accompanying financial statements have been adjusted retroactively to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented.

[Table of Contents](#)

[Accounting Estimates](#)

The preparation of financial statements in conformity with Generally Accepted Accounting Principles (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include accruals for potential liabilities, valuation of notes payable, assumptions used in deriving the fair value of derivative liabilities, share-based compensation and beneficial conversion feature of notes payable, and valuation of deferred tax assets. Actual results could differ from those estimates.

[Stock-Based Compensation](#)

The Company accounts for share-based awards to employees and nonemployees and consultants in accordance with the provisions of ASC 718, Compensation-Stock Compensation. Stock-based compensation cost is measured at fair value on the grant date and that fair value is recognized as expense over the requisite service, or vesting, period.

The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur. Use of the Black-Scholes option pricing model requires the input of subjective assumptions including expected volatility, expected term, and a risk-free interest rate. The Company estimates volatility using as its own historical stock price volatility. The expected term of the instrument is estimated by using the simplified method to estimate expected term. The risk-free interest rate is estimated using comparable published federal funds rates.

**Inflation**

We believe that inflation has not had a material adverse impact on our business or operating results during the periods presented.

**Off-balance Sheet Arrangements**

We have no off-balance sheet arrangements as of September 30, 2021.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

This company qualifies as a smaller reporting company, as defined in 17 C.F.R. §229.10(f)(1) and is not required to provide information by this Item.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer evaluated the effectiveness of our “disclosure controls and procedures” (as such term is defined in Rules 13a-15(e) and 15d-15(e) of the United States Securities Exchange Act of 1934, as amended (the “Exchange Act”)), as of September 30, 2021. Based on that evaluation we have concluded that our disclosure controls and procedures were not effective as of September 30, 2021 as a result of material weaknesses in internal control over financial reporting due to (i) inadequate segregation of duties, (ii) risks of executive override and (iii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both U.S. GAAP and SEC regulation, in each case, as described in “Item 9A. Controls and Procedures” in the Company’s Form 10-K for the year ended December 31, 2020.

The Company is taking steps, and intends to take additional steps, to mitigate the issues identified and implement a functional system of internal control over financial reporting. Such measures will include, but not be limited to: hiring of additional employees in our finance and accounting department; preparation of risk-control matrices to identify key risks and develop and document policies to mitigate those risks; and identification and documentation of standard operating procedures for key financial and SEC reporting activities.

**Changes in Internal Control over Financial Reporting**

Except for the ongoing remediation of the material weaknesses in internal controls over financial reporting noted above, no changes in our internal control over financial reporting were made during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

On August 28, 2019, a complaint was filed in the Superior Court of California, County of Los Angeles, West Judicial District, Santa Monica Courthouse, Unlimited Civil Division by Jeffrey Lion, an individual (“Lion”), and by Daniel Vallera, an individual (“Vallera”). Lion and Vallera are referred to jointly as the “Plaintiffs”. Plaintiffs filed a Second Amended Complaint on December 21, 2020. The Second Amended Complaint alleges causes of action against GT Biopharma, Inc. and its subsidiary Oxis Biotech, Inc. (either of them or jointly, the “Company”). The Plaintiffs allege breach of a license agreement between the Plaintiffs and the Company entered into on or about September 3, 2015. Lion alleges breach of a consulting agreement between Lion and the Company entered into on or about September 1, 2015. Plaintiffs seek actual damages of \$400,000 for breach of the license agreement, and Lion seeks the fair market value of the number of shares of GT Biopharma, Inc. that at the time of judgment represent 15,000,000 shares of such stock as of September 1, 2015. The Company filed an answer to the complaint denying many allegations and asserting affirmative defenses. Discovery has commenced, and trial is scheduled for May 2, 2022.

### **Item 5. Other Information.**

On April 23, 2021, the Compensation Committee of the Board (the “Compensation Committee”) approved an amendment of the compensation terms of Anthony Cataldo, the Chief Executive Officer, increasing his annual base salary to \$500,000 and setting his target bonus at 50% of his annual base salary. Subsequent to such approval the Company entered into an Amended and Restated Employment Agreement with Mr. Cataldo memorializing the increase in his base salary and setting his target bonus, and implementing additional clarifications and revisions to Mr. Cataldo’s Employment Agreement. The Compensation Committee continues to review the Amended and Restated Employment Agreement, Mr. Cataldo’s compensation arrangements and related issues, and will make a final determination regarding the contents of such agreement following additional deliberations.

On April 23, 2021, the Compensation Committee also approved an amendment of the compensation terms of Michael Handelman, the Chief Financial Officer, increasing his annual base salary to \$375,000 and setting his target bonus at 40% of his annual base salary. Subsequent to such approval the Company entered into an Amended and Restated Employment Agreement with Mr. Handelman memorializing the increase in his base salary and setting his target bonus, and implementing additional clarifications and revisions to Mr. Handelman’s Employment Agreement. The Compensation Committee continues to review the Amended and Restated Employment Agreement, Mr. Handelman’s compensation arrangements and related issues, and will make a final determination regarding the contents of such agreement following additional deliberations.

Item 6. Exhibits

Exhibit	Description	Filed Herewith	Incorporated by Reference			
			Form	Number	SEC File No.	Filing Date
<a href="#">3.1</a>	<a href="#">Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002</a>		10-KSB	3.A	000-08092	04/01/2002
<a href="#">3.2</a>	<a href="#">Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., dated February 9, 2011</a>		10-K	3.2	000-08092	03/31/2011
<a href="#">3.3</a>	<a href="#">Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of July 19, 2017</a>		8-K/A	3.1	000-08092	03/15/2018
<a href="#">3.4</a>	<a href="#">Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of February 10, 2021</a>		8-K	3.1	001-40023	02/11/2021
<a href="#">3.5</a>	<a href="#">Bylaws, as restated effective September 7, 1994 and as amended through April 29, 2003</a>		10-QSB	3	000-08092	08/14/2003
<a href="#">4.1</a>	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series J-1 Preferred Stock of GT Biopharma, Inc., dated April 3, 2019</a>		8-K	3.1	000-08092	04/05/2019
<a href="#">4.2</a>	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series K Preferred Stock of GT Biopharma, Inc., dated April 3, 2019</a>		10-K	4.2	001-40023	04/16/2021
<a href="#">31.1</a>	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.</a>	X				
<a href="#">31.2</a>	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.</a>	X				
<a href="#">32.1*</a>	<a href="#">Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).</a>	X				
<a href="#">32.2*</a>	<a href="#">Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).</a>	X				
101.INS	Inline XBRL Instance Document.	X				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X				

\* This certification shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 10, 2021

GT Biopharma, Inc.

By: /s/ Gregory Berk  
Gregory Berk  
Interim Chief Executive Officer

Dated: November 10, 2021

GT Biopharma, Inc.

By: /s/ Gavin Choy  
Gavin Choy  
Acting Chief Financial Officer

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

I, Gregory Berk, certify that:

- a. I have reviewed this report on Form 10-Q of GT Biopharma, Inc.;
- b. 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;
- c. 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;
- d. The registrant's other certifying officers(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:
  - i) 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;
  - ii) 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;
  - iii) 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
  - iv) 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
- e. 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):
  - i) 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
  - ii) 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 10, 2021

By: /s/ Gregory Berk  
Name: Gregory Berk  
Title: Interim Chief Executive Officer

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

I, Gavin Choy, certify that:

- a. I have reviewed this report on Form 10-Q of GT Biopharma, Inc.;
- b. 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;
- c. 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;
- d. 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:
  - i) 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;
  - ii) 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;
  - iii) 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
  - iv) 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
- e. 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):
  - i) 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
  - ii) 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 10, 2021

By: /s/ Gavin Choy  
Name: Gavin Choy  
Title: Acting Chief Financial Officer

CERTIFICATION TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, Gregory Berk, Interim Chief Executive Officer of GT Biopharma, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

- (i) the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: November 10, 2021

By: /s/ Gregory Berk  
Name: Gregory Berk  
Title: Interim Chief Executive Officer



CERTIFICATION TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, Gavin Choy, Acting Chief Financial Officer of GT Biopharma, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

- (i) the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: November 10, 2021

By: /s/ Gavin Choy  
Name: Gavin Choy  
Title: Acting Chief Financial Officer