

**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 June 30, 2021

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

Commission file number: 001-39717

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-2903526**  
(I.R.S. Employer  
Identification Number)

**680 East Colorado Boulevard, Suite 180  
Pasadena, California 91101**  
(Address of principal executive offices, including Zip Code)

**(631) 830-7092**  
(Registrant's telephone number, including area code)

**248 Route 25A, No. 2  
East Setauket, New York 11733**  
(Former name, former address and former fiscal year, if changed since last report)

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

| Title of each class   | Trading Symbol(s) | Name of each exchange on which registered |
|---|-------------------|---|
| Common Stock, par value \$0.0001 per share                      | LIXT              | The Nasdaq Stock Market LLC               |
| Warrants to Purchase Common Stock, par value \$0.0001 per share | LIXTW             | The Nasdaq Stock Market LLC               |

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

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

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 1, 2021, the Company had 13,746,593 shares of common stock, \$0.0001 par value, issued and outstanding.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

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PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

|  | June 30,<br>2021<br><u>(Unaudited)</u> | December 31,<br>2020 |
|--|--|----------------------|
| <b>ASSETS</b>  |  |                      |
| Current assets:  |  |                      |
| Cash   | \$ 6,798,477                           | \$ 5,069,266         |
| Advances on research and development contract services   | 323,333                                | 76,898               |
| Prepaid insurance  | 75,983                                 | 67,311               |
| Other prepaid expenses and current assets  | 44,871                                 | 15,000               |
| Total current assets   | <u>7,242,664</u>                       | <u>5,228,475</u>     |
| Total assets   | <u>\$ 7,242,664</u>                    | <u>\$ 5,228,475</u>  |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |  |                      |
| Current liabilities:   |  |                      |
| Accounts payable and accrued expenses, including \$27,833 and \$0 to related parties at June 30, 2021 and December 31, 2020, respectively  | \$ 162,447                             | \$ 190,292           |
| Accrued offering costs   | —                                      | 10,467               |
| Research and development contract liabilities  | 213,879                                | 15,765               |
| Total current liabilities  | <u>376,326</u>                         | <u>216,524</u>       |
| Commitments and contingencies  |  |                      |
| Stockholders' equity:  |  |                      |
| Preferred Stock, \$0.0001 par value; authorized – 10,000,000 shares; issued and outstanding – 350,000 shares of Series A Convertible Preferred Stock, \$10.00 per share stated value, liquidation preference based on assumed conversion into common shares – 729,167 shares | 3,500,000                              | 3,500,000            |
| Common stock, \$0.0001 par value; authorized – 100,000,000 shares; issued and outstanding – 13,663,260 shares and 12,402,157 shares at June 30, 2021 and December 31, 2020, respectively   | 1,366                                  | 1,240                |
| Additional paid-in capital   | 37,179,050                             | 31,864,479           |
| Accumulated deficit  | <u>(33,814,078)</u>                    | <u>(30,353,768)</u>  |
| Total stockholders' equity   | <u>6,866,338</u>                       | <u>5,011,951</u>     |
| Total liabilities and stockholders' equity   | <u>\$ 7,242,664</u>                    | <u>\$ 5,228,475</u>  |

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)**

|   | Three Months Ended<br>June 30, |                     | Six Months Ended<br>June 30, |                     |
|---|--------------------------------|---------------------|------------------------------|---------------------|
|   | 2021                           | 2020                | 2021                         | 2020                |
| Revenues  | \$ —                           | \$ —                | \$ —                         | \$ —                |
| Costs and expenses:   |                                |                     |                              |                     |
| General and administrative costs, including compensation to officers, directors and affiliates of \$1,033,304 and \$27,000 for the three months ended June 30, 2021 and 2020, respectively, and \$1,849,336 and \$54,000 to related parties for the six months ended June 30, 2021 and 2020, respectively | 1,470,180                      | 255,443             | 2,751,834                    | 547,928             |
| Research and development costs  | 262,415                        | 117,946             | 705,941                      | 212,618             |
| Total costs and expenses  | <u>1,732,595</u>               | <u>373,389</u>      | <u>3,457,775</u>             | <u>760,546</u>      |
| Loss from operations  | (1,732,595)                    | (373,389)           | (3,457,775)                  | (760,546)           |
| Interest income   | 180                            | 264                 | 326                          | 4,246               |
| Interest expense  | (751)                          | —                   | (2,861)                      | —                   |
| Net loss  | <u>\$ (1,733,166)</u>          | <u>\$ (373,125)</u> | <u>\$ (3,460,310)</u>        | <u>\$ (756,300)</u> |
| Net loss per common share – basic and diluted   | <u>\$ (0.13)</u>               | <u>\$ (0.03)</u>    | <u>\$ (0.26)</u>             | <u>\$ (0.07)</u>    |
| Weighted average common shares outstanding – basic and diluted  | <u>13,633,040</u>              | <u>11,174,302</u>   | <u>13,203,010</u>            | <u>11,174,302</u>   |

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
(Unaudited)**

**Three Months and Six Months Ended June 30, 2021 and 2020**

|  | Series A<br>Convertible<br>Preferred Stock |                     | Common Stock      |                 | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity |
|--|--|---------------------|-------------------|-----------------|----------------------------------|------------------------|----------------------------------|
|  | Shares                                     | Amount              | Shares            | Par Value       |                                  |                        |                                  |
| <b>Three months ended June 30, 2021:</b>   |  |                     |                   |                 |                                  |                        |                                  |
| Balance, March 31, 2021  | 350,000                                    | \$ 3,500,000        | 13,538,259        | \$ 1,354        | \$ 36,227,258                    | \$ (32,080,912)        | \$ 7,647,700                     |
| Exercise of options  | —  | —                   | 125,001           | 12              | 100,988                          | —                      | 101,000                          |
| Stock-based compensation expense   | —  | —                   | —                 | —               | 850,804                          | —                      | 850,804                          |
| Net loss for the period  | —  | —                   | —                 | —               | —                                | (1,733,166)            | (1,733,166)                      |
| Balance, June 30, 2021   | <u>350,000</u>                             | <u>\$ 3,500,000</u> | <u>13,663,260</u> | <u>\$ 1,366</u> | <u>\$ 37,179,050</u>             | <u>\$ (33,814,078)</u> | <u>\$ 6,866,338</u>              |
| <b>Six months ended June 30, 2021:</b>   |  |                     |                   |                 |                                  |                        |                                  |
| Balance, December 31, 2020   | 350,000                                    | \$ 3,500,000        | 12,402,157        | \$ 1,240        | \$ 31,864,479                    | \$ (30,353,768)        | \$ 5,011,951                     |
| Proceeds from sale of common stock in<br>direct equity offering, net of offering costs | —  | —                   | 1,133,102         | 113             | 3,689,648                        | —                      | 3,689,761                        |
| Exercise of warrants   | —  | —                   | 3,000             | 1               | 17,099                           | —                      | 17,100                           |
| Exercise of options  | —  | —                   | 125,001           | 12              | 100,988                          | —                      | 101,000                          |
| Stock-based compensation expense   | —  | —                   | —                 | —               | 1,506,836                        | —                      | 1,506,836                        |
| Net loss for the period  | —  | —                   | —                 | —               | —                                | (3,460,310)            | (3,460,310)                      |
| Balance, June 30, 2021   | <u>350,000</u>                             | <u>\$ 3,500,000</u> | <u>13,663,260</u> | <u>\$ 1,366</u> | <u>\$ 37,179,050</u>             | <u>\$ (33,814,078)</u> | <u>\$ 6,866,338</u>              |

(Continued)

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
(Unaudited)  
(Continued)**

**Three Months and Six Months Ended June 30, 2021 and 2020**

|  | Series A<br>Convertible<br>Preferred Stock |                     | Common Stock      |                 | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity |
|--|--|---------------------|-------------------|-----------------|----------------------------------|------------------------|----------------------------------|
|  | Shares                                     | Amount              | Shares            | Par Value       |                                  |                        |                                  |
| <b>Three months ended June 30, 2020:</b> |  |                     |                   |                 |                                  |                        |                                  |
| Balance, March 31, 2020                  | 350,000                                    | \$ 3,500,000        | 11,174,302        | \$ 1,117        | \$ 26,021,904                    | \$ (27,472,061)        | \$ 2,050,960                     |
| Net loss for the period                  | —  | —                   | —                 | —               | —                                | (373,125)              | (373,125)                        |
| Balance, June 30, 2020                   | <u>350,000</u>                             | <u>\$ 3,500,000</u> | <u>11,174,302</u> | <u>\$ 1,117</u> | <u>\$ 26,021,904</u>             | <u>\$ (27,845,186)</u> | <u>\$ 1,677,835</u>              |
| <b>Six months ended June 30, 2020:</b>   |  |                     |                   |                 |                                  |                        |                                  |
| Balance, December 31, 2019               | 350,000                                    | \$ 3,500,000        | 11,174,302        | \$ 1,117        | \$ 26,021,904                    | \$ (27,088,886)        | \$ 2,434,135                     |
| Net loss for the period                  | —  | —                   | —                 | —               | —                                | (756,300)              | (756,300)                        |
| Balance, June 30, 2020                   | <u>350,000</u>                             | <u>\$ 3,500,000</u> | <u>11,174,302</u> | <u>\$ 1,117</u> | <u>\$ 26,021,904</u>             | <u>\$ (27,845,186)</u> | <u>\$ 1,677,835</u>              |

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)**

|   | <b>Six Months Ended<br/>June 30,</b> |                     |
|---|--------------------------------------|---------------------|
|   | <b>2021</b>                          | <b>2020</b>         |
| <b>Cash flows from operating activities:</b>  |                                      |                     |
| Net loss  | \$ (3,460,310)                       | \$ (756,300)        |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b>  |                                      |                     |
| Stock-based compensation expense included in -                                      |                                      |                     |
| General and administrative costs  | 1,506,836                            | —                   |
| <b>Changes in operating assets and liabilities:</b>                                 |                                      |                     |
| <b>(Increase) decrease in -</b>   |                                      |                     |
| Advances on research and development contract services                              | (246,435)                            | —                   |
| Accrued interest receivable   | —                                    | 14,367              |
| Prepaid insurance   | (8,672)                              | 19,889              |
| Other prepaid expenses and current assets   | (29,871)                             | 8,295               |
| <b>Increase (decrease) in -</b>   |                                      |                     |
| Accounts payable and accrued expenses   | (27,845)                             | 15,319              |
| Research and development contract liabilities                                       | 198,114                              | (70,252)            |
| <b>Net cash used in operating activities</b>  | <b>(2,068,183)</b>                   | <b>(768,682)</b>    |
| <b>Cash flows from financing activities:</b>  |                                      |                     |
| Proceeds from sale of common stock in direct equity offering, net of offering costs | 3,689,761                            | —                   |
| Payment of deferred offering costs  | —                                    | (55,850)            |
| Exercise of common stock warrants   | 17,100                               | —                   |
| Exercise of common stock options  | 101,000                              | —                   |
| Payment of public offering costs  | (10,467)                             | —                   |
| <b>Net cash provided by (used in) financing activities</b>                          | <b>3,797,394</b>                     | <b>(55,850)</b>     |
| <b>Cash:</b>  |                                      |                     |
| Net increase (decrease)   | 1,729,211                            | (824,532)           |
| Balance at beginning of period  | 5,069,266                            | 2,598,864           |
| <b>Balance at end of period</b>   | <b>\$ 6,798,477</b>                  | <b>\$ 1,774,332</b> |
| <b>Supplemental disclosures of cash flow information:</b>                           |                                      |                     |
| <b>Cash paid for -</b>  |                                      |                     |
| Interest  | \$ 2,944                             | \$ —                |
| Income taxes  | \$ —                                 | \$ —                |

See accompanying notes to condensed consolidated financial statements.

**LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Unaudited)**

**Three Months and Six Months Ended June 30, 2021 and 2020**

**1. Organization and Basis of Presentation**

The condensed consolidated financial statements of Lixte Biotechnology Holdings, Inc., a Delaware corporation (“Holdings”), including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (“Lixte”) (collectively, the “Company”), at June 30, 2021, and for the three months and six months ended June 30, 2021 and 2020, are unaudited. In the opinion of management of the Company, all adjustments, including normal recurring accruals, have been made that are necessary to present fairly the financial position of the Company as of June 30, 2021, and the results of its operations for the three months and six months ended June 30, 2021 and 2020, and its cash flows for the six months ended June 30, 2021 and 2020. Operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The consolidated balance sheet at December 31, 2020 has been derived from the Company’s audited consolidated financial statements at such date.

The condensed consolidated financial statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. These condensed consolidated financial statements should be read in conjunction with the financial statements and other information included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the SEC.

**2. Business**

The Company is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company’s product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

The Company’s activities are subject to significant risks and uncertainties, including the need for additional capital. The Company has not yet commenced any revenue-generating operations, does not have positive cash flows from operations, and is dependent on periodic infusions of equity capital to fund its operating requirements.

***Going Concern***

At June 30, 2021, the Company had cash of \$6,798,477 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time and resources to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company’s business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. Even if the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

The Company’s consolidated financial statements have been presented on the basis that it will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has no recurring source of revenue and has experienced negative operating cash flows since inception. The Company has financed its working capital requirements primarily through the recurring sale of its equity securities.



As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. The Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2020, has also expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The amount and timing of future cash requirements depends on the pace and design of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Effective November 30, 2020, the Company listed on The Nasdaq Capital Market in conjunction with the completion of its public offering of units of common stock and warrants that generated net cash proceeds of \$4,591,349. Subsequently, on January 18, 2021, the Company entered into a clinical trial agreement to carry out a Phase 1b clinical trial of LB-100, combined with a standard regimen for untreated, extensive stage-disease small cell lung cancer. This new clinical trial is being conducted through City of Hope and is estimated to cost from \$2,500,000 to \$2,900,000 and take approximately 24 to 30 months. Combined with the Company's existing clinical trial commitments, this new clinical trial commitment represents an additional demand on the Company's working capital resources. Although the Company completed a sale of common stock under a registered direct equity offering on March 2, 2021 that generated net proceeds of \$3,689,761, the Company estimates that it will need to raise additional capital to fund its operations, including its various clinical trial commitments, by mid-2022. In addition, the Company's operating plan may change as a result of many factors which are currently unknown to the Company, including possible additional clinical trials, and the Company may need additional funds sooner than currently planned.

As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations. There is also significant uncertainty as to the effect that the coronavirus pandemic may have on the Company's clinical trial schedule and the amount and type of financing available to the Company in the future.

If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its clinical trial program, as well as its licensing and patent prosecution efforts and its technology and product development efforts, or obtain funds, if available, through strategic alliances or joint ventures that could require the Company to relinquish rights to and/or control of LB-100, or to discontinue operations entirely.

#### ***Reverse Stock Split***

On November 18, 2020, the Company effected a 1-for-6 reverse split of its outstanding shares of common stock. No fractional shares were issued in connection with the reverse split, with any fractional shares resulting from the reverse split being rounded up to the nearest whole share.

All share and per share amounts and information presented herein has been retroactively adjusted to reflect the reverse stock split for all periods presented.

### **3. Summary of Significant Accounting Policies**

#### ***Principles of Consolidation***

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and include the financial statements of Holdings and its wholly owned subsidiary, Lixte. Intercompany balances and transactions have been eliminated in consolidation.

### *Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates. Significant estimates include those related to assumptions used in accruals for potential liabilities, valuing equity instruments issued for services, and the realization of deferred tax assets.

### *Cash*

Cash, including accrued interest, is primarily held in a cash bank deposit program maintained by a major financial institution. The Company's policy is to maintain its cash balances with financial institutions with high credit ratings and in accounts insured by the Federal Deposit Insurance Corporation (the "FDIC") and/or by the Securities Investor Protection Corporation (the "SIPC"). The Company may periodically have cash balances in financial institutions in excess of FDIC and SIPC insurance limits of \$250,000 and \$500,000, respectively. The financial institution that currently holds the Company's cash balances also maintains supplemental insurance coverage for its customers' cash balances. The Company has not experienced any losses to date resulting from this practice.

### *Research and Development*

Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the acquisition, design, development and clinical trials with respect to the Company's compounds and product candidates. Research and development costs also include the costs to produce the compounds used in research and clinical trials, which are charged to operations as incurred.

Research and development costs are generally charged to operations ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. However, payments for research and development costs that are contractually defined as non-refundable are charged to operations as incurred.

Obligations incurred with respect to mandatory scheduled payments under research agreements with milestone provisions are recognized as charges to research and development costs in the Company's consolidated statement of operations based on the achievement of such milestones, as specified in the agreement. Obligations incurred with respect to mandatory scheduled payments under research agreements without milestone provisions are accounted for when due, are recognized ratably over the appropriate period, as specified in the agreement, and are recorded as liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations.

Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company's consolidated balance sheet and are then charged to research and development costs in the Company's consolidated statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

### *Prepaid Insurance*

Prepaid insurance represents the premiums paid for directors and officers insurance coverage and for general liability insurance coverage in excess of the amortization of the total policy premium charged to operations to date. Such amortization is determined by amortizing the total policy premium charged on a straight-line basis over the respective policy periods. As the policy premiums incurred are amortizable in the ensuing twelve-month period, they are recorded as a current asset in the Company's consolidated balance sheet at each reporting date and amortized to the Company's consolidated statement of operations for each reporting period.

### ***Patent and Licensing Related Legal and Filing Costs***

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing-related legal and filing costs were \$108,193 and \$143,444 for the three months ended June 30, 2021 and 2020, and \$228,352 and \$276,912 for the six months ended June 30, 2021 and 2020, respectively. Patent and licensing related legal and filing costs are included in general and administrative costs in the Company's consolidated statements of operations.

### ***Concentration of Risk***

The Company periodically contracts with vendors and consultants to provide services related to the Company's operations. Charges incurred for these services can be for a specific time period (typically one year) or for a specific project or task. Costs and expenses incurred that represented 10% or more of general and administrative costs or research and development costs for the three months and six months ended June 30, 2021 and 2020 are described as follows.

General and administrative costs for the three months ended June 30, 2021 and 2020 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 7.5% and 56.3%, respectively, of total general and administrative costs.

General and administrative costs for the six months ended June 30, 2021 and 2020 include charges from a legal firm for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 8.4% and 50.7%, respectively, of total general and administrative costs.

Research and development costs for the three months ended June 30, 2021 include charges from three vendors and consultants representing 26.3%, 26.0%, and 11.4%, respectively, of total research and development costs for that period. Research and development costs for the three months ended June 30, 2020 include charges from three vendors and consultants representing 36.8%, 25.6%, and 10.5%, respectively, of total research and development costs for that period.

Research and development costs for the six months ended June 30, 2021 include charges from two vendors and consultants representing 43.8%, and 19.7%, respectively, of total research and development costs for that period. Research and development costs for the six months ended June 30, 2020 include charges from four vendors and consultants representing 28.3%, 20.4%, 15.1%, and 11.9%, respectively, of total research and development costs for that period.

### ***Income Taxes***

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of June 30, 2021 or December 31, 2020 and does not anticipate any material amount of unrecognized tax benefits within the 12 months subsequent to June 30, 2021.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. The Company had not recorded any liability for uncertain tax positions as of June 30, 2021 or December 31, 2020. Subsequent to June 30, 2021, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

#### ***Stock-Based Compensation***

The Company periodically issues common stock and stock options to officers, directors, employees, Scientific Advisory Committee members, contractors and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant. Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

The Company accounts for stock-based payments to officers, directors, employees, Scientific Advisory Committee members contractors and consultants by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards.

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the expected life of the stock option, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). Estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's consolidated statements of operations. The Company issues new shares of common stock to satisfy stock option exercises.

#### ***Earnings (Loss) Per Share***

The Company's computation of earnings (loss) per share ("EPS") includes basic and diluted EPS. Basic EPS is measured as the income (loss) attributable to common stockholders divided by the weighted average common shares outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares (e.g., preferred shares, warrants and stock options) as if they had been converted at the beginning of the periods presented, or issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS.

Loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the respective periods. Basic and diluted loss per common share was the same for all periods presented because all preferred shares, warrants and stock options outstanding were anti-dilutive.

At June 30, 2021 and 2020, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

|  | June 30,         |                  |
|--|------------------|------------------|
|  | 2021             | 2020             |
| Series A Convertible Preferred Stock                                   | 729,167          | 729,167          |
| Common stock warrants  | 3,110,310        | 1,500,000        |
| Common stock options, including options issued in the form of warrants | 2,550,000        | 1,308,333        |
| Total  | <u>6,389,477</u> | <u>3,537,500</u> |

### ***Fair Value of Financial Instruments***

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers in and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange-based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently traded non-exchange-based derivatives and commingled investment funds and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The carrying value of financial instruments (consisting of accounts payable and accrued expenses) is considered to be representative of their respective fair values due to the short-term nature of those instruments.

### ***Recent Accounting Pronouncements***

In December 2019, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (“ASU 2019-12”). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions and enhances and simplifies various aspects of the income tax accounting guidance in ASC 740. ASU 2019-12 was effective January 1, 2021. The adoption of ASU 2019-12 did not have any impact on the Company’s consolidated financial statement presentation or disclosures.

In August 2020, the FASB issued 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 (“ASU 2020-06”). ASU 2020-06 simplifies the accounting for convertible debt by eliminating the beneficial conversion and cash conversion accounting models. Upon adoption of ASU 2020-06, convertible debt proceeds, unless issued with a substantial premium or an embedded conversion feature that is not clearly and closely related to the host contract, will no longer be allocated between debt and equity components. This modification will reduce the issue discount and result in less non-cash interest expense in financial statements. ASU 2020-06 also updates the earnings per share calculation and requires entities to assume share settlement when the convertible debt can be settled in cash or shares. For contracts in an entity’s own equity, the type of contracts primarily affected by ASU 2020-06 are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and only if adopted as of the beginning of such fiscal year. The Company adopted ASU 2020-06 effective January 1, 2021. The adoption of ASU 2020-06 did not have any impact on the Company’s consolidated financial statement presentation or disclosures.

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"). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure 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 and then apply 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 any impact on the Company's consolidated financial statement presentation or disclosures.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

#### **4. Stockholders' Equity**

##### ***Preferred Stock***

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value \$0.0001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The Company has designated a total of 350,000 shares as Series A Convertible Preferred Stock, which are non-voting and are not subject to increase without the written consent of a majority of the holders of the Series A Convertible Preferred Stock or as otherwise set forth in the Preferences, Rights and Limitations. The holders of each tranche of 175,000 shares of the Series A Convertible Preferred Stock are entitled to receive a per share dividend equal to 1% of the annual net revenue of the Company divided by 175,000, until converted or redeemed. As of June 30, 2021 and December 31, 2020, 9,650,000 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate.

Each share of Series A Convertible Preferred Stock may be converted, at the option of the holder, into 2.0833 shares of common stock (subject to customary anti-dilution provisions) and the Series A Convertible Preferred Stock is subject to mandatory conversion at the conversion rate in the event of a merger or sale transaction resulting in gross proceeds to the Company of at least \$21,875,000. The Series A Convertible Preferred Stock has a liquidation preference based on its assumed conversion into shares of common stock. The Series A Convertible Preferred Stock does not have a cash liquidation preference.

If fully converted, the 350,000 outstanding shares of Series A Convertible Preferred Stock would convert into 729,167 shares of common stock at June 30, 2021 and December 31, 2020. The Company had the right to redeem the Series A Convertible Preferred Stock up to the fifth anniversary of their respective closing dates (March 17, 2015 and January 21, 2016) at a price per share equal to \$50.00. Accordingly, as of December 31, 2020, the Company had the right to redeem the 175,000 shares of Series A Convertible Preferred Stock that were issued on January 21, 2016; however, that right expired on January 21, 2021. The Series A Convertible Preferred Stock has no right to cash, except with respect to the payment of the aforementioned dividend based on the generation of revenues by the Company. The shares of Series A Convertible Preferred Stock do not have any registration rights.

Based on the attributes of the Series A Convertible Preferred Stock as previously described, the Company has accounted for the Series A Convertible Preferred Stock as a permanent component of stockholders' equity.

### **Common Stock**

The Company is authorized to issue a total of 100,000,000 shares of common stock, par value \$0.0001 per share. As of June 30, 2021 and December 31, 2020, the Company had 13,663,260 shares and 12,402,157 shares, respectively, of common stock issued, issuable and outstanding.

On November 30, 2020, the Company raised gross proceeds \$5,700,000 through a public offering of 1,200,000 units at a sale price of \$4.75 per unit. Each unit consists of one share of common stock and one warrant to purchase one share of common stock exercisable for five years at an exercise price of \$5.70 per share. Additionally, on December 7, 2020, the Company received an additional \$1,800 from the sale of 180,000 warrants as part of the overallotment option granted to the underwriters in the public offering. The warrants sold are exercisable for five years and represent the right to purchase one share of common stock at an exercise price of \$5.70 per share. The total cash costs of the public offering were \$1,110,451, resulting in net cash proceeds of \$4,591,349. Pursuant to the underwriting agreement, the Company also granted to the underwriters warrants to purchase up to 120,000 shares of common stock commencing on May 24, 2021 and expiring on November 24, 2025, at an exercise price of \$5.70 per share.

During February and March 2021, the Company issued 3,000 shares of common stock upon the exercise of 3,000 warrants at \$5.70 per share and received cash proceeds of \$17,100.

Effective March 2, 2021, the Company completed the sale of 1,133,102 shares of common stock at a price of \$3.70 per share in a registered direct equity offering, generating gross proceeds of \$4,192,478. The total cash costs of this offering were \$502,717, resulting in net proceeds of \$3,689,761. Pursuant to the placement agents' agreement, the Company granted to the placement agents warrants to purchase up to 113,310 shares of common stock commencing on March 2, 2021 and expiring on March 2, 2026, at an exercise price of \$3.70 per share.

On April 22, 2021, the Company issued 125,001 shares of its common stock upon the exercise of options held by an officer and two of the Company's Directors as follows: 75,000 options at \$0.72 per share, 16,667 options at \$0.90 per share, and 33,334 options at \$0.96 per share, for total cash proceeds of \$101,100.

### **Common Stock Warrants**

A summary of common stock warrant activity during the six months ended June 30, 2021 is presented below.

|   | <u>Number of<br/>Shares</u> | <u>Weighted<br/>Average<br/>Exercise Price</u> | <u>Weighted<br/>Average<br/>Remaining<br/>Contractual<br/>Life (in Years)</u> |
|---|-----------------------------|--|---|
| Warrants outstanding at December 31, 2020 | 3,000,000                   | \$ 5.850                                       |   |
| Issued                                    | 113,310                     | 3.700  |   |
| Exercised                                 | (3,000)                     | 5.700  |   |
| Expired                                   | —                           | —  |   |
| Warrants outstanding at June 30, 2021     | <u>3,110,310</u>            | <u>\$ 5.772</u>                                | <u>2.98</u>   |

At June 30, 2021, all outstanding warrants are exercisable at the following prices per common share:

| Exercise<br>Prices | Warrants<br>Outstanding<br>(Shares) |
|--------------------|-------------------------------------|
| \$ 3.700           | 113,310                             |
| \$ 5.700           | 1,497,000                           |
| \$ 6.000           | 1,500,000                           |
|                    | <u>3,110,310</u>                    |

Based on a fair market value of \$3.03 per share on June 30, 2021, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at June 30, 2021.

Information with respect to the issuance of common stock in connection with various stock-based compensation arrangements is provided at Note 6.

## 5. Related Party Transactions

### *Gil N Schwartzberg*

In September 2007, the Company entered into a consulting agreement with Gil N Schwartzberg for Mr. Schwartzberg to provide financial advisory and consulting services to the Company with respect to financing matters, capital structure and strategic development, and to assist management in communications with investors and stockholders. In January 2014 and August 2018, the Company entered into respective amendments to this consulting agreement, which have extended the consulting agreement through January 28, 2024. Consideration under this consulting agreement, including amendments, has been paid exclusively in the form of stock options. Effective April 9, 2021, Mr. Schwartzberg was appointed to the Company's Board of Directors. Mr. Schwartzberg is currently a significant stockholder of the Company and continues to be a consultant to the Company.

### *Employment Agreements with Officers*

The Company entered into an employment agreement with Dr. Kovach dated July 15, 2020, effective October 1, 2020, for Dr. Kovach to continue to act as the Company's President, Chief Executive Officer and Chief Scientific Officer with an annual salary of \$250,000. During the three months and six months ended June 30, 2020 (periods prior to the above-described employment agreement), the Company paid Dr. Kovach a salary of \$15,000 and \$30,000, respectively, which amount is included in general and administrative costs in the Company's consolidated statements of operations.

The Company entered into an employment agreement with Dr. James S. Miser, M.D., effective August 1, 2020 to act as the Company's Chief Medical Officer with an annual salary of \$150,000. Effective May 1, 2021, Dr. Miser's annual salary was increased to \$175,000. Dr. Miser is required to devote at least 50% of his business time to the Company's activities.

The Company entered into an employment agreement with Eric J. Forman effective July 15, 2020, as amended on August 12, 2020, to act as the Company's Chief Administrative Officer with an annual salary of \$120,000. Eric Forman is the son-in-law of Gil Schwartzberg, a member of the Company's Board of Directors, and a significant stockholder of and consultant to the Company, and is the son of Dr. Stephen Forman, a member of the Company's Board of Directors. Julie Forman, the wife of Eric Forman and the daughter of Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, where the Company's cash is on deposit and the Company maintains a continuing banking relationship. Effective May 1, 2021, Mr. Forman's annual salary was increased to \$175,000. During the three months and six months ended June 30, 2020 (periods prior to his appointment as Chief Administrative Officer), the Company paid legal and consulting fees to the Eric Forman Law Office of \$12,000 and \$24,000, respectively, which amount is included in general and administrative costs in the Company's consolidated statements of operations.



The Company entered into an employment agreement with Robert N. Weingarten effective August 12, 2020 to act as the Company's Vice President and Chief Financial Officer with an annual salary of \$120,000. Effective May 1, 2021, Mr. Weingarten's annual salary was increased to \$175,000. During the three months and six months ended June 30, 2020 (periods prior to his appointment as Vice President and Chief Financial Officer), the Company paid Mr. Weingarten a total of \$14,980 and \$47,375, respectively, for accounting and financial consulting services rendered with respect to the preparation of the Company's consolidated financial statements and certain other financial and compliance matters.

On April 9, 2021, the Board of Directors increased the annual compensation of Eric J. Forman, the Company's Chief Administrative Officer, Dr. James S. Miser, the Company's Chief Medical Officer, and Robert N. Weingarten, the Company's Chief Financial Officer, under the employment agreements such that the total aggregate annual compensation of all officers increased to \$775,000, effective May 1, 2021.

#### **Compensatory Arrangements for Board of Directors**

On April 9, 2021, the Board of Directors approved a comprehensive cash and equity compensation package for the members of the Board of Directors and committee members, effective immediately.

The Board of Directors approved the following cash compensation for non-officer directors, payable quarterly:

- Base director compensation - \$20,000 per year
- Chairman of audit committee - additional \$10,000 per year
- Chairman of any other committees - additional \$5,000 per year
- Member of audit committee - additional \$5,000 per year
- Member of any other committees - additional \$2,500 per year

Stock-based compensation arrangements involving members of the Company's Board of Directors, officers and affiliates are described at Note 6.

A summary of related party costs, including compensation under employment and consulting agreements and fees paid to non-officer directors for their service on the Board of Directors, for the three months and six months ended June 30, 2021 and 2020 is presented below. This summary includes the above-described payments to Mr. Forman in 2020 prior to his appointment as Chief Administrative Officer, but excludes the payments to Mr. Weingarten in 2020 prior to his appointment as Vice President and Chief Financial Officer.

|                      | <b>Three Months Ended<br/>June 30,</b> |                  | <b>Six Months Ended<br/>June 30,</b> |                  |
|----------------------|--|------------------|--------------------------------------|------------------|
|                      | 2021                                   | 2020             | 2021                                 | 2019             |
| Related party costs: |  |                  |                                      |                  |
| Cash-based           | \$ 182,500                             | \$ 27,000        | \$ 342,500                           | \$ 54,000        |
| Stock-based          | 850,804                                | —                | 1,506,836                            | —                |
| Total                | <u>\$ 1,033,304</u>                    | <u>\$ 27,000</u> | <u>\$ 1,849,336</u>                  | <u>\$ 54,000</u> |

#### **6. Stock-Based Compensation**

The Company issues common stock and stock options as incentive compensation to directors and as compensation for the services of employees, contractors and consultants of the Company.

On June 20, 2007, the Board of Directors of the Company approved the 2007 Stock Compensation Plan (the "2007 Plan"), which provided for the granting of awards, consisting of stock options, stock appreciation rights, performance shares, and restricted shares of common stock, to employees and consultants, for up to 416,667 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors. The 2007 Plan terminated on June 19, 2017. As of June 30, 2021, unexpired stock options for 83,333 shares were issued and outstanding under the 2007 Plan, which were exercised effective July 14, 2021.

On July 14, 2020, the Board of Directors of the Company adopted the 2020 Stock Incentive Plan (the “2020 Plan”), which provides for the granting of equity-based awards, consisting of stock options, restricted stock, restricted stock units, stock appreciation rights, and other stock-based awards to employees, officers, directors and consultants of the Company and its affiliates for up to 2,333,333 shares of the Company’s common stock, under terms and conditions as determined by the Company’s Board of Directors. Stockholders holding a majority of the voting power of the common stock of the Company approved the 2020 Plan pursuant to an action by written consent dated July 31, 2020. Stockholders of the Company were notified of such action by written consent pursuant to an Information Statement dated August 31, 2020 and mailed to stockholders on or about September 3, 2020. As of June 30, 2021, unexpired stock options for 400,000 shares were issued and outstanding under the 2020 Plan.

On April 9, 2021, the Board of Directors approved a comprehensive cash and equity compensation package for the members of the Board of Directors and committee members, effective immediately.

Stock-based features of the compensation package consisted of the annual granting of stock options to each non-officer director to purchase 100,000 shares of common stock at the closing market price on the earlier of the date of the annual meeting of shareholders or the last business day of the month ending June 30, vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested, and the granting of stock options to a new director to purchase 250,000 shares of common stock, exercisable at the closing market price on the date of grant for a period of five years, vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested.

Cash-based features of the compensation package are described at Note 8.

The fair value of a stock option award is calculated on the grant date using the Black-Scholes option-pricing model. The risk-free interest rate is based on the U.S. Treasury yield curve in effect as of the grant date. The expected dividend yield assumption is based on the Company’s expectation of dividend payouts and is assumed to be zero. The expected volatility is based on the historical volatility of the Company’s common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the “simplified method”). The fair market value of the common stock is determined by reference to the quoted market price of the common stock on the grant date.

For stock options requiring an assessment of value during the six months ended June 30, 2021, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

|                         |                  |
|-------------------------|------------------|
| Risk-free interest rate | 0.89%            |
| Expected dividend yield | 0%               |
| Expected volatility     | 198.79%          |
| Expected life           | 3.5 to 3.6 years |

There were no stock options requiring an assessment of value during the six months ended June 30, 2020.

On July 15, 2020, as amended on August 12, 2020, in connection with the employment agreement entered into with Eric J. Forman, Mr. Forman was granted options for 58,333 shares of the Company’s common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of \$7.14 per share, which was equal to the closing price of the Company’s common stock on the grant date. The options vested as to 25% on August 12, 2020, and will vest 25% on each of the first, second and third anniversaries of the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$400,855 (\$6.8718 per share), of which \$100,214 was attributable to the stock options fully-vested on August 12, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from August 12, 2020 through August 12, 2023. During the three months and six months ended June 30, 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$24,985 and \$49,695, respectively, with respect to these stock options.

On August 1, 2020, in connection with an employment agreement entered into with Dr. James S. Miser, M.D., Dr. Miser was granted options for 83,334 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of \$7.14 per share, which was equal to the closing price of the Company's common stock on the effective date of the employment agreement. The options vested as to 25% on the effective date, and will vest 25% on each of the first, second and third anniversaries of the effective date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$572,650 (\$6.8718 per share), of which \$143,163 was attributable to the stock options fully-vested on August 1, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from August 1, 2020 through August 1, 2023. During the three months and six months ended June 30, 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$35,693 and \$70,993, respectively, with respect to these stock options.

On August 12, 2020, in connection with the employment agreement entered into with Robert N. Weingarten, Mr. Weingarten was granted options for 58,333 shares of the Company's common stock. The options can be exercised on a cashless basis. The options have a term of five years and an exercise price of \$7.14 per share, which was equal to the closing price of the Company's common stock on the grant date. The options vested as to 25% on August 12, 2020, and will vest 25% on each of the first, second and third anniversaries of the grant date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$400,855 (\$6.8718 per share), of which \$100,214 was attributable to the stock options fully-vested on August 12, 2020 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from August 12, 2020 through August 12, 2023. During the three months and six months ended June 30, 2021, the Company recorded charges to general and administrative costs in the consolidated statement of operations of \$24,985 and \$49,695, respectively, with respect to these stock options.

Effective January 6, 2021, in recognition with their service as directors of the Company over the past year, the Company granted to each of Dr. Winson Sze Chun Ho, Dr. Yun Yen, Dr. Stephen Forman, and Dr. Philip Palmedo, fully-vested stock options to purchase an aggregate of 200,000 shares (50,000 shares to each director) of the Company's common stock, exercisable for a period of five years from the grant date at \$3.21 per share, which was the approximate fair market value of the Company's common stock on such date. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$571,312 (\$2.8566 per share) and was recorded as a charge to general and administrative costs in the consolidated statement of operations on the grant date.

On April 9, 2021, Winson Sze Chun Ho resigned from the Company's Board of Directors to focus on clinical and pre-clinical cancer research in academic medicine. Concurrent with his resignation, the Board of Directors appointed Gil Schwartzberg to fill the vacancy created by Dr. Ho's resignation. In connection with his appointment to the Board of Directors, and in accordance with the recently adopted cash and equity compensation package for the members of the Board of Directors, Mr. Schwartzberg was granted options exercisable for a period of five years to purchase 250,000 shares of the Company's common stock at an exercise price of \$3.20 per share (the closing market price on the date of grant), vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$753,611 (\$3.0144 per share), of which \$376,800 was attributable to the stock options fully-vested on April 9, 2021 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from April 9, 2021 through June 30, 2023. During the three months and six months ended June 30, 2021, the Company recorded a charge to general and administrative costs in the consolidated statement of operations with respect to these stock options of \$414,851.

On May 11, 2021, the Board of Directors appointed Regina Brown to the Board of Directors. In connection with her appointment to the Board of Directors, and in accordance with the recently adopted cash and equity compensation package for the members of the Board of Directors, Ms. Brown was granted options exercisable for a period of five years to purchase 250,000 shares of the Company's common stock at an exercise price of \$2.80 per share (the closing market price on the date of grant), vesting 50% on the grant date and the remainder vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$658,363 (\$2.6335 per share), of which \$329,188 was attributable to the stock options fully-vested on May 11, 2021 and was therefore charged to operations on that date. The remaining unvested portion of the fair value of the stock options will be charged to operations ratably from May 11, 2021 through June 30, 2023. During the three months and six months ended June 30, 2021, the Company recorded a charge to general and administrative costs in the consolidated statement of operations with respect to these stock options of \$350,290.

On June 30, 2021, the Board of Directors, in accordance with the recently adopted cash and equity compensation package for the members of the Board of Directors, granted to each of the five non-officer directors of the Company stock options exercisable for a period of five years to purchase 100,000 shares (a total of 500,000 shares) of the Company's common stock at an exercise price of \$3.03 per share (the closing market price on the date of grant), vesting 12.5% on the last day of each subsequent calendar quarter-end until fully vested. The total fair value of the 500,000 stock options, as calculated pursuant to the Black-Scholes option-pricing model, was determined to be \$1,421,095 (\$2.84225 per share), which will be charged to operations ratably from July 1, 2021 through June 30, 2023.

A summary of stock-based compensation costs for the three months and six months ended June 30, 2021 and 2020 is as follows:

|                                      | Three Months Ended<br>June 30, |             | Six Months Ended<br>June 30, |             |
|--------------------------------------|--------------------------------|-------------|------------------------------|-------------|
|                                      | 2021                           | 2020        | 2021                         | 2020        |
| Related parties                      | \$ 850,804                     | \$ —        | \$ 1,506,836                 | \$ —        |
| Non-related parties                  | —                              | —           | —                            | —           |
| Total stock-based compensation costs | <u>\$ 850,804</u>              | <u>\$ —</u> | <u>\$ 1,506,836</u>          | <u>\$ —</u> |

A summary of stock option activity, including options issued in the form of warrants, during the six months ended June 30, 2021 is presented below.

|  | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average Remaining<br>Contractual<br>Life (in Years) |
|--|---------------------|--|---|
| Stock options outstanding at December 31, 2020 | 1,475,000           | \$ 4.136                                 |   |
| Granted  | 1,200,000           | 3.048                                    |   |
| Exercised                                      | (125,001)           | 0.808                                    |   |
| Expired  | —                   | —  |   |
| Adjustment attributable to reverse stock split | 1                   | —  |   |
| Stock options outstanding at June 30, 2021     | <u>2,550,000</u>    | <u>\$ 3.787</u>                          | <u>3.79</u>   |
| Stock options exercisable at June 30, 2021     | <u>1,650,000</u>    | <u>\$ 3.831</u>                          | <u>3.24</u>   |

Total deferred compensation expense for the outstanding value of unvested stock options was approximately \$2,791,000 at June 30, 2021, which will be recognized subsequent to June 30, 2021 over a weighted-average period of approximately 24 months.

The exercise prices of common stock options outstanding and exercisable, including options issued in the form of warrants, at June 30, 2021 are as follows:

| Exercise<br>Prices | Options<br>Outstanding<br>(Shares) | Options<br>Exercisable<br>(Shares) |
|--------------------|------------------------------------|------------------------------------|
| \$ 0.900           | 33,333                             | 33,333                             |
| \$ 1.200           | 83,333                             | 83,333                             |
| \$ 1.680           | 66,667                             | 66,667                             |
| \$ 2.800           | 250,000                            | 125,000                            |
| \$ 3.000           | 666,667                            | 666,667                            |
| \$ 3.030           | 500,000                            | —                                  |
| \$ 3.200           | 250,000                            | 125,000                            |
| \$ 3.210           | 200,000                            | 200,000                            |
| \$ 6.000           | 166,667                            | 166,667                            |
| \$ 6.600           | 50,000                             | 50,000                             |
| \$ 7.140           | 200,000                            | 50,000                             |
| \$ 12.000          | 83,333                             | 83,333                             |
|                    | <u>2,550,000</u>                   | <u>1,650,000</u>                   |

The intrinsic value of exercisable but unexercised in-the-money stock options at June 30, 2021 was approximately \$362,251, based on a fair market value of \$3.03 per share on June 30, 2021.

Outstanding stock options to acquire 900,000 shares of the Company's common stock had not vested at June 30, 2021.

The Company expects to satisfy such stock obligations through the issuance of authorized but unissued shares of common stock.

## 7. Income Taxes

During the three months and six months ended June 30, 2021 and 2020, there was no provision for income taxes as the Company incurred losses during those periods. Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company recorded a full valuation allowance against its deferred tax assets as the Company believes it is more likely than not the deferred tax assets will not be realized.

## 8. Commitments and Contingencies

### Legal Claims

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of June 30, 2021, the Company was not subject to any pending or threatened legal claims or actions.

### Clinical Trial Agreements

**Moffitt.** Effective August 20, 2018, the Company entered into a Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida, effective for a term of five years, unless terminated earlier by the Company pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS).

In November 2018, the Company received approval from the U.S. Food and Drug Administration for its Investigational New Drug Application ("IND") to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. Patients with MDS, although usually older, are generally well except for severe anemia requiring frequent blood transfusions. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with low and intermediate-1 risk MDS, including patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of patients with del5qMDS are deficient in PP2A by virtue of an acquired mutation and are especially vulnerable to further inhibition of PP2A by LB-100. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. A total enrollment of 41 patients is planned. An interim analysis will be done after the first 21 patients are entered. If there are 3 or more responders but fewer than 7, an additional 20 patients will be entered. If at any point there are 7 or more responders, this will be sufficient evidence to support continued development of LB-100 for the treatment of low and intermediate-1 risk MDS. Recruitment has been slow and the Covid-19 pandemic has further reduced recruitment of patients into the protocol. At the current rate of accrual, the clinical trial is expected to be completed over a period of approximately four years from its initiation. However, with additional funds, the Company's objective would be to add two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual.

During the three months ended June 30, 2021 and 2020, the Company incurred costs of \$10,309 and \$11,698, respectively, pursuant to this agreement. During the six months ended June 30, 2021 and 2020, the Company incurred costs of \$17,693 and \$25,364, respectively, pursuant to this agreement. As of June 30, 2021, total costs of \$103,927 have been incurred pursuant to this agreement.

**GEIS.** Effective July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or “GEIS”), Madrid, Spain, to carry out a study entitled “Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma”. The purpose of this clinical trial is to obtain information about the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas (“ASTS”). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal was to enter the first patient during the quarter ended December 31, 2020, with approximately 150 patients to be enrolled over two years. As advanced sarcoma is a very aggressive disease, the design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when about half of the 102 events required for final analysis is reached.

The Company had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, the Spanish regulatory authority advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These regulations were adopted subsequent to the production of the Company’s existing LB-100 inventory.

A new batch of LB 100 has been prepared and is now undergoing the multitude of analytical studies of the formulated product necessary to gain approval for use in the European Union. Regulatory reviews by the European Union have been delayed until October 2021 as a result of which the final review of the clinical product by Spanish regulatory authorities will also be delayed. Accordingly, the clinical trial is now estimated to begin during the quarter ending June 30, 2022 and take approximately three years to conduct.

The interim analysis of this clinical trial could indicate either inferiority or superiority of LB-100 plus doxorubicin as compared to doxorubicin alone. A positive study would have the potential to change the standard therapy for this disease after four decades of failure to improve the marginal benefit of doxorubicin alone.

The Company's agreement with GEIS provides for various payments based on achieving specific milestones over the term of the agreement. On February 18, 2020, the Company advanced \$43,411 to GEIS towards a second milestone payment obligation of \$87,471, which was expected to become due and payable during the quarter ended June 30, 2020 based on the anticipated achievement of the second milestone, and which was therefore recorded as an advance on the Company's balance sheet at March 31, 2020. However, as a result of the substantial delay in commencing the clinical trial as described above, the achievement of the second milestone had been delayed until mid-2021 and the Company therefore determined to charge such advance to research and development costs in the Company's statement of operations at June 30, 2020. Subsequently, on February 26, 2021, the Company paid an additional \$24,171 to GEIS towards the second milestone payment for current work being done under this agreement.

Accordingly, during the three months ended June 30, 2021 and 2020, the Company incurred costs of \$0 and \$43,411, respectively, pursuant to this agreement. During the six months ended June 30, 2021 and 2020, the Company incurred costs of \$24,171 and \$43,411 respectively, pursuant to this agreement. As of June 30, 2021, total costs of \$155,053 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to the aforementioned clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately \$5,798,000 as of June 30, 2021, consisting of approximately \$5,193,000 relating to the GEIS clinical trial and approximately \$605,000 relating to the Moffitt clinical trial, which are expected to be incurred over approximately the next five years through December 31, 2025.

In order to manufacture a new inventory supply of LB-100 for the GEIS clinical trial, the Company has engaged a number of vendors to carry out the multiple tasks needed to make and gain approval of a new clinical product for investigational study in Spain. These tasks include the synthesis under good manufacturing practices (GMP) of the active pharmacologic ingredient (API), with documentation of each of the steps involved by an independent auditor. The API is then transferred to a vendor that prepares the clinical drug product (DP), also under GMP conditions documented by an independent auditor. The DP is then sent to a vendor to test for purity and sterility, provide appropriate labels, store the drug, and distribute the drug to the clinical centers for use in the clinical trials. A formal application documenting all steps taken to prepare the DP for clinical use must be submitted to the appropriate regulatory authorities for review and approval before being used in a clinical trial.

As of June 30, 2021, the Company estimates that this program to provide new inventory of the DP for the Spanish sarcoma study, and potentially for subsequent multiple trials within the European Union, will cost approximately \$737,000. The Company's remaining aggregate commitments under this program, less amounts previously paid to date, totaled approximately \$371,000 as of June 30, 2021, which are expected to be incurred through the quarter ending March 31, 2022. As the production of the new inventory is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro.

**City of Hope.** Effective January 18, 2021, the Company executed a Clinical Research Support Agreement with the City of Hope National Medical Center, an NCI-designated comprehensive cancer center, and City of Hope Medical Foundation (collectively, "City of Hope"), to carry out a Phase 1b clinical trial of LB-100, the Company's first-in-class protein phosphatase inhibitor, combined with a standard regimen for treatment of untreated extensive-stage disease small cell lung cancer (ED-SCLC). LB-100 will be given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved but marginally effective regimen, to previously untreated ED-SCLC patients. The dose of LB-100 will be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose (RP2D). Patient entry will be expanded so that a total of 12 patients will be evaluable at the RP2D to confirm the safety of the LB-100 combination and to look for potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free-survival and overall survival.

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately 18 to 24 months to complete. If LB-100 does potentiate the benefit of the standard regimen, some evidence could be noted at 12 months into the clinical trial, but an assessment of potential increased activity is likely to require at least 24 months.

The Company is seeking two additional centers to increase the rate of accrual. As described below, a recent publication may heighten the interest of institutions with large populations of small cell lung cancer (SCLC) patients. LB-100 was reported to enhance the effectiveness of elements of standard therapy in models of SCLC (Mirzapioazova et al., *Molecular Cancer Therapeutics*, online July 12, 2021). Dr. Ravi Salgia, MD, PhD, Professor and Chair of the Department of Medical Oncology and Therapeutics Research at the City of Hope National Medical Center, is the corresponding author of the paper and also the principal investigator for the Company's SCLC clinical trial. Dr. Salgia and collaborators found multiple metabolic changes associated with cell death in SCLC cells when exposed to LB-100 alone and when combined with the drugs in a standard clinical regimen for this notoriously aggressive disease.

LB-100 has been reported to increase the effectiveness of a number of anti-cancer drugs against several different types of human cancers without increasing toxicity in animal models. The recent pre-clinical study of SCLC cells observed that (1) LB-100 increases the amount of carboplatin that enters the tumor cells without increasing toxicity, and (2) LB-100 potentiates the action of the immune-blocker, atezolizumab. These observations are important because, taken together, they not only constitute a strong rationale for the clinical trial of LB-100 plus chemo-immunotherapy in SCLC, but they also complement earlier pre-clinical observations that LB-100 can (1) reverse resistance of cancer cells (ovarian) to cisplatin, another widely used chemotherapy drug (Chang et al., *Molecular Cancer Therapeutics*, November 5, 2014), (2) increase the entry of another important anti-cancer agent, doxorubicin, into liver cancer cells associated with increased anti-tumor activity (Bai et al, *Molecular Cancer Therapeutics*, August 14, 2014), and (3) enhance the effectiveness of immune-blockers against several types of cancers (Ho et al. *Nature Comm.*, May 29, 2018). These observations raise the possibility that the addition of LB-100 may be a general way to enhance standard therapies for cancers for which better treatments are urgently needed. The present clinical trial in SCLC is an initial step in testing that hypothesis, as is the planned clinical trial in advanced soft tissue sarcoma in which LB-100 is combined with doxorubicin.

During the three months and six months ended June 30, 2021, the Company incurred costs of \$69,001 and \$309,509, respectively, pursuant to this agreement. As of June 30, 2021, total costs of \$309,509 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to this clinical trial agreement, less amounts previously paid to date under this agreement, totaled approximately \$2,433,000 as of June 30, 2021, which are expected to be incurred over the next two years based upon a target of 42 enrollees. If a significant number of patients fail during the dose-escalation process, an increase of up to 12 patients would likely be necessary, at an estimated additional cost of approximately \$800,000. Alternatively, should fewer than 42 enrollees be required, the Company has agreed to compensate the City of Hope on a per enrollee basis. The Company currently expects that enrollment in this clinical trial will range from approximately 18 to 30 enrollees, with 24 enrollees as the most likely number.

#### ***Clinical Trial Monitoring Agreements***

**Moffitt.** On September 12, 2018, the Company finalized a work order agreement with Theradex Systems, Inc. ("Theradex"), an international contract research organization ("CRO"), to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. At the current rate of accrual, the trial is expected to be completed over a period of four years from its initiation.

Costs under this work order agreement are estimated to be approximately \$954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended June 30, 2021 and 2020, the Company incurred costs of \$7,540 and \$5,790, respectively, pursuant to this work order. During the six months ended June 30, 2021 and 2020, the Company incurred costs of \$8,481 and \$11,476, respectively, pursuant to this work order. As of June 30, 2021, total costs of \$90,636 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$873,000 as of June 30, 2021, which are expected to be incurred over approximately the next five years through June 30, 2025.



**City of Hope.** On February 5, 2021, the Company signed a new work order agreement with Theradex to monitor the City of Hope investigator-initiated clinical trial in small cell lung cancer in accordance with FDA requirements for oversight by the sponsoring party. During the three months and six months ended June 30, 2021, the Company incurred costs of \$10,773 and \$14,313, respectively, pursuant to this work order. As of June 30, 2021, total costs of \$14,313 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$324,000 as of June 30, 2021, which are expected to be incurred through September 30, 2023.

#### ***Patent and License Agreements***

On March 22, 2018, the Company entered into a Patent Assignment and Exploitation Agreement with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research, for the assignment to the Company of INSERM'S interest in United States Patent No. 9,833,450 entitled "Oxabicycloheptanes and Oxabicycloheptenes for the Treatment of Depressive and Stress Disorders", which was filed with the United States Patent and Trademark Office in the name of INSERM and the Company as co-owners on February 19, 2015 and granted on May 12, 2017, and related patent applications and filings. INSERM is a French public institution dedicated to research in the field of health and medicine that had previously entered into a Material Transfer Agreement with the Company to allow INSERM to conduct research on the Company's proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, the Company has agreed to make certain milestone payments to INSERM aggregating up to \$1,750,000 upon achievement of development milestones and up to \$6,500,000 upon achievement of commercial milestones. The Company also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. The Company's current plan is to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of June 30, 2021 and 2020, no amounts were due under this agreement.

Effective August 20, 2018, the Company entered into an Exclusive License Agreement with Moffitt. Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company was obligated to pay Moffitt a non-refundable license issue fee of \$25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. The Company is also obligated to pay Moffitt an annual license maintenance fee of \$25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating \$1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. During the three months ended June 30, 2021 and 2020, the Company recorded charges to operations of \$6,233 and \$6,233, respectively, in connection with its obligations under the License Agreement. During the six months ended June 30, 2021 and 2020, the Company recorded charges to operations of \$12,397 and \$12,398, respectively, in connection with its obligations under the License Agreement. As of June 30, 2021, no milestones had yet been attained.

The Company will be obligated to pay Moffitt earned royalties of 4% on worldwide cumulative net sales of royalty-bearing products, subject to reduction to 2% under certain circumstances, on a quarterly basis, with a minimum royalty payment of \$50,000 in the first four years after sales commence, and \$100,000 in year five and each year thereafter, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first sale of a royalty-bearing product, and shall automatically expire on a country-by-country basis on the date on which the last valid claim of the Licensed Patents expires, lapses or is declared invalid, and the obligation to pay any earned royalties under the License Agreement shall terminate on the date on which the last valid claim of the Licensed Patents expires, lapses, or is declared to be invalid in all countries.

### ***Employment Agreements with Officers***

During July and August 2020, the Company entered into one-year employment agreements with its executive officers, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, which provided for aggregate annual compensation of \$640,000, payable monthly (see Note 5). The employment agreements are automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, or by death, or by termination for cause. On April 9, 2021, the Board of Directors increased the annual compensation of Eric J. Forman, the Company's Chief Administrative Officer, Dr. James S. Miser, the Company's Chief Medical Officer, and Robert N. Weingarten, the Company's Chief Financial Officer, under the employment agreements such that the total aggregate annual compensation of all officers increased to \$775,000, effective May 1, 2021.

### ***Other Significant Agreements and Contracts***

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of \$4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 and \$4,000 for the three months ended June 30, 2021 and 2020, respectively, and \$8,000 and \$8,000 for the six months ended June 30, 2021 and 2020, respectively, which were included in research and development costs in the consolidated statements of operations.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services included, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company's product pipeline, and (iii) prepare and deliver presentations concerning the Company's products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company's Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds.

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. In April 2018, it was mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from February 1, 2018 through the September 13, 2019 anniversary date. In February 2019, the Company and BioPharmaWorks subsequently agreed to resume the Collaboration Agreement effective March 1, 2019, and the Collaboration Agreement is currently in effect. The Company recorded charges to operations pursuant to this Collaboration Agreement of \$30,000 and \$30,000 for the three months ended June 30, 2021 and 2020, respectively, and \$60,000 and \$60,000 for the six months ended June 30, 2021 and 2020, respectively, which were included in research and development costs in the consolidated statements of operations.

Effective August 12, 2020, the Company entered into a Master Service Agreement with the Foundation for Angelman Syndrome Therapy (FAST) to collaborate in supporting pre-clinical studies of the potential benefit of LB-100 in a mouse model of Angelman Syndrome (AS) as reported in The Proceedings of The National Academy of Science (Wang et al, June 3, 2019). The pre-clinical studies will be conducted at The University of California - Davis under the direction of Dr. David Segal, an internationally recognized leader in AS research. If the pre-clinical studies confirm that LB-100 reduces AS signs in rodent models, the Company has agreed to enter into discussions with FAST with respect to possible collaborations to most efficiently assess the benefit of LB-100 in patients with AS, which is a rare disease affecting an estimated one out of 12,000 to one out of 20,000 persons in the United States. The genetic cause of AS, reduced function of a specific maternal gene called Ube3, has been understood for some time, but the molecular abnormality resulting from the genetic lesion has now been shown to be increased concentrations of protein phosphatase 2A (PP2A), a molecular target of the Company's investigational compound, LB-100. The Company has agreed to provide FAST with a supply of LB-100 to be utilized in the conduct of this study, which is initially expected to be completed within three years. Conditioned on FAST's completion of this study, the Company has agreed to pay FAST five percent (5%) of all proceeds, as defined in the Master Service Agreement, received by the Company, up to a maximum of \$250,000 from the exploitation of the study results.

The research team at the University of California, Davis recently completed their pre-clinical study of the potential benefit of LB-100 in a mouse model of AS, and the results are currently under review by FAST. The preliminary analysis indicates that the positive results previously reported by Chinese investigators were not confirmed in the US model. The Company is awaiting input from FAST as to whether it intends to continue to pursue pre-clinical studies of LB 100.

Effective December 21, 2020, the Company entered into a services agreement with IRT Communications, LLC for investor/public relations, financial communications, and strategic consulting services, effective for an initial term of twelve months and renewable annually thereafter. The Company agreed to pay a monthly fee of \$7,500, including any renewal term, and also agreed to issue restricted shares of common stock, fully vested upon issuance, with a grant date fair value of \$100,000 (see Note 4). Upon the commencement of any renewal term, the Company will be obligated to issue additional restricted shares of common stock, fully vested upon issuance, with a grant date fair value of \$100,000. During the three months and six months ended June 30, 2021, the Company incurred charges in the amount of \$22,500 and \$45,000, respectively, with respect to this agreement, which amount is included in general and administrative costs in the Company's consolidated statements of operations.

#### ***Impact of the Novel Coronavirus (Covid-19) on the Company's Business Activities***

The global outbreak of the novel coronavirus (Covid-19) has led to disruptions in general economic activities worldwide, as businesses and governments have taken broad actions to mitigate this public health crisis. In light of the uncertain and continually evolving situation relating to the spread of Covid-19, this pandemic could pose a risk to the Company. The extent to which the coronavirus may impact the Company's business activities will depend on future developments, which are highly uncertain and cannot be predicted at this time. The Company intends to continue to monitor the situation and may adjust its current business plans as more information and guidance become available.

The coronavirus pandemic presents a challenge to medical facilities worldwide. As the Company's clinical trials are conducted on an outpatient basis, it is not currently possible to predict the full impact of this developing health crisis on such clinical trials, which could include delays in and increased costs of such clinical trials. Current indications from the clinical research organizations conducting the clinical trials for the Company are that such clinical trials are being delayed or extended for several months as a result of the coronavirus pandemic.

The most problematic issue directly related to Covid-19 for the Company is the delay in completing the glioblastoma (GBM) pharmacology clinical trial at NCI. This clinical trial is being conducted by the NCI without charge to the Company. The neurosurgical unit at the NCI is closed due to the Covid-19 epidemic. Patient entry remains at two, with the goal to enter eight patients before analyzing results. There is an urgent need to improve therapy for this type of aggressive brain tumor. If the NCI study shows that LB-100 does penetrate the brain, a clinical study of LB-100 in combination with standard therapy for GBM, the drug temozolomide and radiation, both of which have been well documented in pre-clinical studies to be significantly enhanced by LB-100, would be of significant interest to neuro-oncologists frustrated by decades of limited advances in therapy for this common brain tumor in adults.

There is also significant uncertainty as to the effect that the coronavirus may have on the amount and type of financing available to the Company in the future.

The Company intends to continue to monitor the situation and may adjust its current business plans as more information and guidance become available.

#### **9. Subsequent Events**

The Company performed an evaluation of subsequent events through the date of filing of these consolidated financial statements with the SEC. Other than those matters described below, there were no material subsequent events which affected, or could affect, the amounts or disclosures in the consolidated financial statements.

#### ***Exercise of Stock Options***

Effective July 14, 2021, stock options for 83,333 shares of common stock were exercised by a consultant of the Company at \$1.20 per share, generating total cash proceeds of \$100,000.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Forward-Looking Statements

This Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc. (the "Company") contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These might include statements regarding the Company's financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future clinical trials and their timing and costs, product demand, supply, manufacturing costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as "intend", "anticipate", "believe", "estimate", "potential(ly)", "continue", "forecast", "predict", "plan", "may", "will", "could", "would", "should", "expect" or the negative of such terms or other comparable terminology. The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected, anticipated or implied in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q and the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, including the section entitled "Item 1A. Risk Factors". The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

### Overview

The Company is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company's product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital. The Company has not yet commenced any revenue-generating operations, does not have positive cash flows from operations, and is dependent on periodic infusions of equity capital to fund its operating requirements.

### Recent Developments

Phosphatase inhibition by LB-100 enhances BMN-111 stimulation of bone growth:

On July 22, 2021, the Company issued a press release commenting on outside pre-clinical research demonstrating that inhibition of protein phosphatase 2A (PP2A) with LB-100, combined with the experimental drug vosoritide (BioMarin), was more effective than vosoritide alone in stimulating bone and cartilage growth in a mouse model of the most common form of dwarfism, achondroplasia (ACH). Although the BioMarin compound alone was beneficial in clinical trials, the addition of LB-100 enhanced the activity of vosoritide in the animal models of ACH and led the authors to conclude that their study provides a proof of concept that a phosphatase inhibitor may be a beneficial addition to therapy with vosoritide (Shuhaibar et al., JCI Insight 2021).

The Company's development of LB-100 as the only presently available PP2A inhibitor in clinical trials has opened a variety of possibilities for adding inhibition of PP2A to therapeutic regimens for a range of serious diseases. LB-100 has been shown to enhance anti-cancer activity of standard chemotherapy and immunotherapy regimens against a broad spectrum of human cancers in animal models. The Company's focus is to demonstrate the clinical therapeutic benefit of LB-100 in one or more cancers for which more effective treatments are urgently needed. Many investigators, of which Shuhaibar and colleagues are among the most recent, have used LB-100 in pre-clinical studies that have revealed that targeting of the PP2A function appears to have a multitude of potential applications to serious human diseases in addition to cancer.

## **Going Concern**

At June 30, 2021, the Company had cash of \$6,798,477 available to fund its operations. Because the Company is currently engaged in Phase 2 clinical trials, it is expected that it will take a significant amount of time and resources to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, the Company's business is unlikely to generate any sustainable operating revenues in the next several years and may never do so. Even if the Company is able to generate revenues through licensing its technologies or through product sales, there can be no assurance that the Company will be able to achieve positive earnings and operating cash flows.

The Company's consolidated financial statements have been presented on the basis that it will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has no recurring source of revenue and has experienced negative operating cash flows since inception. The Company has financed its working capital requirements primarily through the recurring sale of its equity securities.

As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. The Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2020, has also expressed substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## **Recent Accounting Pronouncements**

Information with respect to recent accounting pronouncements is provided at Note 3 to the condensed consolidated financial statements for the three months and six months ended June 30, 2021 and 2020 included elsewhere in this document.

## **Concentration of Risk**

Information with respect to concentration of risk is provided at Note 3 to the condensed consolidated financial statements for the three months and six months ended June 30, 2021 and 2020 included elsewhere in this document.

## **Critical Accounting Policies and Estimates**

The preparation of the Company's consolidated financial statements in conformity with generally accepted accounting principles in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates. Significant estimates include those related to assumptions used in accruals for potential liabilities, valuing equity instruments issued for services, and the realization of deferred tax assets.

The following critical accounting policies affect the more significant judgements and estimates used in the preparation of the Company's consolidated financial statements.

## **Research and Development**

Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the acquisition, design, development and clinical trials with respect to the Company's compounds and product candidates. Research and development costs also include the costs to produce the compounds used in research and clinical trials, which are charged to operations as incurred.

Research and development costs are charged to operations ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate.

Obligations incurred with respect to mandatory scheduled payments under research agreements with milestone provisions are recognized as charges to research and development costs in the Company's consolidated statement of operations based on the achievement of such milestones, as specified in the agreement. Obligations incurred with respect to mandatory scheduled payments under research agreements without milestone provisions are recognized ratably over the appropriate period, as specified in the agreement, and are recorded as liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations.

Payments made pursuant to research and development contracts are initially recorded as advances on research and development contract services in the Company's consolidated balance sheet and are then charged to research and development costs in the Company's consolidated statement of operations as those contract services are performed. Expenses incurred under research and development contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations. The Company reviews the status of its research and development contracts on a quarterly basis.

## **Patent and Licensing Related Legal and Filing Costs**

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and related patent applications, all patent-related legal and filing fees and licensing-related legal fees are charged to operations as incurred. Patent and licensing related legal and filing costs are included in general and administrative costs in the Company's consolidated statements of operations.

## **Stock-Based Compensation**

The Company periodically issues common stock and stock options to officers, directors, employees, Scientific Advisory Committee members, contractors and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant. Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

The Company accounts for stock-based payments to officers, directors, employees, Scientific Advisory Committee members contractors and consultants by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards.

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the expected life of the stock option, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). Estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's consolidated statements of operations. The Company issues new shares of common stock to satisfy stock option exercises.

## **Summary of Business Activities and Plans**

### ***Company Overview***

The Company is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. The Company's product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and/or x-ray and immune checkpoint blockers, and encompasses two major categories of compounds at various stages of pre-clinical and clinical development that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

The Company has developed two series of pharmacologically active drugs, the LB-100 series and the LB-200 series. The Company believes that the mechanism by which compounds of the LB-100 series affect cancer cell growth is different from cancer agents currently approved for clinical use. Lead compounds from each series have activity against a broad spectrum of common and rarer human cancers in cell culture systems. In addition, compounds from both series have anti-cancer activity in animal models of glioblastoma multiforme, neuroblastoma, and medulloblastoma, all cancers of neural tissue. Lead compounds of the LB-100 series also have activity against melanoma, breast cancer and sarcoma in animal models and enhance the effectiveness of commonly used anti-cancer drugs in these model systems. The enhancement of anti-cancer activity of these anti-cancer drugs occurs at doses of LB-100 that do not significantly increase toxicity in animals. It is therefore hoped that, when combined with standard anti-cancer regimens against many tumor types, the Company's compounds will improve therapeutic benefit without enhancing toxicity in humans.

### ***Product Candidates***

The LB-100 series consists of novel structures which have the potential to be first in their class and may be useful in the treatment of not only several types of cancer but also vascular and metabolic diseases. The LB-200 series contains compounds which may be useful for the treatment of chronic hereditary diseases, such as Gaucher's disease, in addition to cancer and neurodegenerative diseases.

The Company has demonstrated that lead compounds of both the LB-100 series and the LB-200 are active against a broad spectrum of human cancers in cell culture and against several types of human cancers in animal models. The research on these compounds was initiated in 2006 under a Cooperative Research and Development Agreement, or CRADA, with the National Institute of Neurologic Disorders and Stroke, or NINDS, of the National Institutes of Health, or NIH, dated March 22, 2006 that was subsequently extended through a series of amendments until it terminated on April 1, 2013. As discussed below, the Company's primary focus is on the clinical development of LB-100.

The LB-200 series consists of histone deacetylase inhibitors (HDACi). Many pharmaceutical companies are also developing drugs of this type, and at least two companies have HDACi approved for clinical use, in both cases for the treatment of a type of lymphoma. Despite this significant competition, the Company has demonstrated that its HDACi have broad activity against many cancer types, have neuroprotective activity, and have anti-fungal activity. In addition, these compounds have low toxicity. LB-200 has not yet advanced to the clinical stage and would require additional capital to fund further development. Accordingly, because of the Company's focus on the clinical development of LB-100 and analogs for cancer therapy as described below in more detail, the Company have decided not to actively pursue the pre-clinical development of our LB-200 series of compounds at this time. At this time, the Company intend to only maintain composition of matter patents for LB-200.

Collaborations with leading academic research centers in the United States, Europe and Asia have established the breadth of activity of LB-100 in pre-clinical models of several major cancers. There is considerable scientific interest in LB-100 because it exerts its activity by a novel mechanism and is the first of its type to be evaluated so broadly in multiple animal models of cancer and now in human beings. LB-100 is one of a series of serine/threonine phosphatase (s/t ptase) inhibitors designed by the Company. The s/t ptases are ubiquitous enzymes that regulate many cell-signaling networks important to cell growth, division and death. The s/t ptases have long been appreciated as potentially important targets for anti-cancer drugs. However, because of the multi- functionality of these enzymes, it had been widely held that pharmacologic inhibitors of s/t ptases would be too toxic to allow their development as anti-cancer treatments, but the Company has shown that this is not the case. LB-100 was well tolerated at doses associated with objective regression (significant tumor shrinkage) and/or the arresting of tumor progression in patients with progressive cancers.

Pre-clinical studies showed that LB-100 itself inhibits a spectrum of human cancers and that combined with standard cytotoxic drugs and/or radiation, LB-100 potentiates their effectiveness against hematologic and solid tumor cancers without enhancing toxicity. Given at very low doses in animal models of cancer, LB-100 markedly increased the effectiveness of a PD-1 blocker, one of the widely used new immunotherapy drugs. This finding raises the possibility that LB-100 may further expand the value of the expanding field of cancer immunotherapy.

The Company completed a Phase 1 clinical trial of LB-100 to evaluate its safety that showed it is associated with anti-tumor activity in humans at doses that are readily tolerable. Responses included objective regression (tumor shrinkage) lasting for 11 months of a pancreatic cancer and cessation of growth (stabilization of disease) for 4 months or more of 9 other progressive solid tumors out of 20 patients who had measurable disease. As Phase 1 clinical trials are fundamentally designed to determine safety of a new compound in humans, the Company was encouraged by these results. The next step is to demonstrate in Phase 2 clinical trials the efficacy of LB-100 in one or more specific tumor types, against which the compound has well documented activity in pre-clinical models.

As a compound moves through the FDA-approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. As the potential effectiveness of LB-100 has been documented at the clinical trial level, the Company has allocated resources to expand the breadth and depth of its patent portfolio. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The Company's longer-term objective is to secure one or more strategic partnerships or licensing agreements with pharmaceutical companies with major programs in cancer.

#### ***Impact of the Novel Coronavirus (Covid-19) on the Company's Business Activities***

The global outbreak of the novel coronavirus (Covid-19) has led to disruptions in general economic activities worldwide, as businesses and governments have taken broad actions to mitigate this public health crisis. In light of the uncertain and continually evolving situation relating to the spread of Covid-19, this pandemic could pose a risk to the Company. The extent to which the coronavirus may impact the Company's business activities will depend on future developments, which are highly uncertain and cannot be predicted at this time. The Company intends to continue to monitor the situation and may adjust its current business plans as more information and guidance become available.

The coronavirus pandemic presents a challenge to medical facilities worldwide. As the Company's clinical trials are conducted on an outpatient basis, it is not currently possible to predict the full impact of this developing health crisis on such clinical trials, which could include delays in and increased costs of such clinical trials. Current indications from the clinical research organizations conducting the clinical trials for the Company are that such clinical trials are being delayed or extended for several months as a result of the coronavirus pandemic.

The most problematic issue directly related to Covid-19 for the Company is the delay in completing the glioblastoma (GBM) pharmacology clinical trial at NCI. This clinical trial is being conducted by the NCI without charge to the Company. The neurosurgical unit at the NCI is closed due to the Covid-19 epidemic. Patient entry remains at two, with the goal to enter eight patients before analyzing results. There is an urgent need to improve therapy for this type of aggressive brain tumor. If the NCI study shows that LB-100 does penetrate the brain, a clinical study of LB-100 in combination with standard therapy for GBM, the drug temozolomide and radiation, both of which have been well documented in pre-clinical studies to be significantly enhanced by LB-100, would be of significant interest to neuro-oncologists frustrated by decades of limited advances in therapy for this common brain tumor in adults.



There is also significant uncertainty as to the effect that the coronavirus may have on the amount and type of financing available to the Company in the future.

The Company intends to continue to monitor the situation and may adjust its current business plans as more information and guidance become available.

## Results of Operations

At June 30, 2021, the Company had not yet commenced any revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operating requirements.

The Company's consolidated statements of operations as discussed herein are presented below.

|  | Three Months Ended<br>June 30, |              | Six Months Ended<br>June 30, |              |
|--|--------------------------------|--------------|------------------------------|--------------|
|  | 2021                           | 2020         | 2021                         | 2020         |
| Revenues   | \$ —                           | \$ —         | \$ —                         | \$ —         |
| Costs and expenses:  |                                |              |                              |              |
| General and administrative costs                               | 1,470,180                      | 255,443      | 2,751,834                    | 547,928      |
| Research and development costs                                 | 262,415                        | 117,946      | 705,941                      | 212,618      |
| Total costs and expenses                                       | 1,732,595                      | 373,389      | 3,457,775                    | 760,546      |
| Loss from operations   | (1,732,595)                    | (373,389)    | (3,457,775)                  | (760,546)    |
| Interest income  | 180                            | 264          | 326                          | 4,246        |
| Interest expense   | (751)                          | —            | (2,861)                      | —            |
| Net loss   | \$ (1,733,166)                 | \$ (373,125) | \$ (3,460,310)               | \$ (756,300) |
| Net loss per common share – basic and diluted                  | \$ (0.13)                      | \$ (0.03)    | \$ (0.26)                    | \$ (0.07)    |
| Weighted average common shares outstanding – basic and diluted | 13,633,040                     | 11,174,302   | 13,203,010                   | 11,174,302   |

### Three Months Ended June 30, 2021 and 2020

**Revenues.** The Company did not have any revenues for the three months ended June 30, 2021 and 2020.

**General and Administrative Costs.** For the three months ended June 30, 2021, general and administrative costs were \$1,470,180, which consisted of the fair value of vested stock options issued to directors of \$850,804, patent and licensing legal fees and costs of \$108,193, other consulting and professional fees of \$154,495, insurance expense of \$87,757, officer's salary and related costs of \$197,689, cash-based director and committee fees of \$27,833, licensing fees of \$6,233, shareholder reporting costs of \$9,373, listing fees of \$14,500, filing fees of \$2,990, taxes and licenses of \$2,444, and other operating costs of \$7,869.

For the three months ended June 30, 2020, general and administrative costs were \$255,443, which consisted of patent and licensing legal fees and costs of \$143,444, other consulting and professional fees of \$64,177, insurance expense of \$14,132, officer's salary and related costs of \$16,871, licensing fees of \$6,233, shareholder reporting costs of \$2,795, listing fees of \$3,000, filing fees of \$1,294, taxes and licenses of \$580, and other operating costs of \$2,917.

General and administrative costs increased by \$1,214,737, or 475.5%, in 2021 as compared to 2020, primarily as a result of an increase in the fair value of vested stock options issued to directors of \$850,804, an increase in other consulting and professional fees of \$90,318, an increase in insurance expense of \$73,625, and an increase in officer's salary and related costs of \$180,818.

Research and Development Costs. For the three months ended June 30, 2021, research and development costs were \$262,415, which consisted of contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including \$69,001 to the City of Hope, \$10,309 to Moffitt, \$18,553 to Theradex for oversight of the City of Hope and Moffitt studies, \$30,000 to BioPharmaWorks, \$130,461 to three contract research and development firms for the synthesis work to develop a new supply of LB-100 for the GEIS clinical trial, and \$33,883 to various other contractors, offset by a refund of \$29,792 from a cancelled contract.

For the three months ended June 30, 2020, research and development costs were \$117,946, which consisted of contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including \$43,411 to GEIS, \$11,698 to Moffitt, \$9,620 to Theradex for regulatory costs and oversight of the Moffitt study, \$30,201 to BioPharmaWorks, and \$23,016 to various other contractors.

Research and development costs increased by \$144,469, or 122.5% in 2021 as compared to 2020, as a result of an increase in contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline.

Interest Income. For the three months ended June 30, 2021, the Company had interest income of \$180, as compared to interest income of \$264 for the three months ended June 30, 2020, as a result of a reduction in the Company's cash resources previously invested in short-term federally insured certificates of deposit.

Interest Expense. For the three months ended June 30, 2021, the Company had interest expense of \$751 related to the financing of its directors and officers liability insurance premium. The Company had no interest expense during the three months ended June 30, 2020.

Net Loss. For the three months ended June 30, 2021, the Company incurred a net loss of \$1,733,166, as compared to a net loss of \$373,125 for the three months ended June 30, 2020.

#### **Six Months Ended June 30, 2021 and 2020**

Revenues. The Company did not have any revenues for the six months ended June 30, 2021 and 2020.

General and Administrative Costs. For the six months ended June 30, 2021, general and administrative costs were \$2,751,834, which consisted of the fair value of vested stock options issued to directors of \$1,506,836, patent and licensing legal fees and costs of \$228,352, other consulting and professional fees of \$349,376, insurance expense of \$175,513, officer's salary and related costs of \$371,271, cash-based director and committee fees of \$27,833, licensing fees of \$12,397, shareholder reporting costs of \$19,760, listing fees of \$29,000, filing fees of \$12,564, taxes and licenses of \$7,113, and other operating costs of \$11,819.

For the six months ended June 30, 2020, general and administrative costs were \$547,928, which consisted of patent and licensing legal fees and costs of \$276,912, other consulting and professional fees of \$171,919, insurance expense of \$28,416, officer's salary and related costs of \$33,892, licensing fees of \$12,398, shareholder reporting costs of \$6,386, listing fees of \$6,000, filing fees of \$6,294, taxes and licenses of \$1,160, and other operating costs of \$4,551.

General and administrative costs increased by \$2,203,906, or 402.2%, in 2021 as compared to 2020, primarily as a result of an increase in the fair value of vested stock options issued to directors of \$1,506,836, an increase in other consulting and professional fees of \$177,457, an increase in insurance expense of \$147,097, and an increase in officer's salary and related costs of \$337,379.

Research and Development Costs. For the six months ended June 30, 2021, research and development costs were \$705,941, which consisted of contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including \$24,171 to GEIS, \$309,509 to the City of Hope, \$17,693 to Moffitt, \$23,034 to Theradex for oversight of the City of Hope and Moffitt studies, \$60,000 to BioPharmaWorks, \$262,748 to three contract research and development firms for the synthesis work to develop a new supply of LB-100 for the GEIS clinical trial, and \$38,578 to various other contractors, offset by a refund of \$29,792 from a cancelled contract.

For the six months ended June 30, 2020, research and development costs were \$212,618, which consisted of contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline, including \$43,411 to GEIS, \$25,364 to Moffitt, \$20,076 to Theradex for regulatory costs and oversight of the and Moffitt study, \$60,201 to BioPharmaWorks, and \$63,566 to various other contractors.

Research and development costs increased by \$493,323, or 232.0% in 2021 as compared to 2020, as a result of an increase in contractor costs, primarily in connection with the Company's pre-clinical research focused on the development of additional novel anti-cancer compounds to add to its clinical pipeline.

Interest Income. For the six months ended June 30, 2021, the Company had interest income of \$326, as compared to interest income of \$4,246 for the six months ended June 30, 2020, as a result of a reduction in the Company's cash resources previously invested in short-term federally insured certificates of deposit.

Interest Expense. For the six months ended June 30, 2021, the Company had interest expense of \$2,861 related to the financing of its directors and officers liability insurance premium. The Company had no interest expense during the six months ended June 30, 2020.

Net Loss. For the six months ended June 30, 2021, the Company incurred a net loss of \$3,460,310, as compared to a net loss of \$756,300 for the six months ended June 30, 2020.

#### **Liquidity and Capital Resources – June 30, 2021**

At June 30, 2021, the Company had working capital of \$6,866,338, as compared to working capital of \$5,011,951 at December 31, 2020, reflecting an increase in working capital of \$1,854,387 for the six months ended June 30, 2021. The increase in working capital during the six months ended June 30, 2021 was the result of the net cash proceeds of \$3,689,761 from the Company's March 2021 direct equity offering, proceeds of \$17,100 from the exercise of warrants, and proceeds of \$101,000 from the exercise of stock options, utilized to pay public offering costs of \$10,467 and to fund the Company's research and development activities and ongoing operating expenses, including the Company's clinical trial program and maintaining and developing the patent portfolio. At June 30, 2021, the Company had cash of \$6,798,477 available to fund its operations.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The amount and timing of future cash requirements depends on the pace and design of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

Effective November 30, 2020, the Company listed on The Nasdaq Capital Market in conjunction with the completion of its public offering of units of common stock and warrants that generated net cash proceeds of \$4,591,349. Subsequently, on January 18, 2021, the Company entered into a clinical trial agreement to carry out a Phase 1b clinical trial of LB-100, combined with a standard regimen for untreated, extensive stage-disease small cell lung cancer. This new clinical trial is being conducted through City of Hope and is estimated to cost approximately \$2,900,000 and take approximately 24 to 30 months. Combined with the Company's existing clinical trial commitments, this new clinical trial commitment represents an additional demand on the Company's working capital resources. Although the Company completed a sale of common stock under a registered direct equity offering on March 2, 2021 that generated net proceeds of \$3,689,761, the Company estimates that it will need to raise additional capital to fund its operations, including its various clinical trial commitments, by mid-2022. In addition, the Company's operating plan may change as a result of many factors which are currently unknown to the Company, including possible additional clinical trials, and the Company may need additional funds sooner than currently planned.

As market conditions present uncertainty as to the Company's ability to secure additional funds, there can be no assurances that the Company will be able to secure additional financing on acceptable terms, as and when necessary, to continue to conduct operations. There is also significant uncertainty as to the effect that the coronavirus pandemic may have on the Company's clinical trial schedule and the amount and type of financing available to the Company in the future.

If cash resources are insufficient to satisfy the Company's ongoing cash requirements, the Company would be required to scale back or discontinue its clinical trial program, as well as its licensing and patent prosecution efforts and its technology and product development efforts, or obtain funds, if available, through strategic alliances or joint ventures that could require the Company to relinquish rights to and/or control of LB-100, or to discontinue operations entirely.

Operating Activities. For the six months ended June 30, 2021, operating activities utilized cash of \$2,068,183, as compared to utilizing cash of \$768,682 for the six months ended June 30, 2020, to fund the Company's ongoing research and development activities and to fund its other ongoing operating expenses, including maintaining and developing its patent portfolio.

Investing Activities. For the six months ended June 30, 2021 and 2020, the Company had no investing activities.

Financing Activities. For the six months ended June 30, 2021, financing activities consisted of the gross proceeds from the sales of common stock in the Company's direct equity offering of \$4,192,478, reduced by offering costs of \$502,717, \$17,100 from the exercise of common stock warrants, and \$101,000 from the exercise of common stock options. The Company also paid public offering costs of \$10,467 during the six months ended June 30, 2021. For the six months ended June 30, 2020, financing activities consisted of the payment of deferred offering costs of \$55,850.

## **Principal Commitments**

### *Clinical Trial Agreements*

**Moffitt.** Effective August 20, 2018, the Company entered into a Clinical Trial Research Agreement with the Moffitt Cancer Center and Research Institute Hospital Inc., Tampa, Florida, effective for a term of five years, unless terminated earlier by the Company pursuant to 30 days written notice. Pursuant to the Clinical Trial Research Agreement, Moffitt agreed to conduct and manage a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of the Company's lead anti-cancer clinical compound LB-100 to be administered intravenously in patients with low or intermediate-1 risk myelodysplastic syndrome (MDS).

In November 2018, the Company received approval from the U.S. Food and Drug Administration for its Investigational New Drug Application ("IND") to conduct a Phase 1b/2 clinical trial to evaluate the therapeutic benefit of LB-100 in patients with low and intermediate-1 risk MDS who have failed or are intolerant of standard treatment. Patients with MDS, although usually older, are generally well except for severe anemia requiring frequent blood transfusions. This Phase 1b/2 clinical trial utilizes LB-100 as a single agent in the treatment of patients with low and intermediate-1 risk MDS, including patients with del(5q) myelodysplastic syndrome (del5qMDS) failing first line therapy. The bone marrow cells of patients with del5qMDS are deficient in PP2A by virtue of an acquired mutation and are especially vulnerable to further inhibition of PP2A by LB-100. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. A total enrollment of 41 patients is planned. An interim analysis will be done after the first 21 patients are entered. If there are 3 or more responders but fewer than 7, an additional 20 patients will be entered. If at any point there are 7 or more responders, this will be sufficient evidence to support continued development of LB-100 for the treatment of low and intermediate-1 risk MDS. Recruitment has been slow and the Covid-19 pandemic has further reduced recruitment of patients into the protocol. At the current rate of accrual, the clinical trial is expected to be completed over a period of approximately four years from its initiation. However, with additional funds, the Company's objective would be to add two additional MDS centers to the Phase 2 portion of the study to accelerate patient accrual.

During the three months ended June 30, 2021 and 2020, the Company incurred costs of \$10,309 and \$11,698, respectively, pursuant to this agreement. During the six months ended June 30, 2021 and 2020, the Company incurred costs of \$17,693 and \$25,364, respectively, pursuant to this agreement. As of June 30, 2021, total costs of \$103,927 have been incurred pursuant to this agreement.

**GEIS.** Effective July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or “GEIS”), Madrid, Spain, to carry out a study entitled “Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma”. The purpose of this clinical trial is to obtain information about the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas (“ASTS”). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal was to enter the first patient during the quarter ended December 31, 2020, with approximately 150 patients to be enrolled over two years. As advanced sarcoma is a very aggressive disease, the design of the study assumes a median progression free survival (PFS, no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when about half of the 102 events required for final analysis is reached.

The Company had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, the Spanish regulatory authority advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These regulations were adopted subsequent to the production of the Company’s existing LB-100 inventory.

A new batch of LB 100 has been prepared and is now undergoing the multitude of analytical studies of the formulated product necessary to gain approval for use in the European Union. Regulatory reviews by the European Union have been delayed until October 2021 as a result of which the final review of the clinical product by Spanish regulatory authorities will also be delayed. Accordingly, the clinical trial is now estimated to begin during the quarter ending June 30, 2022 and take approximately three years to conduct.

The interim analysis of this clinical trial could indicate either inferiority or superiority of LB-100 plus doxorubicin as compared to doxorubicin alone. A positive study would have the potential to change the standard therapy for this disease after four decades of failure to improve the marginal benefit of doxorubicin alone.

The Company’s agreement with GEIS provides for various payments based on achieving specific milestones over the term of the agreement. On February 18, 2020, the Company advanced \$43,411 to GEIS towards a second milestone payment obligation of \$87,471, which was expected to become due and payable during the quarter ended June 30, 2020 based on the anticipated achievement of the second milestone, and which was therefore recorded as an advance on the Company’s balance sheet at March 31, 2020. However, as a result of the substantial delay in commencing the clinical trial as described above, the achievement of the second milestone had been delayed until mid-2021 and the Company therefore determined to charge such advance to research and development costs in the Company’s statement of operations at June 30, 2020. Subsequently, on February 26, 2021, the Company paid an additional \$24,171 to GEIS towards the second milestone payment for current work being done under this agreement.

Accordingly, during the three months ended June 30, 2021 and 2020, the Company incurred costs of \$0 and \$43,411, respectively, pursuant to this agreement. During the six months ended June 30, 2021 and 2020, the Company incurred costs of \$24,171 and \$43,411 respectively, pursuant to this agreement. As of June 30, 2021, total costs of \$155,053 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to the aforementioned clinical trial agreements, less amounts previously paid to date under these agreements, totaled approximately \$5,798,000 as of June 30, 2021, consisting of approximately \$5,193,000 relating to the GEIS clinical trial and approximately \$605,000 relating to the Moffit clinical trial, which are expected to be incurred over approximately the next five years through December 31, 2025.

In order to manufacture a new inventory supply of LB-100 for the GEIS clinical trial, the Company has engaged a number of vendors to carry out the multiple tasks needed to make and gain approval of a new clinical product for investigational study in Spain. These tasks include the synthesis under good manufacturing practices (GMP) of the active pharmacologic ingredient (API), with documentation of each of the steps involved by an independent auditor. The API is then transferred to a vendor that prepares the clinical drug product (DP), also under GMP conditions documented by an independent auditor. The DP is then sent to a vendor to test for purity and sterility, provide appropriate labels, store the drug, and distribute the drug to the clinical centers for use in the clinical trials. A formal application documenting all steps taken to prepare the DP for clinical use must be submitted to the appropriate regulatory authorities for review and approval before being used in a clinical trial.

As of June 30, 2021, the Company estimates that this program to provide new inventory of the DP for the Spanish sarcoma study, and potentially for subsequent multiple trials within the European Union, will cost approximately \$737,000. The Company's remaining aggregate commitments under this program, less amounts previously paid to date, totaled approximately \$371,000 as of June 30, 2021, which are expected to be incurred through the quarter ending March 31, 2022. As the production of the new inventory is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro.

**City of Hope.** Effective January 18, 2021, the Company executed a Clinical Research Support Agreement with City of Hope National Medical Center, an NCI-designated comprehensive cancer center, and City of Hope Medical Foundation (collectively, "City of Hope"), to carry out a Phase 1b clinical trial of LB-100, the Company's first-in-class protein phosphatase inhibitor, combined with a standard regimen for treatment of untreated extensive-stage disease small cell lung cancer (ED-SCLC). LB-100 will be given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved but marginally effective regimen, to previously untreated ED-SCLC patients. The dose of LB-100 will be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose (RP2D). Patient entry will be expanded so that a total of 12 patients will be evaluable at the RP2D to confirm the safety of the LB-100 combination and to look for potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free-survival and overall survival.

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately 18 to 24 months to complete. If LB-100 does potentiate the benefit of the standard regimen, some evidence could be noted at 12 months into the clinical trial, but an assessment of potential increased activity is likely to require at least 24 months.

The Company is seeking two additional centers to increase the rate of accrual. As described below, a recent publication may heighten the interest of institutions with large populations of small cell lung cancer (SCLC) patients. LB-100 was reported to enhance the effectiveness of elements of standard therapy in models of SCLC (Mirzapoiuzova et al., *Molecular Cancer Therapeutics*, online July 12, 2021). Dr. Ravi Salgia, MD, PhD, Professor and Chair of the Department of Medical Oncology and Therapeutics Research at the City of Hope National Medical Center, is the corresponding author of the paper and also the principal investigator for the Company's SCLC clinical trial. Dr. Salgia and collaborators found multiple metabolic changes associated with cell death in SCLC cells when exposed to LB-100 alone and when combined with the drugs in a standard clinical regimen for this notoriously aggressive disease.

LB-100 has been reported to increase the effectiveness of a number of anti-cancer drugs against several different types of human cancers without increasing toxicity in animal models. The recent pre-clinical study of SCLC cells observed that (1) LB-100 increases the amount of carboplatin that enters the tumor cells without increasing toxicity, and (2) LB-100 potentiates the action of the immune-blocker, atezolizumab. These observations are important because, taken together, they not only constitute a strong rationale for the clinical trial of LB-100 plus chemo-immunotherapy in SCLC, but they also complement earlier pre-clinical observations that LB-100 can (1) reverse resistance of cancer cells (ovarian) to cisplatin, another widely used chemotherapy drug (Chang et al., *Molecular Cancer Therapeutics*, November 5, 2014), (2) increase the entry of another important anti-cancer agent, doxorubicin, into liver cancer cells associated with increased anti-tumor activity (Bai et al., *Molecular Cancer Therapeutics*, August 14, 2014), and (3) enhance the effectiveness of immune-blockers against several types of cancers (Ho et al. *Nature Comm.*, May 29, 2018). These observations raise the possibility that the addition of LB-100 may be a general way to enhance standard therapies for cancers for which better treatments are urgently needed. The present clinical trial in SCLC is an initial step in testing that hypothesis, as is the planned clinical trial in advanced soft tissue sarcoma in which LB-100 is combined with doxorubicin.

During the three months and six months ended June 30, 2021, the Company incurred costs of \$69,001 and \$309,509, respectively, pursuant to this agreement. As of June 30, 2021, total costs of \$309,509 have been incurred pursuant to this agreement.

The Company's aggregate commitments pursuant to this clinical trial agreement, less amounts previously paid to date under this agreement, totaled approximately \$2,433,000 as of June 30, 2021, which are expected to be incurred over the next two years based upon a target of 42 enrollees. If a significant number of patients fail during the dose-escalation process, an increase of up to 12 patients would likely be necessary, at an estimated additional cost of approximately \$800,000. Alternatively, should fewer than 42 enrollees be required, the Company has agreed to compensate the City of Hope on a per enrollee basis. The Company currently expects that enrollment in this clinical trial will range from approximately 18 to 30 enrollees, with 24 enrollees as the most likely number.

#### ***Clinical Trial Monitoring Agreements***

**Moffitt.** On September 12, 2018, the Company finalized a work order agreement with Theradex Systems, Inc. ("Theradex"), an international contract research organization ("CRO"), to monitor the Phase 1b/2 clinical trial being managed and conducted by Moffitt. The clinical trial began in April 2019 and the first patient was entered into the clinical trial in July 2019. At the current rate of accrual, the trial is expected to be completed over a period of four years from its initiation.

Costs under this work order agreement are estimated to be approximately \$954,000, with such payments expected to be divided approximately 94% to Theradex for services and approximately 6% for payments for pass-through costs. The costs of the Phase 1b/2 clinical trial being paid to or through Theradex are being recorded and charged to operations based on the periodic documentation provided by the CRO. During the three months ended June 30, 2021 and 2020, the Company incurred costs of \$7,540 and \$5,790, respectively, pursuant to this work order. During the six months ended June 30, 2021 and 2020, the Company incurred costs of \$8,481 and \$11,476, respectively, pursuant to this work order. As of June 30, 2021, total costs of \$90,636 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$873,000 as of June 30, 2021, which are expected to be incurred over approximately the next five years through June 30, 2025.

**City of Hope.** On February 5, 2021, the Company signed a new work order agreement with Theradex to monitor the City of Hope investigator-initiated clinical trial in small cell lung cancer in accordance with FDA requirements for oversight by the sponsoring party. During the three months and six months ended June 30, 2021, the Company incurred costs of \$10,773 and \$14,313, respectively, pursuant to this work order. As of June 30, 2021, total costs of \$14,313 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date under this agreement, totaled approximately \$324,000 as of June 30, 2021, which are expected to be incurred through September 30, 2023.

### ***Patent and License Agreements***

On March 22, 2018, the Company entered into a Patent Assignment and Exploitation Agreement with INSERM TRANSFERT SA, acting as delegatee of the French National Institute of Health and Medical Research, for the assignment to the Company of INSERM'S interest in United States Patent No. 9,833,450 entitled "Oxabicycloheptanes and Oxabicycloheptenes for the Treatment of Depressive and Stress Disorders", which was filed with the United States Patent and Trademark Office in the name of INSERM and the Company as co-owners on February 19, 2015 and granted on May 12, 2017, and related patent applications and filings. INSERM is a French public institution dedicated to research in the field of health and medicine that had previously entered into a Material Transfer Agreement with the Company to allow INSERM to conduct research on the Company's proprietary compound LB-100 and/or its analogs for the treatment of depressive or stress disorders in humans. Pursuant to the Agreement, the Company has agreed to make certain milestone payments to INSERM aggregating up to \$1,750,000 upon achievement of development milestones and up to \$6,500,000 upon achievement of commercial milestones. The Company also agreed to pay INSERM certain commercial royalties on net sales of products attributed to the Agreement. The Company's current plan is to complete the validation process to evaluate LB-100 for the treatment of depressive or stress disorders in humans within three years; however, the exploitation of this patent for the treatment of depressive and stress disorders in humans will require substantial additional capital and/or a joint venture or other type of business arrangement with a pharmaceutical company with substantially greater capital and business resources than those available to the Company. As there can be no assurances that the Company will be able to obtain the capital or business resources necessary to focus on the exploitation of this patent, it is uncertain as to when, if at all, the Company may reach any of the development or commercialization milestones under the Agreement. As of June 30, 2021 and 2020, no amounts were due under this agreement.

Effective August 20, 2018, the Company entered into an Exclusive License Agreement with Moffitt. Pursuant to the License Agreement, Moffitt granted the Company an exclusive license under certain patents owned by Moffitt (the "Licensed Patents") relating to the treatment of MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim under the Licensed Patents or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under the Licensed Patents. The Company was obligated to pay Moffitt a non-refundable license issue fee of \$25,000 after the first patient is entered into a Phase 1b/2 clinical trial to be managed and conducted by Moffitt. The clinical trial began at a single site in April 2019 and the first patient was entered into the clinical trial in July 2019. The Company is also obligated to pay Moffitt an annual license maintenance fee of \$25,000 commencing on the first anniversary of the Effective Date and every anniversary thereafter until the Company commences payment of minimum royalty payments. The Company has also agreed to pay non-refundable milestone payments to Moffitt, which cannot be credited against earned royalties payable by the Company, based on reaching various clinical and commercial milestones aggregating \$1,897,000, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. During the three months ended June 30, 2021 and 2020, the Company recorded charges to operations of \$6,233 and \$6,233, respectively, in connection with its obligations under the License Agreement. During the six months ended June 30, 2021 and 2020, the Company recorded charges to operations of \$12,397 and \$12,398, respectively, in connection with its obligations under the License Agreement. As of June 30, 2021, no milestones had yet been attained.

The Company will be obligated to pay Moffitt earned royalties of 4% on worldwide cumulative net sales of royalty-bearing products, subject to reduction to 2% under certain circumstances, on a quarterly basis, with a minimum royalty payment of \$50,000 in the first four years after sales commence, and \$100,000 in year five and each year thereafter, subject to reduction by 40% under certain circumstances relating to the status of Valid Claims, as such term is defined in the License Agreement. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first sale of a royalty-bearing product, and shall automatically expire on a country-by-country basis on the date on which the last valid claim of the Licensed Patents expires, lapses or is declared invalid, and the obligation to pay any earned royalties under the License Agreement shall terminate on the date on which the last valid claim of the Licensed Patents expires, lapses, or is declared to be invalid in all countries.

### ***Employment Agreements with Officers***

During July and August 2020, the Company entered into one-year employment agreements with its executive officers, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, which provided for aggregate annual compensation of \$640,000, payable monthly. The employment agreements are automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, or by death, or by termination for cause. On April 9, 2021, the Board of Directors increased the annual compensation of Eric J. Forman, the Company's Chief Administrative Officer, Dr. James S. Miser, the Company's Chief Medical Officer, and Robert N. Weingarten, the Company's Chief Financial Officer, under the employment agreements such that the total aggregate annual compensation of all officers increased to \$775,000, effective May 1, 2021.



### *Other Significant Agreements and Contracts*

On December 24, 2013, the Company entered into an agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to become a member of the Company's Scientific Advisory Committee. The term of the agreement was for one year and provided for a quarterly cash fee of \$4,000. The agreement has been automatically renewed for additional one-year terms on its anniversary date since 2014. Consulting and advisory fees charged to operations pursuant to this agreement were \$4,000 and \$4,000 for the three months ended June 30, 2021 and 2020, respectively, and \$8,000 and \$8,000 for the six months ended June 30, 2021 and 2020, respectively, which were included in research and development costs in the consolidated statements of operations.

Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services included, among other things: (a) assisting the Company to (i) commercialize its products and strengthen its patent portfolio, (ii) identify large pharmaceutical companies with potential interest in the Company's product pipeline, and (iii) prepare and deliver presentations concerning the Company's products; (b) at the request of the Board of Directors, serving as backup management for up to three months should the Company's Chief Executive Officer and scientific leader be temporarily unable to carry out his duties; (c) being available for consultation in drug discovery and development; and (d) identifying providers and overseeing tasks relating to clinical use and commercialization of new compounds.

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party not less than 60 days prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of \$10,000, subject to the right of the Company to pay a negotiated hourly rate in lieu of the monthly payment and agreed to issue to BioPharmaWorks certain equity-based compensation. In April 2018, it was mutually agreed to suspend services and payments under the Collaboration Agreement, without extending its term, for the period from February 1, 2018 through the September 13, 2019 anniversary date. In February 2019, the Company and BioPharmaWorks subsequently agreed to resume the Collaboration Agreement effective March 1, 2019, and the Collaboration Agreement is currently in effect. The Company recorded charges to operations pursuant to this Collaboration Agreement of \$30,000 and \$30,000 for the three months ended June 30, 2021 and 2020, respectively, and \$60,000 and \$60,000 for the six months ended June 30, 2021 and 2020, respectively, which were included in research and development costs in the consolidated statements of operations.

Effective August 12, 2020, the Company entered into a Master Service Agreement with the Foundation for Angelman Syndrome Therapy (FAST) to collaborate in supporting pre-clinical studies of the potential benefit of LB-100 in a mouse model of Angelman Syndrome (AS) as reported in The Proceedings of The National Academy of Science (Wang et al, June 3, 2019). The pre-clinical studies will be conducted at The University of California - Davis under the direction of Dr. David Segal, an internationally recognized leader in AS research. If the pre-clinical studies confirm that LB-100 reduces AS signs in rodent models, the Company has agreed to enter into discussions with FAST with respect to possible collaborations to most efficiently assess the benefit of LB-100 in patients with AS, which is a rare disease affecting an estimated one out of 12,000 to one out of 20,000 persons in the United States. The genetic cause of AS, reduced function of a specific maternal gene called Ube3, has been understood for some time, but the molecular abnormality resulting from the genetic lesion has now been shown to be increased concentrations of protein phosphatase 2A (PP2A), a molecular target of the Company's investigational compound, LB-100. The Company has agreed to provide FAST with a supply of LB-100 to be utilized in the conduct of this study, which is initially expected to be completed within three years. Conditioned on FAST's completion of this study, the Company has agreed to pay FAST five percent (5%) of all proceeds, as defined in the Master Service Agreement, received by the Company, up to a maximum of \$250,000 from the exploitation of the study results.

The research team at the University of California, Davis recently completed their pre-clinical study of the potential benefit of LB-100 in a mouse model of AS, and the results are currently under review by FAST. The preliminary analysis indicates that the positive results previously reported by Chinese investigators were not confirmed in the US model. The Company is awaiting input from FAST as to whether it intends to continue to pursue pre-clinical studies of LB 100.

Effective December 21, 2020, the Company entered into a services agreement with IRTH Communications, LLC for investor/public relations, financial communications, and strategic consulting services, effective for an initial term of twelve months and renewable annually thereafter. The Company agreed to pay a monthly fee of \$7,500, including any renewal term, and also agreed to issue restricted shares of common stock, fully vested upon issuance, with a grant date fair value of \$100,000. Upon the commencement of any renewal term, the Company will be obligated to issue additional restricted shares of common stock, fully vested upon issuance, with a grant date fair value of \$100,000. During the three months and six months ended June 30, 2021, the Company incurred charges in the amount of \$22,500 and \$45,000, respectively, with respect to this agreement, which amount is included in general and administrative costs in the Company's consolidated statements of operations.

#### **Off-Balance Sheet Arrangements**

At June 30, 2021, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Not applicable.

### ITEM 4. CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

As required by Rule 15d-15(b) of the Securities and Exchange Commission (the “SEC”), the Company carried out an evaluation, under the supervision and with the participation of its management, consisting of the Company’s principal executive officer and principal financial officer, of the effectiveness of the design and operation of the Company’s disclosure controls and procedures as of June 30, 2021, the end of the most recent period covered by this report.

The term “disclosure controls and procedures”, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

There are limitations inherent in any internal control, such as the possibility of human error and the circumvention or overriding of controls. As a result, even effective internal controls can provide only reasonable assurance with respect to financial statement preparation. As conditions change over time so too may the effectiveness of internal controls. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

#### Management’s Report on Internal Control Over Financial Reporting

The Company’s management, consisting of its Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. The Company’s internal control over financial reporting is designed to ensure that material information regarding the Company’s operations is made available to management and the Board of Directors to provide them reasonable assurance that the published financial statements are fairly presented.

Based on the Company’s assessment, management has concluded that its internal control over financial reporting was effective as of June 30, 2021 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. Generally Accepted Accounting Principles.

However, if in future periods the Company develops material weaknesses in its internal control over financial reporting, the Company may not detect errors on a timely basis and its consolidated financial statements may be materially misstated. In addition, the Company may also engage in business activities or transactions in future periods that could negatively affect its internal control over financial reporting and result in additional material weaknesses.

Management believes that the consolidated financial statements included in this report fairly present, in all material respects, the Company’s financial condition, results of operations and cash flows as of and for the period ended June 30, 2021.

#### Changes in Internal Control Over Financial Reporting

The Company’s management, consisting of its Chief Executive Officer and its Chief Financial Officer, has determined that no change in the Company’s internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during or subsequent to the period ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

The Company is not currently subject to any pending or threatened legal actions or claims.

### **ITEM 1A. RISK FACTORS**

The Company's business, financial condition, results of operations and cash flows may be impacted by a number of factors, many of which are beyond the Company's control, including those set forth in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the Securities and Exchange Commission on March 26, 2021 (the "2020 Form 10-K").

The Risk Factors set forth in the 2020 Form 10-K should be read carefully in connection with evaluating the Company's business and in connection with the forward-looking statements contained in this Quarterly Report on Form 10-Q. Any of the risks described in the 2020 Form 10-K could materially adversely affect the Company's business, financial condition or future results and the actual outcome of matters as to which forward-looking statements are made. These are not the only risks that the Company faces. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

As of the date of this filing, there have been no material changes to the Risk Factors previously disclosed in the Company's 2020 Form 10-K.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

Not applicable.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

Not applicable.

## ITEM 6. EXHIBITS

The following documents are filed as part of this report:

| <u>Exhibit Number</u> | <u>Description of Document</u>   |
|-----------------------|--|
| 10.1                  | <a href="#">Clinical Research Support Agreement with City of Hope.<sup>1</sup></a>                 |
| 31.1*                 | <a href="#">Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a> |
| 31.2*                 | <a href="#">Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a> |
| 32.1*                 | <a href="#">Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a> |
| 32.2*                 | <a href="#">Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a> |
| 101.INS**             | XBRL Instance Document   |
| 101.SCH**             | XBRL Taxonomy Extension Schema Document  |
| 101.CAL**             | XBRL Taxonomy Extension Calculation Linkbase Document  |
| 101.LAB**             | XBRL Taxonomy Extension Label Linkbase Document  |
| 101.PRE**             | XBRL Taxonomy Extension Presentation Linkbase Document   |
| 101.DEF**             | XBRL Taxonomy Extension Definition Linkbase Document   |

\* Filed herewith.

\*\* In accordance with Regulation S-T, the XBRL related information on Exhibit No. 101 to this Quarterly Report on Form 10-Q shall be deemed "furnished" herewith but not "filed".

<sup>1</sup> Filed as an Exhibit to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on January 22, 2021 and incorporated herein by reference.

**SIGNATURES**

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

LIXTE BIOTECHNOLOGY HOLDINGS, INC.  
(Registrant)

Date: August 10, 2021

By: /s/ JOHN S. KOVACH  
John S. Kovach  
Chief Executive Officer

Date: August 10, 2021

By: /s/ ROBERT N. WEINGARTEN  
Robert N. Weingarten  
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John S. Kovach, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2021

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer

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**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert N. Weingarten, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lixte Biotechnology Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's Board of Directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2021

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten  
Chief Financial Officer

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**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER  
UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, John S. Kovach, the Chief Executive Officer of Lixte Biotechnology Holdings, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

(i) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 10, 2021

By: /s/ JOHN S. KOVACH

John S. Kovach  
Chief Executive Officer

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**CERTIFICATIONS OF CHIEF FINANCIAL OFFICER  
UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert N. Weingarten, the Chief Financial Officer of Lixte Biotechnology Holdings, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

(i) The Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 10, 2021

By: /s/ ROBERT N. WEINGARTEN

Robert N. Weingarten  
Chief Financial Officer

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