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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

or

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

For the transition period from _____ to

Commission File Number: 001-39169

Kiromic BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-4762913**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
7707 Fannin Street, Suite 140, Houston, TX	**77054**
(Address of Principal Executive Offices)	Zip Code

(832) 968-4888
(Registrant's telephone number)

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

Title of Each Class	**Trading symbol**	**Name of Exchange on which registered**
Common Shares, par value $0.001 per share	KRBP	The Nasdaq Stock Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

Large Accelerated Filer ☐	Accelerated Filer ☐
Non-accelerated Filer ☒	Smaller Reporting Company ☒
	Emerging Growth Company ☒

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

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

As of August 13, 2021, there were 15,437,689 shares of the registrant's common stock outstanding.

Kiromic BioPharma, Inc.

Quarterly Report on Form 10-Q
Period Ended June 30, 2021

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Kiromic Biopharma, Inc.

Quarterly Report on Form 10-Q

For the quarterly period ended June 30, 2021

Cautionary Note on Forward-Looking Statements

This report contains forward-looking statements that involve substantial risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the U.S. Private Securities Litigation Reform Act, Section 21E of the Securities Exchange Act of 1934, as amended, and other federal securities laws. All statements other than statements of historical facts are forward-looking statements. The forward-looking statements are contained principally in, but not limited to, the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our goals and strategies;
- our future business development, financial condition and results of operations;
- expected changes in our revenue, costs or expenditures;
- growth of and competition trends in our industry;
- our expectations regarding demand for, and market acceptance of, our products;
- our expectations regarding our relationships with investors, institutional funding partners and other parties we collaborate with;
- fluctuations in general economic and business conditions in the markets in which we operate; including those fluctuations caused by COVID-19; and
- relevant government policies and regulations relating to our industry.

In some cases, you can identify forward-looking statements by terms such as “may,” “could,” “will,” “should,” “would,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “project” or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the heading “Risk Factors” included in our Annual Report on Form 10-K (file no. 001-39169), filed with the Securities and Exchange Commission on March 31, 2021, and elsewhere in this report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements made in this report relate only to events or information as of the date on which the statements are made in this report. Except as expressly required by the federal securities laws, there is no undertaking to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or any other reason.

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 3,070,400	$ 10,150,500
Prepaid expenses and other current assets	875,600	588,800
Total current assets	3,946,000	10,739,300
Property and equipment, net	2,468,700	2,066,000
Other assets	24,400	24,400
Total Assets	$ 6,439,100	$ 12,829,700
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 1,124,100	$ 665,200
Accrued expenses and other current liabilities	350,900	334,200
Interest payable	—	200
Loan payable	—	105,600
Note payable	91,600	362,400
Total current liabilities	1,566,600	1,467,600
Total Liabilities	1,566,600	1,467,600
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Common stock, $0.001 par value: 300,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 7,387,500 shares and 7,332,999 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	1,300	1,200
Additional paid-in capital	55,327,800	52,988,700
Accumulated deficit	(50,456,600)	(41,627,800)
Total Stockholders' Equity	4,872,500	11,362,100
Total Liabilities and Stockholders' Equity	$ 6,439,100	$ 12,829,700

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 2,658,100	$ 1,272,300	$ 4,543,700	$ 2,300,400
General and administrative	2,314,100	10,094,600	4,385,100	10,919,200
Total operating expenses	4,972,200	11,366,900	8,928,800	13,219,600
Loss from operations	(4,972,200)	(11,366,900)	(8,928,800)	(13,219,600)
Other income (expense)				
Gain on loan extinguishment	—	—	105,800	—
Interest expense	(2,100)	—	(5,800)	—
Total other income (expense)	(2,100)	—	100,000	—
Net loss	$ (4,974,300)	$ (11,366,900)	$ (8,828,800)	$ (13,219,600)
Net loss per share, basic and diluted	$ (0.68)	$ (3.80)	$ (1.21)	$ (4.52)
Weighted average common shares outstanding, basic and diluted	7,345,147	3,077,085	7,345,147	3,077,085

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Three and Six Months Ended June 30, 2021				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
Balance at January 1, 2021	7,332,999	$ 1,200	$ 52,988,700	$ (41,627,800)	$ 11,362,100
Common stock discount amortization	—	—	24,700	—	24,700
Warrants underlying common stock issuance	—	—	(24,700)	—	(24,700)
Stock compensation expense	—	—	945,200	—	945,200
Net loss	—	—	—	(3,854,500)	(3,854,500)
Balance at March 31, 2021	7,332,999	$ 1,200	$ 53,933,900	$ (45,482,300)	$ 8,452,800
Common stock discount amortization	—	—	24,900	—	24,900
Warrants underlying common stock issuance	—	—	(24,900)	—	(24,900)
Exercised stock options	18,891	100	125,300	—	125,400
Released restricted stock units	35,610	—	—	—	—
Stock compensation expense	—	—	1,268,600	—	1,268,600
Net loss	—	—	—	(4,974,300)	(4,974,300)
Balance at June 30, 2021	7,387,500	$ 1,300	$ 55,327,800	$ (50,456,600)	$ 4,872,500

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Three and Six Months Ended June 30, 2020								
	Series A-1 Preferred Stock		Series B Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at January 1, 2020	21,822,301	$9,134,700	9,869,659	$1,306,900	2,863,812	$ —	$ 13,965,000	$ (22,427,600)	$ 1,979,000
Issuance of Series B Preferred Stock	—	—	6,521,738	331,700	—	—	—	—	331,700
Series B Preferred Stock discount amortization	—	—	—	368,400	—	—	(368,400)	—	—
Warrants underlying Series B Preferred Stock issuance	—	—	—	—	—	—	2,668,300	—	2,668,300
Stock compensation expense	—	—	—	—	—	—	456,000	—	456,000
Net loss	—	—	—	—	—	—	—	(1,852,700)	(1,852,700)
Balance at March 31, 2020	21,822,301	9,134,700	16,391,397	$2,007,000	2,863,812	$ —	$ 16,720,900	$ (24,280,300)	$ 3,582,300
Series B Preferred Stock discount amortization	—	—	—	324,300	—	—	(324,300)	—	—
Exercise of warrants	—	—	—	—	1,399,921	—	4,900	—	4,900
Common stock issuance to employees and non-employees	—	—	—	—	725,536	—	9,432,000	—	9,432,000
Stock compensation expense	—	—	—	—	—	—	443,000	—	443,000
Net loss	—	—	—	—	—	—	—	(11,366,900)	(11,366,900)
Balance at June 30, 2020	21,822,301	$9,134,700	16,391,397	$2,331,300	4,989,269	$ —	$ 26,276,500	$ (35,647,200)	$ 2,095,300

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (8,828,800)	$ (13,219,600)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	202,400	68,500
Stock compensation expense	2,213,800	10,331,000
Gain on loan extinguishment	(105,800)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	151,500	(141,500)
Accounts payable	41,800	291,000
Accrued expenses and other current liabilities	(19,000)	66,800
Net cash used for operating activities	(6,344,100)	(2,603,800)
Cash flows from investing activities:		
Purchases of property and equipment	(590,600)	(762,300)
Net cash used for investing activities	(590,600)	(762,300)
Cash flows from financing activities:		
Repayments of note payable	(270,800)	—
Exercise of stock options	125,400	—
Proceeds from warrant exercise	—	4,900
Proceeds from loan payable	—	115,600
Proceeds from Series B Preferred Stock issuance	—	3,000,000
Net cash (used for) provided by financing activities	(145,400)	3,120,500
Net change in cash and cash equivalents	(7,080,100)	(245,600)
Cash and cash equivalents:		
Beginning of year	10,150,500	1,929,100
End of period	$ 3,070,400	$ 1,683,500
Supplemental disclosures of non-cash investing and financing activities:		
Accruals for property and equipment	$ 14,500	$ 45,000
Cash paid for interest on note payable	$ 5,800	$ —
Accruals for deferred public offering costs	$ 438,300	$ 594,200
Warrants underlying Series B Preferred Stock issuance	$ —	$ 2,668,300

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. ORGANIZATION

Nature of Business

Kiromic BioPharma, Inc. and subsidiary (the "Company") is a preclinical stage biopharmaceutical company formed under the Texas Business Organizations Code in December 2012. On May 27, 2016, the Company converted from a Texas limited liability company into a Delaware corporation and changed its name from Kiromic LLC to Kiromic Inc. On December 16, 2019, the Company amended and restated its certificate of incorporation charter to re-name the company, Kiromic BioPharma, Inc.

The Company is a target discovery and gene-editing company utilizing artificial intelligence and its proprietary neural network platform with a therapeutic focus on immuno-oncology. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

Going Concern—These condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred significant losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. The Company had negative cash flow from operations of $6,344,100 for the six months ended June 30, 2021, and an accumulated deficit of $50,456,600 as of June 30, 2021. To date, the Company has relied on equity and debt financing to fund its operations. The Company’s product candidates are still in the early stages of development, and substantial additional financing will be needed by the Company to fund its operations and ongoing research and development efforts prior to the commercialization, if any, of its product candidates.

The Company has sufficient cash on hand and available liquidity to meet its obligations through the twelve months following the date the condensed consolidated financial statements are issued. After taking into account the Company’s cash flow projections, the Company does not believe it will have sufficient cash on hand or available liquidity to meet its obligations through the twelve months from the date of issuance of the condensed consolidated financial statements for the three months ending September 30, 2021. Therefore, this condition raises substantial doubt about the Company’s ability to continue as a going concern.

Given its projected operating requirements and its existing cash and cash equivalents, management is currently evaluating different strategies to obtain the required funding of future operations. These strategies may include, but are not limited to, additional funding from current or new investors. However, there can be no assurance that the Company will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs or on favorable terms. Therefore, the plans cannot be deemed probable of being implemented. As a result, the Company has concluded that management’s plans do not alleviate substantial doubt about the Company’s ability to continue as a going concern.

The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

NIH Grant—In August 2018, the National Institute of Health ("the NIH"), the primary agency of the US government responsible for biomedical and public health research, awarded a Phase I/II grant to the Company in the amount of $2,235,000 for the development and non-clinical testing of a new anti-arteriosclerosis gene therapy delivered by engineered adeno-associated viral vectors. Phase I of the grant, approved amounts of $851,000 and covered the period September 2018 through August 2019, entitled the Company to reimbursement for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees. The Company did not complete Phase I by August 2019, but was granted an extension to complete Phase I by the NIH through August 2021. Starting after Phase 1 completion in 2021, Phase II of the grant covers reimbursements for certain salaries and wages, materials and supplies, facilities and administrative costs, and fixed fees of $1,384,000.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information (Accounting Standards Codification ("ASC") 270, Interim Reporting) and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information necessary for a full presentation of financial position, results of operations, and cash flows in conformity GAAP. Operating results for interim periods are not necessarily indicative of results that may be expected for the fiscal year as a whole. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented.

All intercompany balances were eliminated upon 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 and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include determination of the fair value of common stock and related stock-based compensation, warrants to purchase common stock underlying shares of Series B Preferred Stock and Initial Public Offering (“IPO”) common stock, and estimating services incurred by third-party service providers used to recognize research and development expense.

Cash and Cash Equivalents—As of June 30, 2021 and December 31, 2020, cash and cash equivalents consisted entirely of cash on hand and bank deposits. The Company considers all highly liquid instruments with remaining maturities at purchase of 90 days or less to be cash equivalents.

Concentrations of Credit Risk and Other Uncertainties—Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. Substantially all of the Company’s cash and cash equivalents were deposited in accounts at a small number of national financial institutions. Account balances may at times exceed federally-insured limits. The Company has not incurred losses related to these cash and cash equivalents deposited at financial institutions and management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held.

The Company is subject to certain risks and uncertainties from changes in any of the following areas that the Company believes could have a material adverse effect on future financial position or results of operations: the ability to obtain regulatory approval and market acceptance of, and reimbursement for, the Company’s product candidates; the performance of third-party clinical research organizations and manufacturers; protection of the intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; the Company’s ability to attract and retain employees necessary to support commercial success; and changes in the industry or customer requirements including the emergence of competitive products with new capabilities.

Deposit—In connection with one of the Company’s facility leases, a deposit is held by the lessor per the terms of the noncancelable agreement. The deposit has been recorded as a long-term asset on the Company’s condensed consolidated balance sheets.

Deferred Public Offering Costs—In the six months ended June 30, 2021 and 2020, the Company began incurring costs in connection with the filing of a Registration Statements on Form S-1 and Form S-1/A for a public offering and an IPO, respectively, which are deferred in other current assets in accordance with ASC 505-10-25 in the condensed consolidated balance sheets. Public offering costs consist of legal, accounting, and other costs directly related to the Company's efforts to raise capital. As of June 30, 2021 and 2020, $478,900 and $696,700 of deferred costs related to the public offering and IPO were classified as other current assets on the condensed consolidated balance sheets.

Property and Equipment—Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets ranging from 1 to 8 years. Major replacements and improvements are capitalized as leasehold improvements, while general repairs and maintenance are expensed as incurred. Estimated useful lives of leasehold improvements are the shorter of the remaining lease term or the estimated useful economic life of the specific asset.

Estimated useful lives of property and equipment are as follows for the major classes of assets:

Asset Description	Estimated Lives
Laboratory Equipment	3 - 8
Leasehold Improvements	1 - 7
Office Furniture, Fixtures, and Equipment	5
Software	3 - 5

Internal Use Software Development Costs—The Company capitalizes certain costs incurred to develop internal use software. All costs incurred that relate to planning and post-implementation phases of development are expensed as incurred. Costs incurred in the development and implementation phases are capitalized and amortized over the estimated life of the software, generally five years. The Company did not capitalize any software development costs for the three and six months ended June 30, 2021 and 2020.

Impairment of Long-Lived Assets—The Company reviews its long-lived assets, including property and equipment, for impairment indicators. If indicators are noted, the Company compares the carrying amount of the asset to its estimated undiscounted cash flows. If the carrying amount exceeds its estimated undiscounted cash flows, an impairment loss is recognized to adjust the long-lived asset to fair value. There has been no impairment losses on the Company's long-lived assets since inception.

Comprehensive Loss—Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For all periods presented, there was no difference between net loss and comprehensive loss.

Income Taxes—The Company files federal and state income tax returns, utilizing the accrual basis of accounting. Income taxes are provided for the tax effects of transactions reported in the condensed consolidated financial statements and consist of taxes currently due and deferred taxes. Certain transactions of the Company may be subject to accounting methods for income tax purposes, which differ from the accounting methods used in preparing these condensed consolidated financial statements in accordance with GAAP. Accordingly, the net income or loss of the Company reported for income tax purposes may differ from the balances reported for those same items in the accompanying condensed consolidated financial statements.

Deferred tax assets and liabilities are recognized for the future tax consequences attributable between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which such temporary differences are expected to be recovered or settled. The Company records valuation allowances to reduce deferred income tax assets to the amount that is more likely than not to be realized.

The Company records uncertain tax positions in accordance with ASC 740, *Income Taxes*, on the basis of a two-step process in which (1) the Company determines whether it is more-likely-than-not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying condensed consolidated statements of operations. No such interest or penalties were recognized during the three months and six months ended June 30, 2021 and 2020.

Research and Development Expense—The Company expenses research and development costs as incurred. Research and development expenses include personnel and personnel-related costs, costs associated with the Company's pre-clinical development activities including costs of outside consultants and contractors, the submission and maintenance of regulatory filings, equipment and supplies used in developing products prior to market approval and an allocation of certain overhead costs such as facility and related expenses.

The Company accrues and expenses costs of services provided by contract research organizations in connection with preclinical studies and contract manufacturing organizations engaged to manufacture clinical trial material, costs of licensing technology, and costs of services provided by research organizations and service providers. Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred if the technology is not expected to have any alternative future uses other than the specific research and development project for which it was intended. Nonrefundable advance payments for goods or services to

be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed rather than when the payment is made.

Proceeds from Grants—During the three and six months ended June 30, 2021 and 2020, the Company did not recognize any reductions to research and development expense within the condensed consolidated statements of operations pursuant to its grant from the NIH.

Fair Value Measurements—The carrying value of the Company's cash and cash equivalents, prepaid expenses and other assets, accounts payable, accrued expenses and other current liabilities approximate their fair value due to their short-term nature.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In estimating the fair value of an asset or a liability, the Company takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date.

The Company accounts for financial instruments in accordance with ASC 820, *Fair Value Measurements and Disclosures*. ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices in non-active markets or in active markets for similar assets or liabilities, observable inputs other than quoted prices, and inputs that are not directly observable but are corroborated by observable market data.

Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

There were no changes in the fair value hierarchy levels during the three and six months ended June 30, 2021 and 2020.

Nonvested Stock Options and Restricted Stock Units—Pursuant to the Company's 2017 Stock Incentive Plan (the "2017 Plan") and the Omnibus 2021 Equity Incentive Plan (the "2021 Plan"), the Company has the ability to issue a variety of share-based payments and incentives to board members, employees, and non-employees through grants of nonvested stock options and restricted stock units.

The vesting conditions for stock options and restricted stock units include annual and monthly vesting. Annual vesting conditions are for four years. Monthly vesting conditions range from 10 to 48 months. When nonvested options are vested, they become exercisable over a 10-year period from grant date.

The vesting conditions for restricted stock units include cliff vesting conditions. Certain restricted stock units vest with a range of 6 to 12 months following the expiration of employee lock-up agreements. Certain restricted stock units vest based on the later of achievement of key milestones or the expiration of employee lock-up agreements. When nonvested restricted stock units are vested, they are released to the grantee within sixty days.

Stock-Based Compensation—The Company records stock compensation expense related to the 2017 Plan and the 2021 Plan in accordance with ASC 718, *Compensation—Stock Compensation*. The Company measures and recognizes stock compensation expense for all stock-based awards, including stock options, based on estimated fair values recognized using cliff vesting or the straight-line method over the requisite service period. The fair value of stock options is estimated on the grant date using the Black-Scholes option-valuation model (the "Black-Scholes model"). The calculation of stock-based compensation expense requires that the Company make assumptions and judgments about the variables used in the Black-Scholes model, including the fair value of the Company's common stock, expected term, expected volatility of the underlying common stock, and risk-free interest rate. Forfeitures are accounted for when they occur.

Until the Company's common stock became publicly traded, the board of directors' approach to estimating the fair value of the Company's common stock includes utilizing methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately- Held Company Equity Securities Issued as Compensation*.

The Company estimates the grant-date fair value of stock options using the Black-Scholes model and the assumptions used to value such stock options are determined as follows:

Expected Term. The expected term represents the period that the Company's stock options are expected to be outstanding. Due to limitations on the sale or transfer of the Company's common stock under the lock-up agreements and market standoff components of the stock option agreements, the Company does not believe its historical exercise pattern is indicative of the pattern it will experience after restricted periods expire. The Company has previously used the Staff Accounting Bulletin ("SAB") No. 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period.

Risk-Free Interest Rate. The Company bases the risk-free interest rate used in the Black-Scholes model on the implied yield available on US Treasury zero-coupon issues with a term equivalent to that of the expected term of the stock options for each stock option group.

Volatility. The Company determines the price volatility based on the historical volatilities of industry peers as it has no trading history for its common stock price. The Company intends to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of its own common stock price becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

Dividend Yield. The expected dividend assumption is based on the Company's current expectations about its anticipated dividend policy. To date, the Company has not declared any dividends and, therefore, the Company has used an expected dividend yield of zero.

Common Stock Valuations. During the three and six months ended June 30, 2021, the closing price listed on the Nasdaq Capital Market for the Company's common stock on the date of the grant was used as the common stock valuation. During the three and six months ended June 30, 2020, the Company's board of directors, with input from management and third-party valuations, determined the fair value of the common stock underlying all stock-based compensation grants. The Company believes that the board of directors had the relevant experience and expertise to determine the fair value of the Company's common stock before the Company's common stock became publicly traded. The board of

directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of the Company's common stock at each grant date. These factors include:

- valuations of the common stock performed by third-party specialists;
- the prices, rights, preferences, and privileges of the Company's Series A-1 Preferred Stock and Series B Preferred Stock relative to those of the Company's common stock;
- lack of marketability of the common stock;
- current business conditions and projections;
- hiring of key personnel and the experience of management;
- the Company's stage of development;
- likelihood of achieving a liquidity event, such as an initial public offering, a merger or acquisition of the Company given prevailing market conditions, or other liquidation event;
- the market performance of comparable publicly traded companies; and
- the US and global capital market conditions.

In valuing the common stock, the board of directors determined the equity value of the Company's business using various valuation methods including combinations of income and market approaches. The income approach estimates value based on the expectation of future cash flows that a company will generate. These future cash flows are discounted to their present values using a discount rate derived from an analysis of the cost of capital of comparable publicly traded companies in the Company's industry or similar business operations as of each valuation date and is adjusted to reflect the risks inherent in the Company's cash flows. The market approach references actual transactions involving (i) the subject being valued, or (ii) similar assets and/or enterprises.

For each valuation, the equity value determined by the income and market approaches was then allocated to the common stock using either the option pricing method ("OPM") or probability—weighted expected return model ("PWERM").

The option pricing method is based on the Black-Scholes option valuation model, which allows for the identification of a range of possible future outcomes, each with an associated probability. The OPM is appropriate to use when the range of possible future outcomes is difficult to predict and thus creates highly speculative forecasts. In general, while simple in its application, management did not use the OPM approach when considering allocation techniques for the valuation of equity interests in early stage, privately held life science companies. Management determined that applying the OPM would violate the major assumptions of the Black Scholes option valuation model approach. Additionally, the simulation approach can generally be reasonably approximated by a scenario-based approach like the PWERM as described below.

PWERM involves a forward-looking analysis of the possible future outcomes of the enterprise. This method is particularly useful when discrete future outcomes can be predicted at a relatively high confidence level with a probability distribution. Discrete future outcomes considered under the PWERM include an initial public offering, as well as non-initial public offering market-based outcomes. Determining the fair value of the enterprise using the PWERM requires the Company to develop assumptions and estimates for both the probability of an initial public offering liquidity event and stay private outcomes, as well as the values the Company expects those outcomes could yield. From February 2018 to October 2020, the Company has valued its common stock based on a PWERM.

Application of the Company's approach involves the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding expected future revenue, expenses, and future cash flows, discount rates, market multiples, the selection of comparable companies, and the probability of possible future events. Changes in any or all of these estimates and assumptions or the relationships between those assumptions impact valuations as of each valuation date and may have a material impact on the valuation of the common stock.

For valuations after the completion of an initial public offering, the board of directors determines the fair value of each share of underlying common stock based on the closing price of the common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in assumptions or market conditions.

Segment Data—The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Recently Issued Accounting Pronouncements—From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position, results of operations, or cash flows upon adoption.

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On October 16, 2019, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2022. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

In June 2016, FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The amendments in ASU 2016-13 affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. On October 16, 2019, the FASB has changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2023. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

3. NET LOSS PER COMMON SHARE

Basic and diluted net loss per common share is determined by dividing net loss less deemed dividends by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the stock options, restricted stock units, convertible Series A-1 Preferred Stock, and the convertible Series B Preferred Stock have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average common shares outstanding used to calculate both basic and diluted loss per common shares are the same. The following table illustrates the computation of basic and diluted earnings per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	$ (4,974,300)	$ (11,366,900)	$ (8,828,800)	$ (13,219,600)
Less: Series B Preferred Stock discount amortization	—	(324,300)	—	(692,700)
Less: IPO Common Stock discount amortization	(24,900)	—	(49,600)	—
Net loss attributable to common shareholders, basic and diluted	$ (4,999,200)	$ (11,691,200)	$ (8,878,400)	$ (13,912,300)
Weighted average common shares outstanding, basic and diluted	7,345,147	3,077,085	7,345,147	3,077,085
Net loss per common share, basic and diluted	$ (0.68)	$ (3.80)	$ (1.21)	$ (4.52)

For the six months ended June 30, 2021 and 2020, potentially dilutive securities excluded from the computations of diluted weighted-average common shares outstanding were:

	June 30, 2021	June 30, 2020
Options to purchase	167	—
Restricted Stock Units	66,668	—
Series A-1 Preferred Stock	—	624,594
Series B Preferred Stock	—	469,136
Total	66,835	1,093,730

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of June 30, 2021 and December 31, 2020:

	June 30, 2021	December 31, 2020
Equipment	$ 1,514,300	$ 780,500
Leasehold improvements	1,284,600	1,229,700
Office furniture, fixtures, and equipment	16,600	16,600
Software	151,700	151,700
Construction in progress	265,600	449,200
	3,232,800	2,627,700
Less: Accumulated depreciation	(764,100)	(561,700)
Total	$ 2,468,700	$ 2,066,000

Depreciation expense was $106,800 and $34,700 for the three months ended June 30, 2021 and 2020, respectively, and $202,400 and $68,500 for the six months ended June 30, 2021 and 2020, respectively. Depreciation expense is allocated between research and development and general and administrative operating expenses on the condensed consolidated statements of operations.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following as of June 30, 2021 and December 31, 2020:

	June 30, 2021	December 31, 2020
Accrued consulting and outside services	$ 294,500	$ 143,200
Accrued compensation	56,400	191,000
Total	$ 350,900	$ 334,200

6. LOAN PAYABLE

On May 1, 2020, the Company received a loan in the principal amount of $115,600 (the “SBA Loan”) under the Paycheck Protection Program (“PPP”), which was established under the recently enacted Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) administered by the U.S. Small Business Administration (the “SBA”). The intent and purpose of the PPP is to support companies, during the COVID-19 pandemic, by providing funds for certain specified business expenses, with a focus on payroll. As a qualifying business as defined by the SBA, the Company is using the proceeds from this loan to primarily help maintain its payroll. The term of the SBA Loan promissory note (“the Note”) is two years, though it may be payable sooner in connection with an event of default under the Note. The SBA Loan carries a fixed interest rate of one percent per year, with the first payment due seven months from the date of initial cash receipt. Under the CARES Act and the PPP, certain amounts of loans made under the PPP may be forgiven if the recipients use the loan proceeds for eligible purposes, including payroll costs and certain rent or utility costs, and meet other requirements regarding, among other things, the maintenance of employment and compensation levels. The Company intends to use the SBA Loan for qualifying expenses and to apply for forgiveness of the SBA Loan in accordance with the terms of the CARES Act.

The Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, materially false or misleading representations to the SBA, and adverse changes in the Company’s financial condition or business operations that may materially affect its ability to pay the SBA Loan.

As the legal form of the Note is a debt obligation, the Company accounts for it as debt under ASC 470, *Debt*, and recorded $105,600 as of December 31, 2020 in the condensed consolidated balance sheet. During the year ended December 31, 2020, the Company received initial proceeds of $115,600 and made a repayment of $10,000 on the SBA Loan, bringing the balance to $105,600 as of December 31, 2020. The Company accrued interest over the term of the loan and did not impute additional interest at a market rate because the guidance on imputing interest in ASC 835-30, *Interest*, excludes transactions where interest rates are prescribed by a government agency.

During the year ended December 31, 2020, the Company applied for forgiveness of the SBA Loan in accordance with the terms of the CARES Act. On February 16, 2021, the SBA granted forgiveness of the SBA Loan and all applicable interest. On the date of forgiveness, the principal and accrued interest totaled $105,800. The forgiveness was classified as a gain on loan extinguishment in the condensed consolidated statement of operations.

7. NOTE PAYABLE

In November 2020, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months. As of June 30, 2021 and December 31, 2020, the remaining payable balance on the financed amount was $91,600 and $362,400, respectively.

8. COMMITMENTS AND CONTINGENCIES

Facility Lease Agreements—The Company leases its premises in Houston, Texas under an operating lease which was renewed on November 19, 2020. This renewed lease agreement will commence under an operating lease agreement that is noncancelable from commencement until May 1, 2024.

On March 22, 2021, the Company's board of directors approved a lease expansion within its premises in Houston, Texas. The amended lease agreement commenced on August 1, 2021 under an operating lease agreement that is noncancelable from commencement until May 1, 2024. The amended lease agreement adds approximately 15,385 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after a 90-day notice of cancellation.

If the Company exercises the cancellation option, the Company must also pay the lessor a termination payment equal to three months of base rent.

The total lease payments per month are $22,477, 45,554, and $46,116 beginning May 1, 2021, August 1, 2021, and May 1, 2023, respectively. The Company records rent expense as incurred over the term of the leases.

As of June 30, 2021, the future minimum commitments under the amended lease agreement will be as follows:

	Amount
2021	$ 250,200
2022	546,700
2023	551,100
2024	461,200
Total	$ 1,809,200

Rent expense for the facility lease agreements was $74,900 and $67,100 during the three months ended June 30, 2021 and 2020, respectively, and $143,900 and $127,100 during the six months ended June 30, 2021 and 2020, respectively. Rent expense is included as an allocation between research and development and general and administrative expense in the condensed consolidated statements of operations.

License Agreements—The Company has entered into a number of licensing arrangements for various intellectual property and licensed patent rights for technologies being developed for commercial sale. As part of these arrangements, the Company is subject to contingent milestone payments in accordance with agreed-upon development objectives, as well as future royalty payments on product sales of the underlying assets. As of June 30, 2021 and December 31, 2020, the Company has not incurred any milestone or royalty liabilities related to these license agreements.

Strategic Alliance Agreement with Leon Office (H.K.)—On January 28, 2021, the Company executed a strategic alliance agreement with Leon Office (H.K.) ("Leon") a company established under existing laws of Hong Kong. It is intended that Leon acts as an independent business development advisor on behalf of the Company. Leon will seek to introduce organizations and individuals that will create business development opportunities for the Company, to expand the Company's reach to international markets with a focus on certain Asian markets and to increase brand recognition and exposure through developing liaisons, collaborations, branches and subsidiaries. They will also use commercially reasonable efforts to research the Asian market, with a primary, but not exclusive, focus on determining the most suitable structures for the development of medical partnerships or joint ventures with scientific partners in the Asian market with a mission to test products to be created by the joint venture resulting from such partnership and to develop validation programs for any products produced by such joint venture, including programs for clinical trials and human testing and, ultimately, for product certification. The cost of the agreement is $360,000 annually, payable in four quarterly installments.

Membership Purchase Agreement with In Silico Solutions, LLC—On June 14, 2021, the Company entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with In Silico Solutions, LLC ("In Silico") and Michael Ryan (the "Seller") pursuant to which the Company will acquire all of the outstanding membership interests of

In Silico from the Seller for an aggregate purchase price of $540,000 (the "Purchase Price"). The Purchase Price is payable in full through (i) the delivery to the Seller of a number of shares of the Company's stock that is equal to $400,000 and (i) the delivery to the employees of In Silico of the Company's restricted stock units under the Company's 2021 Plan that is equal to $140,000.

Pursuant to the Purchase Agreement, as soon as practicable following the closing, the Purchase Price shall be subject to a working capital adjustment. In addition, the Purchase Agreement contains customary representations, warranties, covenants (including restrictive covenants), indemnification and other terms for transactions of this nature. The Purchase Agreement may be terminated by either the Company or the Seller if the closing does not occur on or before the 45th day following execution of the Purchase Agreement.

Legal Proceedings—In the normal course of business, the Company may have various claims in process and other contingencies. A complaint was filed on March 22, 2021 in the Court of Chancery of the State of Delaware against the Company by a former consultant and director. The complaint alleges, among other things, that the plaintiff is entitled to additional stock options and he is seeking declaratory judgment and specific performance. The Company believes that all of the claims in the complaint are without merit and the Company intends to defend vigorously against them.

The Company regularly assesses all contingencies and believes, based on information presently known, the Company is not involved in any matters that would have a material effect on the Company's financial position, results of operations and cash flows.

9. STOCKHOLDERS' EQUITY

On June 17, 2020, the Company filed an amendment to its amended and restated certificate of incorporation to complete a 1-for-3.494 reverse split of the Company's outstanding shares common stock.

Accordingly, unless otherwise noted, all share and per share information has been restated to retroactively show the effect of this stock split.

As of June 30, 2021 and December 31, 2020, the Company was authorized to issue 300,000,000 shares of common stock and 60,000,000 shares of Preferred Stock, of which 24,000,000 shares were designated as Series A-1 Preferred Stock and 16,500,000 shares were designated as Series B Preferred Stock.

Common Stock—As of June 30, 2021 and December 31, 2020, the Company has a single class of common stock.

On October 15, 2020, the Company received net proceeds of $12,332,700 from its IPO, after deducting underwriting discounts and commissions of $1,275,000 and other offering expenses of $1,392,300 incurred. The Company issued and sold 1,250,000 shares of common stock in the IPO at a price of $12.00 per share.

In connection with the IPO, all shares of the Company's Series A-1 Preferred Stock and Series B Preferred Stock were converted into 624,594 and 469,136 shares of common stock, respectively.

Below is a table that outlines the initial value of issuances allocated to the IPO common stock, the IPO common stock discount amortized, and value of IPO common stock that was converted into additional-paid-in-capital during the three and six months ended June 30, 2021:

	2021
Common Stock	
Balance at January 1,	$ 11,975,400
Common stock IPO discount amortization	24,700
Balance at March 31,	$ 12,000,100
Common stock IPO discount amortization	24,900
Balance at June 30,	$ 12,025,000

On June 8, 2020, the Company agreed to amend the warrant vesting schedule such that the warrants underlying shares of Series B Preferred Stock became immediately exercisable for each warrant holder. On June 8, 2020, warrant holders exercised their option to purchase 335,982 shares of common stock for proceeds of $1,200. Then, on June 10, 2020, warrant holders exercised their option to purchase an additional 1,063,939 shares of common stock for proceeds of $3,700.

On June 8, 2020, the Company issued 3,106 and 430 shares of common stock to the Company’s Chief Medical Officer and another employee, respectively. In addition, on June 19, 2020, the Company issued 402,000 and 320,000 shares of common stock to the Company’s Chief Financial Officer and Chief Operating Officer ("the CFO and COO") and Chief Strategy and Innovation Officer ("the CSO"), respectively. The shares were issued in exchange for services rendered and no cash considerations. These issuances resulted in $9,432,000 in stock compensation expenses.

Each holder of outstanding shares of common stock shall be entitled to one vote in respect of each share. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of a majority of the outstanding shares of common stock and preferred stock voting together as a single class.

The Company has never paid dividends and has no plans to pay dividends on common stock. As of December 31, 2017, the Company adopted the 2017 Plan. On September 25, 2019, the board of directors approved an additional 10,000,000 shares to be reserved and authorized under the 2017 Plan. This approval increased the total number of authorized shares from 20,000,000 to 30,000,000. After the reverse stock splits, the total number of authorized shares was updated to 858,615. On June 19, 2020, the board of directors approved an additional 850,000 shares to be reserved and authorized under the 2017 Plan. This approval increased the total number of authorized shares from 858,615 to 1,708,615.

As of June 25, 2021, the Company adopted the 2021 Plan. Under the 2021 Plan, the board of directors approved an additional 200,000 shares to be reserved and authorized under the 2021 Plan plus any unallocated shares from the 2017 Plan.

There were 193,679 shares and 379,563 shares available for issuance as of June 30, 2021 and 2020, respectively.

Series B Preferred Stock—On January 24, 2020, the Company issued 4,782,608 shares of Series B Preferred Stock for $2,200,000. On January 29, 2020, the Company filed a certificate of correction to its amended and restated its certificate of incorporation to authorize the issuance of up to 16,500,000 shares of Series B Preferred Stock. On January 31, 2020, the Company issued an additional 1,739,130 shares of Series B Preferred Stock for $800,000.

On matters submitted to a vote of the stockholders of the Company, Series B Preferred Stock, Series A-1 Preferred Stock, and common stock vote together as one class, with the vote of the Series B Preferred Stock on an as-converted basis. Each holder of Series B Preferred Stock shall have a number of votes equal to the shares of common stock into which the shares of Series B Preferred Stock held by such holder are then convertible.

With respect rights on liquidation, winding up and dissolution, shares of Series B Preferred Stock rank senior to all shares of common stock, but not senior to Series A-1 Preferred Stock.

Each share of Series B Preferred Stock is convertible at any time at the option of the holder at the then current conversion rate. In addition, upon the closing of the sale of shares of common stock to the public in an initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, all shares of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate.

Accordingly, in connection with the IPO, all shares of the Company's Series B Preferred Stock were converted into 469,136 shares of common stock on October 15, 2020.

Below is a table that outlines the initial value of issuances allocated to Series B Preferred Stock and the Series B Preferred Stock discount amortized during the three and six months ended June 30:

	2020
Series B Preferred Stock	
Balance at January 1,	$ 1,306,900
Series B Preferred Stock proceeds	3,000,000
Series B Preferred Stock discount	(2,668,300)
Series B Preferred Stock discount amortization	368,400
Balance at March 31,	$ 2,007,000
Series B Preferred Stock discount amortization	324,300
Balance at June 30,	$ 2,331,300

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or the occurrence of a liquidation, the holders of the shares of Series B Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to $0.46, the original issue price.

Warrants Underlying Series B Preferred Stock—In connection with the sale of the Series B Preferred Stock, each investor was issued warrants to purchase 0.0859 shares of common stock for each share of Series B Preferred Stock purchased at a price of $0.003494 per share of common stock. The warrants become exercisable in accordance with the schedule set forth below following completion by the Company of an initial public offering and thereafter may be exercised at any time prior to expiration ten years from the date of issuance.

- 30% of the warrants beginning six months after the date on which the securities of the Company are first listed on a United States national securities exchange (such date, the "Listing Date");
- An additional 30% of the warrants beginning nine months after the Listing Date; and
- The remainder of the warrants beginning twelve months after the Listing Date.

As of June 30, 2020, the Company sold 16,391,397 shares of Series B Preferred Stock, which contained 1,399,921 underlying warrants to purchase common stock based on the exercise price and vesting schedule outlined above. These warrants are equity classified and the fair value of $5,533,000 is reflected as additional paid-in capital.

On June 8, 2020, the Company agreed to amend the warrant vesting schedule such that the warrants became immediately exercisable for each warrant holder.

On June 8, 2020, warrant holders exercised their option to purchase 335,982 shares of common stock for proceeds of $1,200. Then, on June 10, 2020, warrant holders exercised their option to purchase an additional 1,063,939 shares of common stock for proceeds of $3,700. As of June 30, 2021, there were no warrants underlying Series B Preferred Stock.

The Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions for the six months ended June 30, 2020:

Risk-free interest rate	1.54% - 1.88 %
Expected volatility	71.95% - 72.71 %
Expected life (years)	10
Expected dividend yield	0 %

Representative's Warrants—In connection with the IPO on October 15, 2020, the Company granted the underwriters warrants (the "Underwriters' Warrants") to purchase an aggregate of 62,500 shares of common stock at an exercise price of $15.00 per share, which is 125% of the initial public offering price. The Underwriters' Warrants have a five-year term and are not exercisable prior to April 13, 2021. All of the Underwriters' Warrants were outstanding at June 30, 2021.

These warrants were equity classified. As of June 30, 2021 and December 31, 2020, the warrant fair values of $307,700 and $357,300, respectively, is reflected as additional paid-in capital. On the issuance date, the Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following weighted-average assumptions on October 15, 2020:

Risk-free interest rate	0.18 %
Expected volatility	94.08 %
Expected life (years)	2.74
Expected dividend yield	0 %

10. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan— Stock Options

The Black-Scholes option-pricing model was used to estimate the fair value of stock options with the following weighted-average assumptions for the six months ended June 30:

	June 30, 2021	June 30, 2020
Risk-free interest rate	1.09 %	0.23% - 2.92 %
Expected volatility	83.34 %	72.29% - 82.15 %
Expected life (years)	6.22	4.93 - 6.07
Expected dividend yield	0 %	0 %

In the six months ended June 30, 2021, the fair value of the common shares underlying the stock options was determined by the closing stock price listed on the Nasdaq Capital Market on the grant date.

Prior to the Company’s initial public offering, the fair value of the common shares underlying the stock options had historically been determined by the board of directors, with input from management. Because there was no public market for the Company’s common shares prior to October 15, 2020, the board of directors determined the fair value of the common shares at the time of grant of the stock option by considering a number of objective and subjective factors, including important developments in the Company’s operations, third-party valuations performed, sales of Series A-1 Preferred Stock, sales of Series B Preferred Stock, actual operating results and financial performance, the conditions in

the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company's common shares, among other factors.

The following table summarizes the activity for all stock options outstanding at June 30 under the 2017 Plan:

	2021		2020	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	489,718	$ 10.03	598,083	$ 11.04
Granted	147,038	8.47	65,424	19.15
Exercised	(18,891)	6.64	—	—
Cancelled and forfeited	(59,430)	17.86	(45,508)	14.25
Balance at June 30	558,435	$ 8.90	617,999	$ 11.84
Options exercisable at June 30:	391,572	$ 8.84	382,204	$ 8.50
Weighted average grant date fair value for options granted during the year:		$ 8.47		$ 20.54

The intrinsic value of the options exercised during the six months ended June 30, 2021 was $33,000.

The following table summarizes additional information about stock options outstanding and exercisable at June 30, 2021 and 2020 under the 2017 Plan:

	Options Outstanding				Options Exercisable		
As of June 30,	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
2021	558,435	7.43	8.90	—	391,572	8.84	—
2020	617,999	8.03	11.84	2,008,892	382,204	8.50	1,718,959

Total stock compensation expense recognized from stock-based compensation awards classified as stock options were recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2021 and 2020 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 22,900	$ 386,000	$ 41,900	$ 811,000
General and administrative	54,900	57,000	156,900	88,000
Total	$ 77,800	$ 443,000	$ 198,800	$ 899,000

On August 20, 2020, the board of directors canceled and terminated 15,792 stock options, granted during the quarter ended June 30, 2020 to four non-employees. Thereafter, on August 20, 2020, the board of directors granted 21,112 stock options to the same individuals with a grant date fair value of $12.81 per share. There were 3,959 stock option grants that were considered vested on the grant date. The effects of the stock option modifications resulted in $14,000 and $34,900 of stock compensation expense allocable to general and administrative for the three and six months ended June 30, 2021, respectively. Included in that amount were $6,400 and $16,000 of incremental compensation costs resulting from the modifications for the three and six months ended June 30, 2021, respectively.

As of June 30, 2021, total unrecognized stock compensation expense is $1,054,500, related to unvested stock options to be recognized over the remaining weighted-average vesting period of 3.47 years.

2017 Stock Incentive Plan—Restricted Stock Units

In January 2017, the Company's board of directors approved the adoption of the 2017 Plan. The 2017 Plan permits the Company to grant up to 1,708,615 shares of the Company's common stock awards, including incentive stock options; non-statutory stock options; and conditional share awards to employees, directors, and consultants of the Company. All granted shares that are canceled, forfeited, or expired are returned to the 2017 Plan and are available for grant in conjunction with the issuance of new common stock awards. Restricted stock units ("RSUs") vest over a specified amount of time or when certain performance metrics are achieved by the Company.

In the six months ended June 30, 2021, the fair value of the common shares underlying restricted stock units was determined by the closing stock price listed on the Nasdaq Capital Market on the grant date.

Prior to the Company's initial public offering, the fair value of the common shares underlying the stock options had historically been determined by the board of directors, with input from management. As there was no public market for Company's common shares prior to October 15, 2020, the board of directors determined the fair value of the common shares at the time of grant of the RSUs by considering a number of objective and subjective factors, including important developments in the Company's operations, third-party valuations performed, sales of Series A-1 Preferred Stock, sales of Series B Preferred Stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company's common shares, among other factors.

The following table summarizes the activity for all RSUs outstanding at June 30 under the 2017 Plan:

	2021	
	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	946,245	$ 12.81
Granted	166,660	7.98
Vested	(36,791)	6.44
Cancelled and forfeited	(627)	9.00
Nonvested RSUs at June 30,	1,075,487	$ 12.28

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock units were recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2021, as follows:

	Three Months Ended June 30,	Six Months Ended June 30,
	2021	2021
Research and development	$ 866,100	$ 1,133,800
General and administrative	283,800	840,300
Total	$ 1,149,900	$ 1,974,100

On August 20, 2020, the board of directors canceled and terminated 709,334 RSUs, granted during the quarter ended June 30, 2020. The cancelled RSUs were originally granted to five individuals with a grant date fair value of $12.87 per share. Thereafter, on August 20, 2020, the board of directors granted 946,245 RSUs to the same individuals with a grant date fair value of $12.81 per share. None of the RSU grants were considered vested on the grant date. The RSU grants were modified for three employees and two non-employees.

The effects of the RSU modifications resulted in $268,900 and $621,800 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three months ended June 30, 2021. Included in those amounts were incremental compensation costs of $20,600 and $45,200 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three months ended June 30, 2021.

The effects of the RSU modifications resulted in $536,600 and $1,178,300 of stock compensation expense allocable to research and development and general and administrative, respectively, during the six months ended June 30, 2021. Included in those amounts were incremental compensation costs of $41,000 and $89,900 of stock compensation expense allocable to research and development and general and administrative, respectively, during the six months ended June 30, 2021.

2021 Stock Incentive Plan—Restricted Stock Units

In June 2021, the Company's board of directors approved the adoption of the 2021 Plan. The 2021 Plan permits the Company to grant up to 217,292 shares of the Company's common stock awards, including incentive stock options; non-statutory stock options; and conditional share awards to employees, directors, and consultants of the Company. All granted shares that are canceled, forfeited, or expired are returned to the 2021 Plan and are available for grant in conjunction with the issuance of new common stock awards. RSUs vest over a specified amount of time or when certain performance metrics are achieved by the Company.

In the six months ended June 30, 2021, the fair value of the common shares underlying restricted stock units was determined by the closing stock price listed on the Nasdaq Capital Market on the grant date.

The following table summarizes the activity for all RSUs outstanding at June 30, 2021 under the 2021 Plan:

	2021		2020	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	—	$ —	—	$ —
Granted	23,613	8.47	—	—
Vested	(4,723)	8.47	—	—
Cancelled and forfeited	—	—	—	—
Nonvested RSUs at June 30,	18,890	$ 8.47	—	$ —

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock units were recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2021 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
General and administrative	40,900	—	40,900	—
Total	$ 40,900	$ —	$ 40,900	$ —

11. INCOME TAXES

The Company’s effective tax rate from continuing operations was 0% for the three and six months ended June 30, 2021 and 2020. The Company recorded no income tax provision for the three and six months ended June 30, 2021 and 2020.

The provision for income taxes during the interim reporting periods is calculated by applying an estimate of the annual effective tax rate for the full fiscal year to "ordinary" income or loss for the reporting period. Each quarter, the estimate of the annual effective tax rate is updated, and if the estimated effective tax rate changes, a cumulative adjustment is made. There is a potential for volatility of the effective tax rate due to several factors, including changes in the mix of the pre-tax income and the jurisdictions to which it relates, changes in tax laws, business reorganizations and settlements with taxing authorities.

The income tax rates vary from the US federal statutory rate of 21% primarily due to the full valuation allowance on the Company’s deferred tax assets. The Company has recorded the full valuation allowance based on an evaluation of both positive and negative evidence, including latest forecasts and cumulative losses in recent years. The Company has concluded that it was more likely than not that none of its deferred tax assets would be realized.

12. RELATED PARTY TRANSACTIONS

During the three and six months ended June 30, 2020, the Company maintained two separate consulting agreements with the Company's CSIO, and the CFO and COO.

Beginning in the year ended December 31, 2014, the Company entered into its first consulting agreement with the CSIO. Pursuant to the amended agreement dated July 20, 2018, the CSIO is entitled to a consulting fee of $400 per hour, provided that he is limited to nineteen (19) hours per month unless he obtains approval from the Company's Chief Executive Officer. The consulting agreement indicates that the CSIO will provide a leadership role for the Company's business development strategies. The consulting fees paid to the CSO totaled $540,700 in the six months ended June 30, 2020. In addition, the Company issued the CSIO 320,000 shares of common stock on June 19, 2020 in exchange for services rendered and no cash considerations.

Beginning in the year ended December 31, 2018, the Company entered into its first consulting agreement with the CFO and COO. Initially, his title was "Consultant", and the Company changed his title to CFO and COO on October 25, 2019. The CFO and COO was elected as a director of the Company on January 17, 2020. Pursuant to the agreement on April 18, 2018 and amended on September 4, 2019, the CFO and COO is entitled to a consulting fee of $2,500 per month amended to $10,000 per month plus discretionary bonuses approved by management. The consulting fees paid to the CFO and COO totaled $100,000 in the six months ended June 30, 2020. In addition, the Company issued the CFO and COO 402,000 shares of common stock on June 19, 2020 in exchange for services rendered and no cash considerations.

After the Company completed the IPO on October 15, 2020, the CFO and COO and the CSIO became full time employees, at which time their consulting agreements were terminated.

There were no related party transactions during the three and six months ended June 30, 2021.

13. SUBSEQUENT EVENTS

Public Offering

On July 2, 2021, the Company received net proceeds of $37,121,200 for its public offering, after deducting underwriting discounts and commissions of $2,399,900 and other offering expenses of $478,900 incurred. The Company issued and sold 8,000,000 shares of common stock in the public offering at a price of $5.00 per share. In connection with the public offering, 400,000 representative warrants were issued with an exercise price of $6.25 per share.

Completion of In Silico Acquisition

On July 26, 2021, the Company completed its previously announced acquisition of In Silico, a bioinformatics and artificial intelligence company, pursuant to the Purchase Agreement with In Silico and the Seller.

Pursuant to the terms of the Purchase Agreement, the Company acquired 100% of the membership interest of In Silico by delivering 50,189 shares to the Seller, and granting 33,177 restricted stock units to the employees of In Silico under the Company's 2021 Plan (the "Acquisition"). At the closing of the Acquisition, In Silico became a wholly-owned subsidiary of the Company.

Due to the recent nature of the acquisition, the Company has not yet completed its assessment of the fair value of the assets acquired and liabilities assumed as of the date these condensed consolidated financial statements are issued. Once determined, the acquisition purchase price will be allocated to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition date assessed by management.

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

The following management's discussion and analysis of financial condition and results of operations provides information that management believes is relevant to an assessment and understanding of our plans and financial condition. The following financial information is derived from our financial statements and should be read in conjunction with such financial statements and notes thereto set forth elsewhere herein.

Overview

Kiromic BioPharma, Inc. (together with its subsidiary, "we," "us," "our" or the "Company") is a target discovery and gene-editing company utilizing artificial intelligence and our proprietary neural network platform with a therapeutic focus on immuno-oncology. Our proprietary target discovery engine is called "DIAMOND." We are focused on extending the benefits of immunotherapy by leveraging our proprietary technologies. Our approach seeks to generate a therapeutic immune response in patients by unleashing the demonstrated natural power of a patient's own immune system to recognize tumor-specific peptide sequences presented on cancer cells, known as tumor specific iso-antigens, capable of generating an immunological response and therefore eradicate cancer cells.

We are developing our brand of chimeric antigen receptor ("CAR") T cell product candidates known as ALEXIS. Our two product candidates are called ALEXIS-ISO-1 and ALEXIS-PRO-1. ALEXIS-ISO-1 is our allogenic gamma delta CAR-T cell therapy product candidate targeting Isomesothelin (the isoform of Mesothelin). ALEXIS-PRO-1 is our allogeneic gamma delta chimeric T cell therapy product candidate targeting PD-L1. These are designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells. These product candidates are in the pre-initial new drug ("IND") stages of the US Food and Drug Administration (the "FDA") clinical trial process. We are currently going through the IND enabling trials process and we expect that first in human dosing in Phase I of clinical trials will commence in the first quarter of 2022.

CAR T cell therapy, a form of cancer immunotherapy, has recently emerged as a revolutionary and potentially curative therapy for patients with hematologic cancers, including refractory cancers. In 2017, two autologous anti-CD19 CAR T cell therapies, Kymriah, developed by Novartis International AG, and Yescarta, developed by Kite Pharma, Inc., were approved by the FDA for the treatment of relapsing/remitting B-cell precursor acute lymphoblastic leukemia and relapsing/remitting large B cell lymphoma, respectively. Autologous CAR T cell therapies are manufactured individually for the patient's use by modifying the patient's own T cells outside the body, causing the T cells to express CARs. The entire manufacturing process is dependent on the viability of each patient's T cells and takes approximately two to four weeks. Allogenic T cell therapies involve engineering healthy donor T cells, which we believe will allow for the creation of an inventory of off-the-shelf products that can be delivered to a larger portion of eligible patients throughout the world.

We have not generated any revenue from sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since we began principal business operations in 2012.

Trends and Uncertainties—COVID-19

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on our business is highly uncertain and difficult to predict, as the responses that we, other businesses and governments are taking continue to evolve. Furthermore, capital markets and economies worldwide have also been negatively impacted by the COVID-19 pandemic, and it is possible that it could cause a local and/or global economic recession. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole. The magnitude and overall effectiveness of these actions remain uncertain.

The severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company's service providers, suppliers, contract research organizations and our clinical trials, all of which are uncertain and cannot be predicted. As of the date of this report, the extent to which the COVID-19 pandemic may in the future materially impact our financial condition, liquidity or results of operations is uncertain.

Recent Developments

We have sufficient cash on hand and available liquidity to meet our obligations through the twelve months following the date the condensed consolidated financial statements are issued. After taking into account the Company's cash flow projections, we don't believe we will have sufficient cash on hand or available liquidity to meet our obligations through the twelve months from the date of issuance of the condensed consolidated financial statements for the three months ending September 30, 2021. Therefore, this condition raises substantial doubt about the Company's ability to continue as a going concern. Management's plans were updated to further finance operations through additional equity or debt financing arrangements, and/or third-party collaboration funding; however, if we are unable to raise additional funding to meet working capital needs, we will be forced to delay or reduce the scope of its research programs and/or limit or cease operations. The negative cash flows and lack of financial resources raised substantial doubt as to our ability to continue as a going concern, and that substantial doubt has not been alleviated.

New Investigational Drug Application Resubmission Announcement

On December 17, 2020, we filed two investigational new drug applications with the U.S. Food and Drug Administration ("FDA"). The first application was for a Phase 1 clinical trial of intravenously administered allogenic CAR-T for epithelial ovarian carcinoma ("EOC") and malignant pleural mesothelioma ("MPM"). The second application was for a Phase 1 clinical trial of an intrapleural/intraperitoneal administered allogenic CAR-T for EOC and MPM.

Since filing the original applications in December 2020, we have had communications with the FDA, and numerous consults with scientific board and clinical advisors regarding resubmission. On March 9, 2021, we announced that we planned to resubmit the two investigational new drug applications. The revised applications will be for first in-human dosing of our Off-the-Shelf, Allogenic Gamma-Delta T cell therapy for metastatic and progressive locally advanced solid malignancies.

In May 2021, we resubmitted the two IND applications. The revised IND applications are for first in-human dosing of our Off-the-Shelf, Allogenic Gamma-Delta T cell therapy for metastatic and progressive locally advanced solid malignancies. On May 17, 2021, we announced that the first IND application was for a Phase I clinical trial of our ALEXIS-PRO-1 product candidate. On May 24, 2021, we announced that the second IND application was for a Phase 1 clinical trial of our ALEXIS-ISO-1 product candidate.

Principal Factors Affecting Our Financial Performance

Our operating results are primarily affected by the following factors:

- slow or delayed IND applications;
- slow or delayed clinical trial enrollment;
- patent reinforcement and prosecution; and
- changes in laws or the regulatory environment affecting our company.

Emerging Growth Company

We qualify as an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As a result, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. For so long as we are an emerging growth company, we will not be required to:

- have an auditor report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;

- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);

- submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay" and "say-on-frequency;" and

- disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We will remain an emerging growth company for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our total annual gross revenues exceed $1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. We will record revenue from collaboration agreements, including amounts related to upfront payments, annual fees for licenses of our intellectual property and research and development funding. However, none of those agreements have been executed as of the issuance date of this report.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates. These include the following:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;

- expenses incurred under agreements with third parties, including contract research organizations and other third parties that conduct preclinical research and development activities and clinical trials on our behalf;

- costs of developing and scaling our manufacturing process and manufacturing drug products for use in our preclinical studies and future clinical trials, including the costs of contract manufacturing organizations, that will manufacture our clinical trial material for use in our preclinical studies and potential future clinical trials;

- costs of outside consultants, including their fees and related travel expenses;

- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;

- license payments made for intellectual property used in research and development activities; and

- facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs if specifically, identifiable to research activities.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future and will comprise a larger percentage of our total expenses as we initiate a Phase 1/2a clinical trial for our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates and continue to discover and develop additional product candidates.

We cannot determine with certainty the duration and costs of future clinical trials of our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, or any other product candidate we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates and any other our product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation for personnel in our executive, finance, business development, operations and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs that are not specifically attributable to research activities.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued research activities and development of product candidates. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

The following table sets forth key components of our results of operations for the three months ended June 30, 2021 and 2020.

	Three Months Ended June 30,		Increase (Decrease)	
	2021	2020	$	%
Operating expenses:				
Research and development	$ 2,658,100	$ 1,272,300	$ 1,385,800	108.92 %
General and administrative	2,314,100	10,094,600	(7,780,500)	(77.08)%
Total operating expenses	4,972,200	11,366,900	(6,394,700)	(56.26)%
Loss from operations	(4,972,200)	(11,366,900)	(6,394,700)	(56.26)%
Other expense				
Interest expense	(2,100)	—	(2,100)	(100.00)%
Total other expense	(2,100)	—	(2,100)	(100.00)%
Net loss	$ (4,974,300)	$ (11,366,900)	$ (6,396,800)	(56.28)%

Research and development expenses. Our research and development expenses increased by $1,385,800, or 108.92%, to $2,658,100 for the three months ended June 30, 2021, from $1,272,300 for the three months ended June 30, 2020. The following table summarizes our research and development expenses by product candidate or development program:

	Three Months Ended June 30,		Increase (Decrease)	
	2021	2020	$	%
Direct research and development expenses by product candidate:				
ALEXIS-PRO-1	$ 7,900	$ 21,500	$ (13,600)	(100.00)%
ALEXIS-ISO-1	407,400	39,900	367,500	100.00 %
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	929,600	703,200	226,400	32.20 %
Laboratory supplies and services	239,000	58,900	180,100	305.77 %
Outsourced research and development	746,000	282,100	463,900	164.45 %
Laboratory equipment and maintenance	27,500	12,400	15,100	121.77 %
Facility-related costs	208,500	99,200	109,300	110.18 %
Intellectual Property	88,800	54,300	34,500	63.54 %
Other research and development costs	3,400	800	2,600	325.00 %
Total research and development expenses	$ 2,658,100	$ 1,272,300	$ 1,385,800	108.92 %

As illustrated above, the increase in research and development expenses resulted from (i) a $367,500 increase in ALEXIS-ISO-1 direct research and development costs which primarily included a $289,100 increase in disposables and consumables, and a $44,200 increase in outsourced research and development fees, all of which attributed to Gamma Delta T-Cell manufacturing and in-vivo experimentation; (ii) a $226,400 increase in employee related costs, which primarily included a $365,200 increase in wages, benefits and payroll taxes, offset by reduced stock compensation expenses of $110,800 attributable to research and development employees; (iii) a $463,900 increase in outsourced research and development costs, which primarily included a $532,900 increase in regulatory consulting fees with the offsetting balance resulting from reduced research studies totaling $60,100, and stock compensation expenses attributed to non-employees compared to the prior period; (iv) a $109,300 increase in facility-related costs, primarily driven by $71,400 increase in allocated depreciation expenses, $5,200 increase in allocated rent expenses, and the remaining increase attributed to repairs, maintenance, and utilities; (v) a $180,100 increase in laboratory supplies in services, which primarily included a $25,000 increase in supplies and a $159,200 increase in spending on disposables and consumables for experimentation, testing, validation of our other key value drivers, with the remaining offsetting balance driven by

reduced postage spending; and (vi) a $34,500 increase in intellectual property which consists of increased legal expenses and intellectual property filing primarily attributed to DIAMOND and other technologies currently in development.

These cost increases were primarily incurred to support Gamma Delta T-Cell manufacturing as well as experimentation and validation of our product candidates.

1. Augmented our research and development team: In the three months ended June 30, 2021 and 2020, our average headcount increased to 21.5 employees from seven employees allocable to research and development and clinical trials preparation.

2. ALEXIS-ISO-1 Manufacturing and Experimentation: $367,500 increase in spending during the three months ended June 30, 2021 from manufacturing expanded Gamma Delta T-Cells in the recently completed GMP facilities. In addition, in-vivo experimentation costs in the recently completed vivarium facilities contributed to the increase.

General and administrative expenses. Our general and administrative expenses decreased by $7,780,500, or 77.08%, to $2,314,100 for the three months ended June 30, 2021 from $10,094,600 for the three months ended June 30, 2020.

During the three months ended June 30, 2021, the decrease primarily resulted from a decrease in stock compensation expenses of $8,486,700. That decrease was offset by increased professional services of $130,300, wages and salaries of $351,700, and insurance of $142,400.

The decrease in stock compensation expense was driven by the June 2020 common stock issuances of 722,000 shares to our Chief Financial Officer, and Chief Strategy and Innovation Officer which resulted in $9,386,000 of non-recurring stock compensation expenses. That decrease was offset by expenses related to stock option grant modification totaling $890,700 incurred during the three months ended June 30, 2021.
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The increase in professional services expenses was primarily driven by an increase of $138,000 from consulting and corporate development fees incurred during the three months ended June 30, 2021 compared to the same period in the prior year.

Employee related expenses were impacted by increases to headcount, and employee salary rates. During the three months June 30, 2021 and 2020, the headcount for employees allocated to general and administrative purposes increased to eight employees from four employees, respectively. In addition, the Chief Executive Officer's salary increased to an annual rate of $504,000 from $280,000 as of June 30, 2021 and 2020, respectively.

Finally, the increase in insurance costs is driven by our financing arrangement for the Director and Officer Insurance policy. We entered this policy in November of 2020. The total amount of expense incurred from that policy during the three months ended June 30, 2021 totaled $135,100.

Interest expense. Interest expense was $2,100 and $0 for the three months ended June 30, 2021 and 2020, respectively. The increase is entirely driven by cash paid for interest attributed to the financing arrangement for our Director and Officer Insurance policy. The total amount financed was $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months. As of June 30, 2021, the remaining payable balance on the financed amount was $91,600.

Net loss. As a result of the cumulative effect of the factors described above, our net loss decreased to $4,974,300 during the three months ended June 30, 2021 compared to $11,366,900 during the three months ended June 30, 2020.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table sets forth key components of our results of operations for the six months ended June 30, 2021 and 2020.

	Six Months Ended June 30,		Increase (Decrease)	
	2021	2020	$	%
Operating expenses:				
Research and development	$ 4,543,700	$ 2,300,400	$ 2,243,300	97.52 %
General and administrative	4,385,100	10,919,200	(6,534,100)	(59.84)%
Total operating expenses	8,928,800	13,219,600	(4,290,800)	(32.46)%
Loss from operations	(8,928,800)	(13,219,600)	(4,290,800)	(32.46)%
Other income (expense)				
Gain on loan extinguishment	105,800	—	105,800	100.00 %
Interest expense	(5,800)	—	(5,800)	(100.00)%
Total other income (expense)	100,000	—	(22,400)	(100.00)%
Net loss	$ (8,828,800)	$ (13,219,600)	$ (4,313,200)	(32.63)%

Research and development expenses. Our research and development expenses increased by $2,243,300, or 97.52%, to $4,543,700 for the six months ended June 30, 2021, from $2,300,400 for the six months ended June 30, 2020. The following table summarizes our research and development expenses by product candidate or development program:

	Six Months Ended June 30,		Increase (Decrease)	
	2021	2020	$	%
Direct research and development expenses by product candidate:				
ALEXIS-PRO-1	$ 33,900	$ 39,400	$ (5,500)	(13.96)%
ALEXIS-ISO-1	892,100	54,600	837,500	100.00 %
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	1,785,500	1,127,100	658,400	58.42 %
Laboratory supplies and services	359,700	125,500	234,200	186.61 %
Outsourced research and development	896,000	678,100	217,900	32.13 %
Laboratory equipment and maintenance	59,900	26,800	33,100	123.51 %
Facility-related costs	364,300	177,900	186,400	104.78 %
Intellectual Property	148,800	69,000	79,800	115.65 %
Other research and development costs	3,500	2,000	1,500	75.00 %
Total research and development expenses	$ 4,543,700	$ 2,300,400	$ 2,243,300	97.52 %

As illustrated above, the increase in research and development expenses resulted from (i) a $837,500 increase in ALEXIS-ISO-1 direct research and development costs which primarily included a $673,400 increase in disposables and consumables, a $44,400 increase in outsourced research and development fees, a $25,800 increase in non-capitalizable equipment and maintenance, and a $57,500 increase in supplies, all of which attributed to Gamma Delta T-Cell manufacturing and in-vivo experimentation; (ii) a $658,400 increase in employee related costs, which primarily included a $654,000 increase in wages, benefits and payroll taxes; (iii) a $217,900 increase in outsourced research and development costs, which primarily included a $564,100 increase in regulatory consulting fees with the offsetting balance resulting from reduced stock compensation expenses attributed to non-employees compared to the prior period; (iv) a $186,400 increase in facility-related costs, primarily driven by $132,700 increase in allocated depreciation expenses, $13,500 increase in allocated rent expenses with the remaining amount attributed to repairs, maintenance, and utilities; (v) a $234,200 increase in laboratory supplies in services, which primarily included a $65,600 increase in supplies and a $166,800 increase in spending on disposables and consumables for experimentation, testing, validation of our other key value drivers, with the remaining balance driven by postage spending; and (vi) a $79,800 increase in

intellectual property which consists of increased legal expenses and intellectual property filing primarily attributed to DIAMOND and other technologies currently in development;

These cost increases were primarily incurred to support Gamma Delta T-Cell manufacturing as well as experimentation and validation of our product candidates.

1. Augmented our research and development team: In the six months ended June 30, 2021 and 2020, our average headcount increased to 18.5 employees from 6 employees allocable to research and development and clinical trials preparation.

2. ALEXIS-ISO-1 Manufacturing and Experimentation: $837,500 increase in spending during the six months ended June 30, 2021 from manufacturing expanded Gamma Delta T-Cells in the recently completed GMP facilities. In addition, in-vivo experimentation costs in the recently completed vivarium facilities contributed to the increase.

General and administrative expenses. Our general and administrative expenses decreased by $6,534,100, or 59.54%, to $4,385,100 for the six months ended June 30, 2021 from $10,919,200 for the six months ended June 30, 2020.

During the six months ended June 30, 2021, the decrease primarily resulted from a decrease in stock compensation expenses of $7,859,200. That decrease was offset by increased professional services of $641,700, wages and salaries of $550,300, and insurance of $284,700.

The decrease in stock compensation expense was driven by the June 2020 common stock issuances of 722,000 shares to our Chief Financial Officer, and Chief Strategy and Innovation Officer which resulted in $9,386,000 of non-recurring stock compensation expenses. That decrease was offset by expenses related to stock option grant modification totaling $1,178,300 incurred during the six months ended June 30, 2021. The remaining offsetting balance is mainly driven by increased stock compensation expense during the six months ended June 30, 2021 from amortized expense of executive performance-based restricted stock unit grants.

The increase in professional services expenses was driven by an increase of $361,900 from accounting and audit fees and an increase of $279,900 of other consulting and corporate development fees incurred during the six months ended June 30, 2021 compared to the same period in the prior year.

Employee related expenses were impacted by increases to headcount, and employee salary rates. During the six months June 30, 2021 and 2020, the headcount for employees allocated to general and administrative purposes increased to 8 employees from 3.5 employees, respectively. In addition, the Chief Executive Officer's salary increased to an annual rate of $504,000 from $280,000 as of June 30, 2021 and 2020, respectively.

Finally, the increase in insurance costs is driven by our financing arrangement for the Director and Officer Insurance policy. We entered this policy in November of 2020. The total amount of expense incurred from that policy during the six months ended June 30, 2021 totaled $270,200.

Gain on loan extinguishment. Gain on loan extinguishment was $105,800 and $0 for the six months ended June 30, 2021 and 2020, respectively. During the year ended December 31, 2020, we applied for forgiveness of the SBA Loan in accordance with the terms of the CARES Act. On February 16, 2021 the SBA granted forgiveness of the SBA Loan and all applicable interest. On the date of forgiveness, the principal and accrued interest totaled $105,800.

Interest expense. Interest expense was $5,800 and $0 for the six months ended June 30, 2021 and 2020, respectively. The increase is entirely driven by cash paid for interest attributed to the financing arrangement for our Director and Officer Insurance policy. The total amount financed was $540,500 with an annual interest rate of 4.59%, to be paid over a period of nine months. As of June 30, 2021, the remaining payable balance on the financed amount was $91,600.

Net loss. As a result of the cumulative effect of the factors described above, our net loss decreased to $8,828,800 during the six months ended June 30, 2021 compared to $13,219,600 during the six months ended June 30, 2020.

Liquidity and Capital Resources

As of June 30, 2021, we had cash and cash equivalents of $3,070,400. As of December 31, 2020 we had cash and cash equivalents of $10,150,500. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sale of our convertible promissory notes, preferred stock, and common stock from the initial public offering.

Based on our forecasted expenditures related to our ongoing clinical trials and research and development efforts following the completion of our public offering on July 2, 2021, we determined that we have sufficient cash on hand and available liquidity to meet our obligations through the twelve months following the date the condensed consolidated financial statements are issued. After taking into account our cash flow projections, we do not believe we will have sufficient cash on hand or available liquidity to meet our obligations through the twelve months from the date of issuance of the condensed consolidated financial statements for the three months ending September 30, 2021. We have incurred significant operating losses since inception, and we expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will increase. These costs include conducting preclinical studies and clinical trials for our product candidates, contracting with clinical research organizations and building out internal capacity to have product candidates manufactured to support preclinical studies and clinical trials, expanding our intellectual property portfolio and providing general and administrative support for our operations. As a result, substantial doubt exists regarding the going concern assumption on our condensed consolidated financial statements. Therefore, these condition raises substantial doubt about our ability to continue as a going concern.

We are seeking significant additional capital funding to develop our platform, additional hiring of scientific professionals, hiring other general and administrative employees, and clinical trials. However, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable. In consideration of our plans, substantial doubt is not alleviated.

Summary of Cash Flow

The following table sets forth a summary of our cash flows for the periods presented:

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (6,344,100)	$ (2,603,800)
Net cash used in investing activities	(590,600)	(762,300)
Net cash (used for) provided by financing activities	(145,400)	3,120,500
Net decrease in cash and cash equivalents	(7,080,100)	(245,600)
Cash and cash equivalents at beginning of the period	10,150,500	1,929,100
Cash and cash equivalents at end of the period	3,070,400	1,683,500

Cash flows from operating activities

Net cash used in operating activities was $6,344,100 for the six months ended June 30, 2021, as compared to $2,603,800 for six months ended June 30, 2020. In the six months ended June 30, 2021, net loss of $8,828,800 and outflows from

the gain on loan extinguishment of $105,800. These cash outflows were offset by stock compensation expenses from stock options and restricted stock units of $2,213,800, prepaid expenses and other current assets of $151,500, and depreciation of $202,400. Net cash used in operating activities decreased by a total of $3,470,300 period-over-period. The main driver for the decrease is the $8,817,200 decrease in stock compensation expenses, offset by the decrease in net loss of $4,390,800. We primarily used cash to augment our headcount, develop our ALEXIS-ISO-1 product candidate, and pay for other corporate development costs. See "Results of Operations" above for further details.

Cash flows from investing activities

Net cash used in investing activities was $590,600 for the six months ended June 30, 2021, as compared to $762,300 for the six months ended June 30, 2020. Our net cash used in investing activities consisted entirely of purchases of property and equipment. This decrease was primarily driven by reduced cash outflows from equipment and leasehold improvements attributed to our Clean Room and Vivarium current good manufacturing practices facilities located in our Houston office.

Cash flows from financing activities

Cash outflows from financing activities was $145,400 during the six months ended June 30, 2021. Net cash provided by financing activities during the six months ended June 30, 2020 totaled $3,120,500.

During the six months ended June 30, 2021, we paid $270,800 towards our financing arrangement for our Director and Officer Insurance policy. This outflow was offset by exercised stock options resulting in proceeds of $125,400. During the six months ended June 30, 2020, the net cash provided by financing activities consisted of proceeds from the Series B Preferred Stock round of financing totaling $3,000,000 and proceeds from a loan payable of $115,600.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements for any of the periods presented.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles ("U.S. GAAP") requires our management to make assumptions, estimates and judgments that affect the amounts reported, including the notes thereto, and related disclosures of commitments and contingencies, if any. We have identified certain accounting policies that are significant to the preparation of our financial statements. These accounting policies are important for an understanding of our financial condition and results of operation. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require management's difficult, subjective, or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Certain accounting estimates are particularly sensitive because of their significance to financial statements and because of the possibility that future events affecting the estimate may differ significantly from management's current judgments. We believe the following critical accounting policies involve the most significant estimates and judgments used in the preparation of our financial statements:

Fair Value Measurements—The carrying value of our cash and cash equivalents, prepaid expenses and other assets, accounts payable, accrued expenses and other current liabilities approximate their fair value due to their short-term nature.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In estimating the fair value of an asset or a liability, we take into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date.

We account for financial instruments in accordance with Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures*. ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices in non-active markets or in active markets for similar assets or liabilities, observable inputs other than quoted prices, and inputs that are not directly observable but are corroborated by observable market data.

Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

There were no changes in the fair value hierarchy leveling during the six months ended June 30, 2021 and 2020.

Stock-Based Compensation— We record stock compensation expense related to our 2017 Equity Incentive Plan and 2021 Equity Incentive Plan in accordance with ASC 718, *Compensation—Stock Compensation*. We measure and recognize stock compensation expense for all stock-based awards, including stock options and restricted stock units ("RSUs").

Stock compensation expense for RSUs is based on estimated fair values recognized using the straight-line method over the requisite service period, as long as the performance obligations in the RSU agreement are deemed probable by management. Stock compensation expense for stock options is based on estimated fair values recognized using the straight-line method over the requisite service period. The fair value of stock options is estimated on the grant date using the Black-Scholes option-valuation model. The calculation of stock-based compensation expense requires that we make assumptions and judgments about the variables used in the Black- Scholes option-valuation model, including the fair value of our common stock, expected term, expected volatility of the underlying common stock, and risk-free interest rate. Forfeitures are accounted for when they occur.

We estimate the grant-date fair value of stock options using the Black-Scholes option-valuation model. During the six months ended June 30 2021 and 2020, all stock option equity grants under the 2017 Equity Incentive Plan and 2021 Equity Incentive Plan contained assumptions used to value such stock options, and were determined as follows:

Expected Term. The expected term represents the period that our stock options are expected to be outstanding. We have used the SAB No. 110, simplified method to calculate the expected term, which is the average of the contractual term and vesting period. We do not plan to continue to use the SAB 110 simplified method after we have sufficient trading history as a publicly traded company.

Risk-Free Interest Rate. We base the risk-free interest rate used in the Black-Scholes option-valuation model on the implied yield available on US Treasury zero-coupon issues with a term equivalent to that of the expected term of the stock options for each stock option group.

Volatility. We determine the price volatility based on the historical volatilities of industry peers as we have limited trading history for our common stock price. We intend to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of our own common stock price becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

Dividend Yield. The expected dividend assumption is based on our current expectations about our anticipated dividend policy. To date, we have not declared any dividends and, therefore, we used an expected dividend yield of zero.

Common Stock Valuations. During the six months ended June 30, 2021, we used our listed Nasdaq Capital Market closing price on the grant date to determine common stock valuation.

During the six months ended June 30, 2020, the fair value of the common stock underlying our stock-based compensation grants was determined by our board of directors, with input from management and third-party valuations. We believe that the board of directors had the relevant experience and expertise to determine the fair value of our common stock. Given the absence of a public trading market of our common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately- Held Company Equity Securities Issued as Compensation*, the board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors include:

- valuations of the common stock performed by third-party specialists;
- the prices, rights, preferences, and privileges of our Series A-1 Preferred Stock and Series B Preferred Stock relative to those of our common stock;
- lack of marketability of the common stock;

- current business conditions and projections;
- hiring of key personnel and the experience of management;
- our stage of development;
- likelihood of achieving a liquidity event, a merger or acquisition of our company given prevailing market conditions, or other liquidation event;
- the market performance of comparable publicly traded companies; and
- the U.S. and global capital market conditions.

In valuing our common stock, the board of directors determined the equity value of our business using various valuation methods including combinations of income and market approaches. The income approach estimates value based on the expectation of future cash flows that a company will generate. These future cash flows are discounted to their present values using a discount rate derived from an analysis of the cost of capital of comparable publicly traded companies in our industry or similar business operations as of each valuation date and is adjusted to reflect the risks inherent in our cash flows. The market approach references actual transactions involving (i) the subject being valued, or (ii) similar assets and/or enterprises.

For each valuation, the equity value determined by the income and market approaches was then allocated to the common stock using either the option pricing method, or OPM, or probability—weighted expected return model, or PWERM.

The option pricing method is based on the Black Scholes option valuation model, which allows for the identification of a range of possible future outcomes, each with an associated probability. The OPM is appropriate to use when the range of possible future outcomes is difficult to predict and thus creates highly speculative forecasts. In general, while simple in its application, management did not use the OPM approach when considering allocation techniques for the valuation of equity interests in early stage, privately held life science companies. Management determined that applying the OPM would violate the major assumptions of the Black Scholes option valuation model approach. Additionally, the simulation approach can generally be reasonably approximated by a scenario-based approach like the PWERM as described below.

PWERM involves a forward-looking analysis of the possible future outcomes of the enterprise. This method is particularly useful when discrete future outcomes can be predicted at a relatively high confidence level with a probability distribution. Discrete future outcomes considered under the PWERM include an initial public offering, as well as non- initial public offering market-based outcomes. Determining the fair value of the enterprise using the PWERM requires us to develop assumptions and estimates for both the probability of an initial public offering liquidity event and stay private outcomes, as well as the values we expect those outcomes could yield. Since in February 2018, we have valued our common stock based on a PWERM.

Application of our approach involves the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding expected future revenue, expenses, and future cash flows, discount rates, market multiples, the selection of comparable companies, and the probability of possible future events. Changes in any or all of these estimates and assumptions or the relationships between those assumptions impact valuations as of each valuation date and may have a material impact on the valuation of our common stock.

For valuations after the completion of an initial public offering, the board of directors will determine the fair value of each share of underlying common stock based on the closing price of the common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in assumptions or market conditions.

Warrants Underlying Shares of IPO Common Stock— We record warrants to purchase shares of common stock underlying our shares of IPO common stock in accordance with ASC 470, *Debt with conversion and other options*. The fair value of the warrants was estimated on the IPO date using the Black-Scholes option- valuation model. The calculation of warrants requires that we make assumptions and judgments about the variables used in the Black-Scholes option-valuation model, including the fair value of our common stock, expected term, expected volatility of the underlying common stock, risk-free interest rate, and exercise price.

We estimate the fair value of warrants using the Black-Scholes option-valuation model and the assumptions used to value such warrants are determined as follows:

Expected Term. The expected term represents the period that our warrants are expected to be outstanding. The expected term was calculated by taking the average of the vesting period and contract period.

Risk-Free Interest Rate. We base the risk-free interest rate used in the Black-Scholes option-valuation model on the implied yield available on US Treasury zero-coupon issues with a term equivalent to that of the expected term of the warrants.

Volatility. We determine the price volatility based on the historical volatilities of industry peers as we had one day of trading history as of the initial public offering date. We intend to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of our own common stock price becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

Dividend Yield. The expected dividend assumption is based on our current expectations about our anticipated dividend policy. To date, we have not declared any dividends and, therefore, we used an expected dividend yield of zero.

Common Stock Valuations. The fair value of our common stock when the warrants were issued is equal to the IPO common stock issuance price of $12.00 per share.

Exercise Price. The representative warrants' exercise price to purchase common stock is $15.00 per share.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position, results of operations, or cash flows upon adoption.

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which requires lessees to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. In July 2018, the FASB issued ASU 2018-11 to amend certain aspects of Topic 842. These amendments provide entities with an additional (and optional) transition method to adopt Topic 842. Under this transition method, an entity initially applies the transition requirements in Topic 842 at that Topic's effective date with the effects of initially applying Topic 842 recognized as a cumulative effect adjustment to the opening balance of retained earnings (or other components of equity or net assets, as appropriate) in the period of adoption. On April 8, 2020, the FASB changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2022. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

In June 2016, FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The amendments in ASU 2016-13 affect entities holding financial assets and net investment in leases that are not accounted for at fair value

through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. On April 8, 2020, the FASB has changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2023. The Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2021. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under 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. Management recognizes that 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. Under the supervision, and with the participation, of our current management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our 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”), as of June 30, 2021. Based on this evaluation of our disclosure controls and procedures, our management, including our CEO and CFO, have concluded that our disclosure controls and procedures were not effective as of June 30, 2021 because of the material weaknesses in our internal control over financial reporting described below.

Material Weaknesses

In connection with the audit of our financial statements for the year ended December 31, 2020, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses are because we do not have a formal process for period end financial closing and reporting, and also because we have insufficient resources to conduct an effective monitoring and oversight function independent from our operations. These material weaknesses result in an increased risk of material misstatement in the financial statements.

We believe we are addressing these weaknesses through measures including:

- implementation of additional internal control processes and procedures regarding the financial close and reporting process, procure to pay process, and human resources and payroll process;

- designing those controls with the appropriate segregation of duties

- The recruitment of a full time accounting and finance personnel, including, but not limited to, personnel focused upon enhanced scrutiny of accounting entries in the areas where we have observed material weaknesses in our internal control over financial reporting.

Our management is monitoring these weaknesses and will continue to evaluate whether the remedial actions being taken by the Company have remediated these weaknesses when it completes its evaluation of the Company's internal control over financial reporting for the year ending December 31, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

From time to time in the future, we may become involved in litigation or other legal proceedings that arise in the ordinary course of business. A complaint was filed on March 22, 2021 in the Court of Chancery of the State of Delaware against us by a former consultant and director. The complaint alleges, among other things, that the plaintiff is entitled to additional stock options and he is seeking declaratory judgment and specific performance. We believe that all of the claims in the complaint are without merit and we intend to defend vigorously against them.

We are not currently party to any other legal proceedings, and we are not aware of any other pending or threatened litigation against us that we believe could have a material adverse effect on our business, operating results or financial condition. To the extent that we are subject to a legal proceeding, it could have a material adverse impact on us because of litigation costs and diversion of management resources.

ITEM 6. EXHIBITS.

See Exhibit Index.

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
2.1	Membership Interest Purchase Agreement dated as of June 14, 2021 among Kiromic BioPharma, Inc., In Silico Solution, LLC and Michael Ryan (incorporated by reference to Exhibit 2.1 to Form 8-K filed on June 17, 2021)
10.1	Executive Employment Agreement by and between the Company and Mr. Ignacio Nunez, effective as of June 7, 2021 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 7, 2021)
10.2	Executive Employment Agreement by and between the Company and Dr. Michael Ryan, effective as of July 1, 2021 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 8, 2021)
31.1	Certifications of Principal Executive Officer filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certifications of Principal Financial Officer filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certifications of Principal Executive Officer furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certifications of Principal Financial Officer furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

SIGNATURES

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

Date: August 13, 2021

KIROMIC BIOPHARMA, INC.

/s/ Maurizio Chiriva-Internati

Name: Maurizio Chiriva-Internati

Title: Chief Executive Officer

(Principal Executive Officer)

/s/ Tony Tontat

Name: Tony Tontat

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Maurizio Chiriva-Internati, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Kiromic BioPharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2021

/s/ Maurizio Chiriva-Internati

Maurizio Chiriva-Internati
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Tony Tontat, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Kiromic BioPharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2021

/s/ Tony Tontat
Tony Tontat
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

The undersigned Chief Executive Officer of KIROMIC BIOPHARMA, INC. (the "Company"), DOES HEREBY CERTIFY that:

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

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement on August 13, 2021.

/s/ Maurizio Chiriva-Internati
Maurizio Chiriva-Internati
Chief Executive Officer
(Principal Executive Officer)

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

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

The undersigned Chief Financial Officer of KIROMIC BIOPHARMA, INC. (the "Company"), DOES HEREBY CERTIFY that:

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

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement on August 13, 2021.

/s/ Tony Tontat
Tony Tontat
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.