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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 September 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 Stock, 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 March 11, 2022, there were 15,585,587 shares of the registrant's common stock outstanding.

Kiromic BioPharma, Inc.

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

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Kiromic BioPharma, Inc.

Quarterly Report on Form 10-Q

For the quarterly period ended September 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 sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and “Risk Factors”. 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;
- our expected timing of human clinical trials and other related milestones;
- 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;
- relevant government policies and regulations relating to our industry; and
- the outcome of any pending or threatened litigation.

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 Registration Statement on Form S-1 (Registration No. 333-257427) , originally filed with the Securities and Exchange Commission (SEC) on June 25, 2021, as amended, and under “Risk Factors” included 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)

	September 30, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 35,161,800	$ 10,150,500
Accounts receivable	5,800	—
Prepaid expenses and other current assets	750,500	588,800
Total current assets	35,918,100	10,739,300
Property and equipment, net	2,578,800	2,066,000
Other assets	31,200	24,400
Intangible assets, net	41,800	—
Goodwill	386,000	—
Total Assets	$ 38,955,900	$ 12,829,700
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 927,700	$ 665,200
Accrued expenses and other current liabilities	517,100	334,200
Interest payable	—	200
Loan payable	—	105,600
Note payable	—	362,400
Total current liabilities	1,444,800	1,467,600
Total Liabilities	1,444,800	1,467,600
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Common stock, $0.001 par value: 300,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 15,477,518 shares and 7,332,999 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	9,300	1,200
Additional paid-in capital	94,083,200	52,988,700
Accumulated deficit	(56,581,400)	(41,627,800)
Total Stockholders' Equity	37,511,100	11,362,100
Total Liabilities and Stockholders' Equity	$ 38,955,900	$ 12,829,700

See accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 3,486,700	$ 1,225,700	$ 8,030,400	$ 3,526,100
General and administrative	2,655,600	1,190,000	7,040,700	12,109,200
Total operating expenses	6,142,300	2,415,700	15,071,100	15,635,300
Loss from operations	(6,142,300)	(2,415,700)	(15,071,100)	(15,635,300)
Other income (expense)				
Gain on loan extinguishment	—	—	105,800	—
Other income	18,000		18,000	
Interest expense	(500)	—	(6,300)	—
Total other income (expense)	17,500	—	117,500	—
Net loss	$ (6,124,800)	$ (2,415,700)	$ (14,953,600)	$ (15,635,300)
Net loss per share, basic and diluted	$ (0.40)	$ (0.48)	$ (1.50)	$ (4.39)
Weighted average common shares outstanding, basic and diluted	15,366,075	4,989,269	10,048,170	3,719,132

See accompanying notes to the condensed consolidated financial statements

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

	Three and Nine Months Ended September 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
Common stock issuance net of issuance costs and discount amortization	8,000,000	8,000	36,144,400	—	36,152,400
Warrants underlying common stock issuances discount amortization	—	—	(85,500)	—	(85,500)
Warrants underlying common stock issuances	—	—	1,051,200	—	1,051,200
Common shares issued for Insilico Solutions LLC Membership Purchase Agreement	50,189	—	400,000	—	400,000
Restricted stock units issued for Insilico Solutions LLC Membership Purchase Agreement	33,177	—	140,000	—	140,000
Released restricted stock units	6,652	—	—	—	—
Stock compensation expense	—	—	1,105,300	—	1,105,300
Net loss	—	—	—	(6,124,800)	(6,124,800)
Balance at September 30, 2021	15,477,518	$ 9,300	$ 94,083,200	$ (56,581,400)	$ 37,511,100

See accompanying notes to the condensed consolidated financial statements

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

	Three and Nine Months Ended September 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
Stock compensation expense	—	—	—	—	—	—	1,249,000	—	1,249,000
Net loss	—	—	—	—	—	—	—	(2,415,700)	(2,415,700)
Balance at September 30, 2020	21,822,301	$9,134,700	16,391,397	$2,331,300	4,989,269	—	27,525,500	(38,062,900)	928,600

See accompanying notes to the condensed consolidated financial statements

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (14,953,600)	$ (15,635,300)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	331,200	118,900
Amortization	2,200	
Stock compensation expense	3,319,100	11,580,000
Gain on loan extinguishment	(105,800)	—
Changes in operating assets and liabilities, net of effects from acquisitions:		
Accounts receivable	20,200	—
Prepaid expenses and other current assets	(168,500)	(149,800)
Accounts payable	216,000	398,300
Accrued expenses and other current liabilities	182,900	130,700
Net cash used for operating activities	(11,156,300)	(3,557,200)
Cash flows from investing activities:		
Purchases of property and equipment, net of effects from acquisitions	(797,500)	(1,013,100)
Cash received from acquisition	84,000	—
Net cash used for investing activities	(713,500)	(1,013,100)
Cash flows from financing activities:		
Proceeds from issuance of common stock	40,000,000	—
Issuance cost	(2,881,900)	—
Exercise of stock options	125,400	—
Proceeds from warrant exercise	—	4,900
Proceeds from loan payable	—	115,600
Loan repayments	(362,400)	(10,000)
Proceeds from Series B Preferred Stock issuance	—	3,000,000
Net cash provided by financing activities	36,881,100	3,110,500
Net change in cash and cash equivalents	25,011,300	(1,459,800)
Cash and cash equivalents:		
Beginning of year	10,150,500	1,929,100
End of period	$ 35,161,800	$ 469,300
Supplemental disclosures of non-cash investing and financing activities:		
Accruals for property and equipment	$ 46,500	$ 130,200
Cash paid for interest on note payable	$ 6,300	$ —
Common stock issuance for acquisition	$ 400,000	$ —
Restricted stock units granted for acquisition	$ 140,000	$ —
Acquisitions net of cash acquired	$ 456,000	$ —
Accruals for deferred public offering costs	$ —	$ 813,000
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 subsidiaries (the "Company") is a clinical stage fully integrated biotherapeutics 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 an artificial intelligence-driven, end-to-end CAR-T and gene therapy company, developing the first multi-indication allogeneic CAR-T cell therapy, that exploits the natural potency of Gamma Delta T-cells to target solid cancers. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

In June 2021, the FDA placed the IND applications on clinical hold and asked the Company to address key components regarding the chemical manufacturing and control components of the applications. Those components included tracing of all reagents used in manufacturing, flow chart of manufacturing processes, and Certificate of Analysis. The Company is still working towards addressing each of the FDA's comments.

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 $11,156,300 for the nine months ended September 30, 2021, and an accumulated deficit of $56,581,400 as of September 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 does not have sufficient cash on hand or available liquidity to meet its obligations through the twelve months following the date the condensed consolidated financial statements are issued. 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's plans include evaluating different strategies to obtain the required funding of future operations. These plans 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 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. The Company applied for

another Phase I extension in August 2021, and the extension was not granted. The Company does not expect to be reimbursed for any of the amounts for Phase II.

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 with 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 Public Offering common stock, and estimating services incurred by third-party service providers used to recognize research and development expense.

Cash and Cash Equivalents—As of September 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 Initial Public Offering Costs—In the nine months ended September 30, 2020, the Company began incurring costs in connection with the filing of a Registration Statement on Form S-1/A for an initial public offering, which are deferred in other current assets in accordance with ASC 505-10-25 in the condensed consolidated balance sheet. Initial public offering costs consist of legal, accounting, and other costs directly related to the Company’s efforts to raise capital. As of September 30, 2020, $933,100 of deferred costs related to the initial public offering were classified as other current assets on the condensed consolidated balance sheet.

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 capitalized software development costs of $180,000 and $10,200 for the nine months ended September 30, 2021 and both the nine months ended September 30, 2020 and year ended December 31, 2020, respectively.

Goodwill— In connection with the Insilico Solutions LLC acquisition, the Company recognized goodwill for the excess of the purchase price over the fair value of tangible and identifiable intangible net assets of the business acquired. The Company will review goodwill for impairment annually on November 30, and whenever events or circumstances in interim periods indicate that it is more likely than not that an impairment may have occurred. The Company will continue to monitor results in future periods to determine whether any indicators of impairment exist that would cause us to perform an impairment review.

Intangible Assets—In connection with the Insilico Solutions LLC acquisition, the Company recognized the fair value of non-compete contracts, which are classified as intangible assets. The fair value of intangible assets was determined by the income approach. The income approach of valuation is where an evaluation is conducted as to the potential future income is expected from intangible assets. Then a present value calculation is done on the future income flow, to reach the recognized fair value at the date of purchase.

Subsequently, intangible assets will be amortized over their remaining useful life, which is estimated to be 5 years.

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 have 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 nine months ended September 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 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 nine months ended September 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, accounts receivable, 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 nine months ended September 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' ("the Board") 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 nine months ended September 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 nine months ended September 30, 2020, the Board, 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 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 a follow-on 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 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 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. Accordingly, Topic 842 is effective for the Company beginning in the first quarter of 2022. Modified retroactive transition approach will be required for operating leases existing at or entered into after the beginning of the earliest comparative period presented. Though the Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows, the Company expects that adopting the new standard will result in recording a material lease liability and right-of-use asset associated with the Company's facility lease agreement and subsequent amendments thereto.

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 SHARE OF COMMON STOCK

Basic and diluted net loss per share of common stock is determined by dividing net loss less deemed dividends by the weighted-average shares of common stock outstanding during the period. For all periods presented, the shares of common stock 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 shares of common stock outstanding used to calculate both basic and diluted loss per share of common stock are the same. The following table illustrates the computation of basic and diluted earnings per share:

	Three Months Ended September 30,		Nine Months Ended September30,	
	2021	2020	2021	2020
Net loss	$ (6,124,800)	$ (2,415,700)	$ (14,953,600)	$ (15,635,300)
Less: Series B Preferred Stock discount amortization	—	—	—	(692,700)
Less: Initial Public Offering Common Stock discount amortization	(25,200)	—	(74,800)	—
Less: Public Offering Common Stock discount amortization	(60,300)	—	(60,300)	—
Net loss attributable to common shareholders, basic and diluted	$ (6,210,300)	$ (2,415,700)	$ (15,088,700)	$ (16,328,000)
Weighted average common shares outstanding, basic and diluted	15,366,075	4,989,269	10,048,170	3,719,132
Net loss per common share, basic and diluted	$ (0.40)	$ (0.48)	$ (1.50)	$ (4.39)

Subsequent to the issuance of the June 30, 2021 condensed consolidated financial statements, the Company identified an error related to the calculation of net loss per share for the three months ended September 30, 2020. The Company used an incorrect calculation of weighted average shares outstanding during that period to calculate net loss per share. Accordingly, the Company restated the weighted average shares outstanding calculation for the three months ended September 30, 2020 from 3,719,132 shares to 4,989,269 shares and the resulting net loss per share calculation from $(0.65) to $(0.48) per share on the condensed consolidated statement of operations and the related footnote. The Company has evaluated the materiality of this error and concluded that it is not material to the prior period.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Options to purchase	—	1,484	—	1,484
Restricted Stock Units	6,698	36,368	73,366	36,368
Series A-1 Preferred Stock	—	624,594	—	624,594
Series B Preferred Stock	—	496,136	—	452,378
Total	6,698	1,158,582	73,366	1,114,824

4. PROPERTY AND EQUIPMENT

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

	September 30, 2021	December 31, 2020
Equipment	$ 1,586,500	$ 780,500
Leasehold improvements	1,403,300	1,229,700
Office furniture, fixtures, and equipment	16,600	16,600
Software	331,700	151,700
Construction in progress	133,600	449,200
	3,471,700	2,627,700
Less: Accumulated depreciation	(892,900)	(561,700)
Total	$ 2,578,800	$ 2,066,000

Depreciation expense was $128,800 and $50,400 for the three months ended September 30, 2021 and 2020, respectively, and $331,200 and $118,900 for the nine months ended September 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 September 30, 2021, and December 31, 2020:

	September 30, 2021	December 31, 2020
Accrued consulting and outside services	$ 385,700	$ 143,200
Accrued compensation	131,400	191,000
Total	$ 517,100	$ 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 September 30, 2021, this financing arrangement was paid in its entirety. As of December 31, 2020, the remaining payable balance on the financed amount was $362,400.

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 Board 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 lease.

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

	Amount
2021	$ 136,700
2022	546,700
2023	551,100
2024	461,200
Total	$ 1,695,700

Rent expense for the facility lease agreement was $126,900 and $67,700 during the three months ended September 30, 2021 and 2020, respectively, and $270,810 and $194,800 during the nine months ended September 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 September 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.

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 has filed a motion to dismiss the complaint which is pending.

On or about August 17 and 23, 2021, Tony Tontat, who at the time was the Chief Financial Officer and a member of the Board, submitted substantially identical reports (the "Complaints") through our complaint hotline. These Complaints, alleged, among other topics, risks associated with our public disclosures in our securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the FDA authorization of our IND applications and (ii) the anticipated timing of human clinical trials. These Complaints were subsequently submitted to the Audit Committee of the Board.

After receiving the Complaints, the Audit Committee recommended that the Board form, and the Board did in turn form, a Special Committee comprised of three independent directors (the "Special Committee") to review the Complaints and other related issues (the "Internal Review"). The Special Committee retained an independent counsel to assist it in conducting the Internal Review.

On February 2, 2022, following the conclusion of the Internal Review, the Company's Special Committee reported the results of its Internal Review to the Board. The Board approved certain actions to address the fact that the Company had received communications from the FDA on June 16 and June 17, 2021 that the FDA was placing the IND applications that the Company submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively, on clinical hold (the "June 16 and 17, 2021 FDA Communications"). On July 13, 2021, the Company received the FDA's formal clinical hold letters, which asked the Company to address key components regarding the chemical, manufacturing, and control components of the IND applications. On July 16, 2021, the Company issued a press release disclosing that it had received comments from the FDA on the two INDs, but did not use the term "clinical hold." The Company then consummated a public offering of $40 million of its common stock pursuant to the Registration Statement on July 2, 2021. On August 13, 2021, the Company issued a press release announcing that these INDs were placed on clinical hold. The Company did not disclose the June 16 and 17, 2021 FDA Communications in (i) the Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"); or (ii) the Form 10-Q for the fiscal quarter ended June 30, 2021 that was filed with the Securities and Exchange Commission on August 13, 2021.

As a result of the disclosure omission of the June 16 and 17 FDA Communications, the Company has concluded that it is reasonably possible that unasserted claims exist for future litigation and losses as of September 30, 2021. However, the Company is unable to estimate any possible range of loss attributed to these unasserted claims at this time. See Note 14 for additional information regarding loss contingencies associated with these unasserted claims transpiring after September 30, 2021.

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

9. ACQUISITIONS

InSilico Solutions, LLC

On July 26, 2021, the Company completed its previously announced acquisition of InSilico Solutions, LLC ("InSilico") pursuant to the Membership Interest Purchase Agreement (the "Purchase Agreement") with InSilico and Michael Ryan (the "Seller").

Pursuant to the terms of the Purchase Agreement, the Company acquired 100% of the membership interest of InSilico by delivering 50,189 shares to the Seller, and granting 33,177 restricted stock units to the employees of InSilico under the Company's 2021 Plan (the "Acquisition"). At the closing of the Acquisition, InSilico became a wholly-owned subsidiary of the Company. InSilico, based in Fairfax, VA, is a world class bioinformatics and artificial intelligence services company.

The Company has provisionally estimated fair values for the assets purchased, liabilities assumed, and purchase consideration as of the date of acquisition in the following table. The determination of the estimated fair value required management to make significant estimates and assumptions. The amounts reported are considered provisional as the Company is completing the valuations that are required to allocate the purchase price in areas such as intangible assets and goodwill. As a result, the allocation of the items below may change in the future. See below for the fair value of purchase consideration and fair value of net assets acquired.

	Estimated Fair Value at Acquisition Date
Fair value of purchase consideration	
Fair value of common stock issued to Seller	$ 400,000
Fair value of restricted stock units granted	140,000
Fair value of purchase consideration	$ 540,000
Fair value of net assets acquired	
Cash	$ 84,000
Accounts receivable	26,000
Fixed asset	1,000
Intangible assets (a)	44,000
Goodwill (b)	386,000
Other current liabilities	(1,000)
Fair value of net assets acquired	540,000

(a) Intangible assets are composed of non-compete contracts ($44,000 fair value and 5 year amortization period).

(b) Goodwill represents the excess of the purchase price over the fair value of tangible and identifiable intangible net assets of the business acquired. This amount also includes intangible assets that do not qualify for separate recognition, combined with synergies expected from integrating InSilico processes with the Company's.

10. 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 September 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 September 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 Initial Public Offering ("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.

On July 2, 2021, the Company received net proceeds of $37,118,100 from a public offering, after deducting underwriting discounts and commissions of $2,494,900 and other offering expenses of $387,000 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.

Below is a table that outlines the initial value of issuances allocated to the IPO and public offering of common stock and the IPO and public offering common stock discount amortization, during the three and nine months ended September 30, 2021:

	2021
Common Stock	
Balance at January 1,	$ 11,975,400
Common stock initial public offering discount amortization	24,700
Balance at March 31,	$ 12,000,100
Common stock initial public offering discount amortization	24,900
Balance at June 30,	$ 12,025,000
Common stock issuance from public offering, net of underwriting discounts and commissions and other offering expenses	37,118,100
Common stock public offering discount	(1,051,200)
Common stock public offering discount amortization	25,200
Common stock public offering discount amortization	60,300
Balance at September 30,	$ 48,177,400

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 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 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 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 251,916 shares and 270,933 shares available for issuance as of September 30, 2021, and December 31, 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 nine months ended September 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
Series B Preferred Stock discount amortization	—
Balance at September 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 September 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 nine months ended September 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 September 30, 2021.

These warrants were equity classified. As of September 30, 2021, and December 31, 2020, the warrant fair values of $282,500 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 %

In connection with the public offering on July 2, 2021, the Company granted the underwriters warrants to purchase an aggregate of 400,000 shares of common stock at an exercise price of $6.25 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 January 2, 2022. All of the Underwriters' Warrants were outstanding at September 30, 2021.

These warrants were equity classified. As of September 30, 2021, the warrants contained a fair value of $991,000 and 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 July 2, 2021:

Risk-free interest rate	0.40 %
Expected volatility	98.27 %
Expected life (years)	2.75
Expected dividend yield	0 %

11. 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 nine months ended September 30:

	September 30, 2021	September 30, 2020
Risk-free interest rate	1.09 %	0.15% - 2.92 %
Expected volatility	83.34 %	72.29% - 82.52 %
Expected life (years)	6.22	4.93 – 6.07
Expected dividend yield	0 %	0 %

In the nine months ended September 30, 2021, the fair value of the shares of common stock 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 shares of common stock underlying the stock options had historically been determined by the Board, with input from management. Because there was no public market for the Company's shares of common stock prior to October 15, 2020, the Board determined the fair value of the shares of common stock 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 shares of common stock, among other factors.

The following table summarizes the activity for all stock options outstanding at September 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	86,536	17.95
Exercised	(18,891)	6.64	—	—
Cancelled and forfeited	(64,427)	17.67	(66,109)	15.06
Balance at September 30	553,438	$ 8.84	618,510	$ 11.58
Options exercisable at September 30:	396,020	$ 8.87	390,075	$ 8.51
Weighted average grant date fair value for options granted during the year:		$ 8.47		$ 17.43

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

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

	Options Outstanding				Options Exercisable		
As of September 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	553,438	6.49	8.84	—	396,020	8.87	—
2020	618,510	7.79	11.58	1,787,200	390,075	8.51	1,521,400

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 nine months ended September 30, 2021 and 2020 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 44,500	$ 169,000	$ 86,400	$ 980,000
General and administrative	32,500	160,000	189,400	248,000
Total	$ 77,000	$ 329,000	$ 275,800	$ 1,228,000

On August 20, 2020, the Board 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 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 $0 and $34,900 of stock compensation expense allocable to general and administrative for the three and nine months ended September 30, 2021, respectively. Included in that amount were $0 and $16,000 of incremental compensation costs resulting from the modifications for the three and nine months ended September 30, 2021, respectively.

The effects of the stock option modifications resulted in $71,600 of stock compensation expense allocable to general and administrative for the three and nine months ended September 30, 2020. Included in that amount were $19,700 of incremental compensation costs resulting from the modifications for the three and nine months ended September 30, 2020.

As of September 30, 2021, total unrecognized stock compensation expense is $919,900, related to unvested stock options to be recognized over the remaining weighted-average vesting period of 3.42 years.

2017 Stock Incentive Plan—Restricted Stock Units

In January 2017, the Company's Board 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 nine months ended September 30, 2021, the fair value of the shares of common stock 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 shares of common stock underlying the stock options had historically been determined by the Board, with input from management. As there was no public market for Company's shares of common stock prior to October 15, 2020, the Board of directors determined the fair value of the shares of common stock 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 shares of common stock, among other factors.

The following table summarizes the activity for all RSUs outstanding at September 30 under the 2017 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	946,245	$ 12.81	—	$ —
Granted	166,660	7.98	1,655,579	15.23
Vested	(37,802)	6.51	—	—
Cancelled and forfeited	(136,445)	12.79	(709,334)	19.00
Nonvested RSUs at September 30,	938,658	$ 12.28	946,245	$ 12.81

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 nine months ended September 30, 2021, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 99,400	$ 299,000	$ 2,000,600	$ 299,000
General and administrative	866,900	621,000	939,800	621,000
Total	$ 966,300	$ 920,000	$ 2,940,400	$ 920,000

On August 20, 2020, the Board 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 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 $62,300 and $108,500 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three months ended September 30, 2021. Included in those amounts were incremental compensation costs of $11,500 and $25,300 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three months ended September 30, 2021.

The effects of the RSU modifications resulted in $598,900 and $1,286,800 of stock compensation expense allocable to research and development and general and administrative, respectively, during the nine months ended September 30, 2021. Included in those amounts were incremental compensation costs of $52,500 and $115,200 of stock compensation expense allocable to research and development and general and administrative, respectively, during the nine months ended September 30, 2021.

The effects of the RSU modifications resulted in $299,000 and $621,000 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three and nine months ended September 30, 2020. Included in those amounts were incremental compensation costs of $65,600 and $141,200 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three and nine months ended September 30, 2020.

2021 Stock Incentive Plan—Restricted Stock Units

In June 2021, the Board 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 nine months ended September 30, 2021, the fair value of the shares of common stock 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 September 30, 2021 under the 2021 Plan:

	2021	
	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	—	$ —
Granted	102,613	5.20
Vested	(37,900)	4.75
Cancelled and forfeited	—	—
Nonvested RSUs at September 30,	64,713	$ 5.46

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 nine months ended September 30, 2021, as follows:

	Three Months Ended September 30,	Nine Months Ended September 30,
	2021	2021
Research and development	11,000	11,000
General and administrative	51,000	91,900
Total	$ 62,000	$ 102,900

12. INCOME TAXES

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

13. RELATED PARTY TRANSACTIONS

Through September 30, 2020, the Company maintained two separate consulting agreements with the Company's Chief Strategy and Innovation Officer ("CSIO"), and the Chief Financial Officer and Chief Operating Officer ("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 CSIO totaled $579,700 in the nine months ended September 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 $140,000 in the nine months ended September 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 nine months ended September 30, 2021.

14. SUBSEQUENT EVENTS

Director and Officer Insurance Policy Renewal

In November 2021, the Company entered into a financing arrangement to renew its Director and Officer Insurance policy. The total amount financed was approximately $665,900 with an annual interest rate of 4.59%, to be paid over a period of ten months. As of February 28, 2022 the remaining payable balance on the financed amount was $342,200. The effective date for the policy was October 16, 2021 and has a term of thirteen months from the effective date.

Legal Complaint Filed Against the Company

Sabby Volatility Warrant Master Fund Ltd., et al. v. Kiromic BioPharma, Inc. et al., Case No. 22-cv-1927 (SDNY). On March 7, 2022, entities related to Sabby Management LLC (the "Sabby Entities") and Empery Asset Management, LP (the "Empery Entities") filed a complaint in the District Court for the Southern District of New York alleging claims against the Company and certain current and former officers and directors of the Company for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock through the Company's public offering that closed on July 2, 2021. The plaintiffs seek unspecified damages; rescission to the extent they still hold the Company's securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. The Company expects to vigorously defend against this claim. The Company has evaluated that it is reasonably possible that the Sabby Entities' and Empery Entities' claims may result in an estimated loss ranging between $0 and $8,100,000. Similarly, the Company has evaluated that it is reasonably possible that other unasserted claims in future litigation and losses may occur. However, the Company is unable to estimate any possible range of loss attributed to other unasserted claims at this time.

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 immune-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. We filed two IND applications in May 2021 for ALEXIS-ISO-1 and ALEXIS-PRO-1. The FDA has placed these applications under a clinical hold as of June 2021. We are currently working on addressing the FDA's comments. Accordingly, we expect the clinical hold will be lifted in the second half of 2022 allowing the activation of ALEXIS-PRO-1 clinical trial by the end of the last quarter, followed by that of ALEXIS-ISO-1.

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 and Recent Events

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 caused a local and/or global economic recession and global supply chain shortages. 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, the effective of vaccines against new or emerging variants 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 do not 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. Therefore, this condition raises substantial doubt about the Company's ability to continue as a going concern. Management's plans were updated to evaluate different strategies to obtain the required funding of future operations. These plans may include, but are not limited to, additional funding from current or new investors; 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 our 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.

Updates on KiroVAX/BSK01 Phase 1 clinical trial

On October 25, 2021, we announced to the public, results of a published pilot Phase 1 clinical trial of KiroVAX/BSK01 that showed that the KiroVax/BSK01 vaccine, in combination with chemotherapy, demonstrated a significant progression free survival (PFS) benefit in one of the patients with metastatic pancreatic cancer who participated in the trial.

KiroVax/BSK01, was the Company's Phase 1 cancer vaccine candidate and consisted of professional antigen presenting cells (dendritic cells) which were matured and pulsed with tumor specific antigens, yielding a tumor-targeted, next-generation therapeutic vaccine designed for multiple types of solid cancers. The trials terminated during fiscal year 2018 due to enrollment limitations. Although strategies have not yet been activated to advance the KiroVax/BSK01 platform, Kiromic is planning to leverage its clinical experience with KiroVax/BSK01 to develop an innovative technology aimed to boost the persistency of its allogenic cell therapy products.

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. 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.

In June 2021, the FDA placed the IND applications on clinical hold and asked us to address key components regarding the chemical manufacturing and control components of the application. Those components included tracing of all reagents used in manufacturing, flow chart of manufacturing processes, and Certificate of Analysis. We are still working towards addressing each of the FDA's comments.

InSilico Solutions LLC Acquisition

In July 2021, we completed our previously announced acquisition of InSilico Solutions, LLC ("InSilico") pursuant to the Purchase Agreement with InSilico and Dr. Michael Ryan ("the Seller"). InSilico, based in Fairfax, VA, is a world class bioinformatics and artificial intelligence services company.

Pursuant to the terms of the Purchase Agreement, the Company acquired 100% of the membership interest of InSilico by delivering 50,189 shares to the Seller, and granting 33,177 restricted stock units to the employees of InSilico under the Company's 2021 Omnibus Equity Incentive Plan. At the closing of the acquisition, InSilico became a wholly-owned subsidiary of the Company.

We note that we may not recognize all the benefits from this acquisition, including certain intangible assets. Accordingly, we will periodically review the goodwill and intangible assets for impairment. If we find any events or circumstances that causes the carrying amount to exceed fair value, an impairment loss will be recognized to adjust the fair value of the goodwill or intangible asset.

Results from our Internal Review

On or about August 17 and 23, 2021, Tony Tontat, who at the time was the Chief Financial Officer and a member of the Board of Directors ("the Board"), submitted substantially identical reports (the "Complaints") through our complaint hotline. These Complaints, alleged, among other topics, risks associated with our public disclosures in our securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the U.S. Food and Drug Administration's ("FDA") authorization of our investigational new drug ("IND") applications and (ii) the anticipated timing of human clinical trials. These Complaints were subsequently submitted to the Audit Committee of the Board.

After receiving the Complaints, the Audit Committee recommended that the Board form, and the Board did in turn form, a Special Committee comprised of three independent directors (the "Special Committee") to review the Complaints and other related issues (the "Internal Review"). The Special Committee retained an independent counsel to assist it in conducting the Internal Review.

On February 2, 2022, following the conclusion of the Internal Review, the Special Committee reported the results of its Internal Review to the Board. The Board approved certain actions to address the fact that we had received communications from the FDA on June 16 and June 17, 2021 that the FDA was placing our IND applications that we submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively, on clinical hold (the "June 16 and 17, 2021 FDA Communications"). On July 13, 2021, we received the FDA's formal clinical hold letters, which asked us to address key components regarding the chemical, manufacturing, and control components of the IND applications. On July 16, 2021, we issued a press release disclosing that it had received comments from the FDA on our two INDs, but did not use the term "clinical hold." On August 13, 2021, we issued a press release announcing that these INDs were placed on clinical hold. We did not disclose the June 16 and 17, 2021 FDA Communications in (i) our Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"); or (ii) our Form 10-Q for the fiscal quarter ended June 30, 2021 that was filed with the Securities and Exchange Commission on August 13, 2021. We consummated a public offering of $40 million of our common stock pursuant to the Registration Statement on July 2, 2021.

In the course of the Internal Review, the Special Committee also identified that Mr. Tontat submitted incorrect information regarding his educational background to us. Specifically, although Mr. Tontat represented to us that he held a BA in Economics from Harvard University, it was determined that he had actually received an ALB, a degree conferred by the Harvard Extension School. We have implemented changes to our vetting process for prospective director and officer candidates including the implementation of thorough background checks to verify background information provided by such candidates.

Remediation Actions resulting from the Internal Review

1. The Board approved the inclusion of certain Risk Factors for inclusion in this Quarterly Report on Form 10-Q for its fiscal quarter ended September 30, 2021. See Item 4. Controls and Procedures for more information.

2. On January 10, 2022, the Board approved the formation of a Disclosure Committee comprised of certain members of the management including (i) its Chief Executive Officer; (ii) the executive in charge of overseeing submissions of any nature to the FDA; (iii) its Chief Financial Officer; (iv) its General Counsel, if any; (v) its Controller, if any; (vi) any other finance executive overseeing financial disclosures; (vii) the executive in charge of investor relations, if any; and (viii) such other employees as the Chief Financial Officer, who serves as chairman of the Disclosure Committee, may invite from time to time. The Disclosure Committee shall be responsible for preparing and reviewing all corporate disclosures made by us to our security holders, the Securities and Exchange Commission and/or the broader investment community to ensure that such disclosures (i) shall be accurate and complete; (ii) shall fairly present, in all material respects, our financial condition, results of operations and cash flows; and (iii) shall be made on a timely basis in accordance with all applicable requirements of (A) the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder, (B) the Securities Act of 1933, as amended and the rules and regulations promulgated thereunder (C) the Nasdaq Stock Market or such other stock exchange on which the our securities may be traded and (D) any other applicable laws or legal requirements. The Board adopted and approved the Disclosure Committee Charter.

3. The Board terminated Maurizio Chiriva-Internati as Chief Executive Officer for cause on January 27, 2022, after the Special Committee's Internal Review found evidence of conduct that the Board believed was inconsistent with the company policies. Under the terms of the Executive Employment Agreement between Dr. Chiriva and the Company effective as of July 1, 2020, as amended October 21, 2021, as the result of the termination of his employment, Dr. Chiriva also is deemed to have resigned as a Director on the Board effective as of January 27, 2022.

4. The Board named Pietro Bersani as Interim Chief Executive Officer, effective as of January 27, 2022. A search for a permanent Chief Executive Officer will be commenced with the assistance of an executive recruiter. Mr. Bersani has resigned from all Committees of the Board.

5. The Board named independent Director Michael Nagel as Chairperson of the Board, effective as of January 27, 2022.

6. The Board approved the appointment of Frank Tirelli as a member of the Board to fill a vacancy, effective as of January 28, 2022. The Board has determined that Mr. Tirelli is "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). Mr. Tirelli has been named Chairperson of the Audit Committee effective January 28, 2022. He was also nominated and appointed as a member of the Nominating and Corporate Governance Committee effective March 1, 2022. Mr. Tirelli was nominated by our Nominating and Corporate Governance Committee of the Board after a thorough review of all his background, relevant experience, and professional and personal reputations.

7. On February 10, 2022, we and Dr. Scott Dahlbeck ("Dr. Dahlbeck") entered into a Modification to Employment Agreement dated as of February 9, 2022 (the "Dahlbeck Agreement"). The Dahlbeck Agreement amends and supersedes certain terms of the Employment Agreement dated as of January 1, 2020, between the Company and Dr. Dahlbeck. Pursuant to the Dahlbeck Agreement, effective as of February 9, 2022, Dr. Dahlbeck's title was changed to Chief of Staff, and he ceased to be our Chief Medical Officer and Head of Clinical.

8. On February 10, 2022, we and Mr. Gianluca Rotino ("Mr. Rotino") entered into a Transition and Consulting Agreement dated as of February 9, 2022 (the "Rotino Agreement"). Pursuant to the terms of the Rotino Agreement, effective as of February 9, 2022, Mr. Rotino's employment as our Chief Strategy and Innovation Officer terminated and the Company retained Mr. Rotino to provide consulting services to the Company for a period of nine months (or until November 9, 2022). Notwithstanding the foregoing, the Rotino Agreement may be terminated by either us or Mr. Rotino upon 30 days' prior written notice, except no such prior notice shall be required in the event we terminate the Rotino Agreement for cause.

Under the terms of the Executive Employment Agreement between Mr. Rotino and the Company effective as of July 1, 2020, as amended October 21, 2020, as the result of the termination of Mr. Rotino's employment, Mr. Rotino is deemed to have resigned as a member of the Board effective as of February 9, 2022.

9. The Board approved the appointment of Karen Reeves as a member of the Board to fill a vacancy, effective as of February 14, 2022. The Board has determined that Dr. Reeves is "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). Dr. Reeves was nominated and appointed to be the Nominating and Corporate Governance Committee Chairperson and a member of the Compensation Committee effective March 1, 2022. Dr. Reeves was nominated by our Nominating and Corporate Governance Committee of the Board after a thorough review of all her background, relevant experience, and professional and personal reputations.

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 ½a 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;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- our ability to effectively address the deficiencies elucidated in the FDA's clinical hold letters for our IND applications related to key chemical manufacturing and control components.

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, development, and manufacturing of product candidates. We also have incurred and expect to continue 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 September 30, 2021 and 2020

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

	Three Months Ended September 30,		Increase (Decrease)	
	2021	2020	$	%
Operating expenses:				
Research and development	$ 3,486,700	$ 1,225,700	$ 2,261,000	184.47 %
General and administrative	2,655,600	1,190,000	1,465,600	123.16 %
Total operating expenses	6,142,300	2,415,700	3,726,600	154.27 %
Loss from operations	(6,142,300)	(2,415,700)	3,726,600	154.27 %
Other income (expense)				
Other income	18,000	—	18,000	100.00 %
Interest expense	(500)	—	(500)	(100.00)%
Total other expense	17,500	—	17,500	100.00 %
Net loss	$ (6,124,800)	$ (2,415,700)	$ 3,709,100	153.54 %

Research and development expenses. Our research and development expenses increased by $2,261,000, or 184.47%, to $3,486,700 for the three months ended September 30, 2021, from $1,225,700 for the three months ended September 30, 2020. The following table summarizes our research and development expenses by product candidate or development program:

	Three Months Ended September 30,		Increase (Decrease)	
	2021	2020	$	%
Direct research and development expenses by product candidate:				
ALEXIS-PRO-1	$ 20,300	$ 3,000	$ 17,300	576.67 %
ALEXIS-ISO-1	434,100	177,400	256,700	144.70 %
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	1,288,200	813,300	474,900	58.39 %
Laboratory supplies and services	384,200	100,000	284,200	284.20 %
Outsourced research and development	984,400	(23,800)	1,008,200	(4,236.13)%
Laboratory equipment and maintenance	31,200	22,300	8,900	39.91 %
Facility-related costs	204,800	104,600	100,200	95.79 %
Intellectual Property	137,300	28,800	108,500	376.74 %
Other research and development costs	2,200	100	2,100	2,100.00 %
Total research and development expenses	$ 3,486,700	$ 1,225,700	$ 2,261,000	184.47 %

As illustrated above, the increase in research and development expenses resulted from (i) a $256,700 increase in ALEXIS-ISO-1 direct research and development costs which primarily included a $249,100 increase in disposables and consumables, which contributed to Gamma Delta T-Cell manufacturing and invitro and in-vivo experimentation; (ii) a $474,900 increase in employee related costs, which primarily included a $773,200 increase in wages, benefits and payroll taxes, offset by reduced stock compensation expenses of $313,100 attributable to research and development employees; (iii) a $1,008,200 increase in outsourced research and development costs, which primarily included a $797,600 increase in regulatory consulting fees, and a $194,200 increase in research studies; (iv) a $100,200 increase in facility-related costs, primarily driven by $75,100 increase in allocated depreciation expenses, $39,500 increase in allocated rent expenses, and the remaining offsetting difference attributed to repairs, maintenance, and utilities; (v) a $284,200 increase in laboratory supplies in services, which was driven by increased in spending on supplies, disposables, and consumables for experimentation, testing, validation of our other key value drivers; and (vi) a $108,500

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 September 30, 2021 and 2020, our average headcount increased to 31 employees from nine employees allocable to research and development and clinical trials preparation.

2. ALEXIS-ISO-1 Manufacturing and Experimentation: $256,700 increase in spending during the three months ended September 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.

3. Increased regulatory consulting costs: in the three months ended September 30, 2021, we incurred an increase of $797,600 in regulatory and chemical manufacturing and control consulting fees compared to the same three months in 2020 as we are working towards addressing the FDA's comments regarding our IND applications filed during May 2021.

General and administrative expenses. Our general and administrative expenses increased by $1,465,600, or 123.16%, to $2,655,600 for the three months ended September 30, 2021, from $1,190,000 for the three months ended September 30, 2020.

During the three months ended September 30, 2021, the increase primarily resulted from an increase in professional services of $594,600, employee related expenses of $480,900, and stock compensation expenses of $169,400.

The increase in professional services expenses was primarily driven by an increase of $266,600 in legal expenses, $193,200 from corporate finance professional fees, and $134,800 in accounting, audit, tax, and other professional consulting fees during the three months ended September 30, 2021, compared to the same period in the prior year. We incurred significant legal expenses and accounting professional fees related to the Internal Review after September 30, 2021. Between October 1, 2021 and January 31, 2022, we incurred $3,147,900 in legal fees and other professional services attributed to the Internal Review and related matters. During that same period, we incurred $427,200 in accounting professional fees directly related to the Internal Review. These elevated legal, accounting, and other related professional services expenses are continuing through the date of this report, and will likely continue thereafter.

Employee related expenses were impacted by increases to headcount, recruiting, and employee salary rate increases. During the three months September 30, 2021 and 2020, the headcount for employees allocated to general and administrative purposes increased to 12 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 September 30, 2021 and 2020, respectively.

The increase in stock compensation expense was driven by the July 2020 grant of $140,000 in relation to the InSilico Solutions, LLC acquisition. This was a non-recurring item attributed to the three months ended September 30, 2021, which allowed us consummate the membership purchase agreement with InSilico Solutions, LLC.

Other income. Other income was $18,000 and $0 for the three months ended September 30, 2021 and 2020, respectively. The increase is entirely driven by service billings from our bioinformatics employees to large academic institutions. The bioinformatics employees joined us in July 2021 as part of the InSilico Solutions, LLC acquisitions. The contracts whereby these billings were generated is not considered part of our ordinary course of business.

Interest expense. Interest expense was an expense of $500 and $0 for the three months ended September 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 September 30, 2021, the remaining payable balance on the financed amount was $0.

Net loss. As a result of the cumulative effect of the factors described above, our net loss increased to $6,124,800 during the three months ended September 30, 2021, compared to $2,415,700 during the three months ended September 30, 2020.

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

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

	Nine Months Ended September 30,		Increase (Decrease)	
	2021	2020	$	%
Operating expenses:				
Research and development	$ 8,030,400	$ 3,526,100	$ 4,504,300	127.74 %
General and administrative	7,040,700	12,109,200	(5,068,500)	(41.86)%
Total operating expenses	15,071,100	15,635,300	(564,200)	(3.61)%
Loss from operations	(15,071,100)	(15,635,300)	(564,200)	(3.61)%
Other income (expense)				
Gain on loan extinguishment	105,800	—	105,800	100.00 %
Other income	18,000	—	18,000	100.00 %
Interest expense	(6,300)	—	(6,300)	(100.00)%
Total other income (expense)	117,500	—	117,500	(100.00)%
Net loss	$ (14,953,600)	$ (15,635,300)	$ (681,700)	(4.36)%

Research and development expenses. Our research and development expenses increased by $4,504,300, or 127.74%, to $8,030,400 for the nine months ended September 30, 2021, from $3,256,100 for the nine months ended September 30, 2020. The following table summarizes our research and development expenses by product candidate or development program:

	Nine Months Ended September 30,		Increase (Decrease)	
	2021	2020	$	%
Direct research and development expenses by product candidate:				
ALEXIS-PRO-1	$ 54,200	$ 42,400	$ 11,800	27.83 %
ALEXIS-ISO-1	1,326,200	232,000	1,094,200	100.00 %
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	3,073,700	1,940,400	1,133,300	58.41 %
Laboratory supplies and services	743,900	225,500	518,400	229.89 %
Outsourced research and development	1,880,400	654,300	1,226,100	187.39 %
Laboratory equipment and maintenance	91,100	49,100	42,000	85.54 %
Facility-related costs	569,100	282,500	286,600	101.45 %
Intellectual Property	286,100	97,800	188,300	192.54 %
Other research and development costs	5,700	2,100	3,600	171.43 %
Total research and development expenses	$ 8,030,400	$ 3,526,100	$ 4,504,300	127.74 %

As illustrated above, the increase in research and development expenses resulted from (i) a $1,094,200 increase in ALEXIS-ISO-1 direct research and development costs which primarily included a $928,300 increase in disposables and consumables, a $31,900 increase in outsourced research and development fees, a $25,300 increase in non-capitalizable equipment and maintenance, and a $64,800 increase in supplies, all of which attributed to Gamma Delta T-Cell manufacturing and in-vivo experimentation; (ii) a $1,133,300 increase in employee related costs, which primarily

included a $1,317,400 increase in wages, benefits and payroll taxes. This was offset by a decrease in employee stock based compensation of $245,900; (iii) a $1,226,100 increase in outsourced research and development costs, which primarily included a $1,361,700 increase in regulatory and clinical consulting fees with the primary offsetting balance resulting from reduced stock compensation expenses attributed to non-employees compared to the prior period; (iv) a $286,600 increase in facility-related costs, primarily driven by $207,800 increase in allocated depreciation expenses, $47,600 increase in allocated rent expenses with the remaining amount attributed to repairs, maintenance, and utilities; (v) a $518,400 increase in laboratory supplies in services, which mainly consisted of increased spending on supplies, disposables, and consumables for experimentation, testing, validation of our other key value drivers; and (vi) a $188,300 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, regulatory and chemical manufacturing and control consulting fees, as well as experimentation and validation of our product candidates.

1. Augmented our research and development team: In the nine months ended September 30, 2021 and 2020, our average headcount increased to 29.5 employees from 8 employees allocable to research and development and clinical trials preparation.

2. ALEXIS-ISO-1 Manufacturing and Experimentation: $1,094,200 increase in spending during the nine months ended September 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.

3. Increased regulatory consulting costs: In the nine months ended September 30, 2021, we incurred $1,361,600 in regulatory and chemical manufacturing and control consulting fees compared to the same nine months in 2020 as we are working towards addressing the FDA's comments regarding our IND applications filed during May 2021.

General and administrative expenses. Our general and administrative expenses decreased by $5,068,500, or 41.86%, to $7,040,700 for the nine months ended September 30, 2021 from $12,109,200 for the nine months ended September 30, 2020.

During the nine months ended September 30, 2021, the decrease primarily resulted from a decrease in stock compensation expenses of $7,689,800. That decrease was offset by increased wages and salaries of $921,500, professional services of $1,195,200, and insurance of $426,000.

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. The remaining offsetting balance is mainly driven by increased stock compensation expense during the nine months ended September 30, 2021 from stock grant modifications.

Employee related expenses were impacted by increases to headcount, and employee salary rates. During the nine months September 30, 2021 and 2020, the headcount for employees allocated to general and administrative purposes increased to 12 employees from 4 employees, respectively. In addition, the Chief Executive Officer's salary increased to an annual rate of $504,000 from $280,000 as of September 30, 2021 and 2020, respectively.

The increase in professional services expenses was driven by an increase of $776,600 from accounting, audit, tax and other consulting fees, and an increase of $418,600 of legal fees incurred during the nine months ended September 30, 2021 compared to the same period in the prior year. We incurred significant legal expenses and accounting professional fees related to the Internal Review after September 30, 2021. Between October 1, 2021 and January 31, 2022, we incurred $3,147,900 in legal fees and other professional services attributed to the Internal Review and related matters. During that same period, we incurred $427,200 in accounting professional fees directly related to the Internal Review. These elevated legal, accounting, and other related professional services expenses are continuing through the date of this report, and will likely continue thereafter.

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 nine months ended September 30, 2021 totaled $405,300.

Gain on loan extinguishment. Gain on loan extinguishment was $105,800 and $0 for the nine months ended September 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.

Other income. Other income was $18,000 and $0 for the nine months ended September 30, 2021 and 2020, respectively. The increase is entirely driven by service billings from our bioinformatics employees to large academic institutions. The bioinformatics employees joined us in July 2021 as part of the InSilico Solutions, LLC acquisition. The contracts whereby these billings were generated is not considered part of our ordinary course of business.

Interest expense. Interest expense was $5,800 and $0 for the nine months ended September 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 September 30, 2021, the remaining payable balance on the financed amount was $0.

Net loss. As a result of the cumulative effect of the factors described above, our net loss decreased to $14,953,600 during the nine months ended September 30, 2021 compared to $15,635,300 during the nine months ended September 30, 2020.

Liquidity and Capital Resources

As of September 30, 2021, we had cash and cash equivalents of $35,161,800. As of December 31, 2020, we had cash and cash equivalents of $10,150,500. As of February 28, 2022, we had cash and cash equivalents of $18,081,000. 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, common stock from the initial public offering and follow-on 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 do not 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. 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.

In fiscal year 2022, we intend to seek 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. Further, the results of our Internal Review demonstrated that we had ineffective disclosure controls and procedures during the third quarter of 2021 and earlier periods, which resulted in our failure to disclose certain information, which could result in our potential exposure to litigation and could adversely affect our ability to raise capital in the future. Further, there are other factors which may make financing our operations more difficult, including potential governmental investigation, continued elevated legal and accounting professional fees associated with the Internal Review, and other risk factors listed in Item 1A. of Part I of our Annual Report on Form 10-

K for the year ended December 31, 2020, and Part II Item 1A within this report. 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:

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (11,156,300)	$ (3,557,200)
Net cash used in investing activities	(713,500)	(1,013,100)
Net cash provided by financing activities	36,881,100	3,110,500
Net increase (decrease) in cash and cash equivalents	25,011,300	(1,459,800)
Cash and cash equivalents at beginning of the period	10,150,500	1,929,100
Cash and cash equivalents at end of the period	35,161,800	469,300

Cash flows from operating activities

Net cash used in operating activities was $11,156,300 for the nine months ended September 30, 2021, as compared to $3,557,200 for nine months ended September 30, 2020. In the nine months ended September 30, 2021, the primary cash outflows were from the net loss of $14,953,600 and outflows from the gain on loan extinguishment of $105,800. These cash outflows were partly offset by stock compensation expenses from stock options and restricted stock units of $3,319,100, prepaid expenses and other current assets of $168,500, and depreciation of $331,200. Net cash used in operating activities increased by a total of $7,599,100 period-over-period. The main driver for the increase is the $8,260,900 decrease in stock compensation expenses, partly offset by the decrease in net loss of $681,700. 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 for in investing activities was $713,500 for the nine months ended September 30, 2021, as compared to $1,013,100 for the nine months ended September 30, 2020. Our net cash used in investing activities consisted of purchases of property and equipment, as well as $84,000 cash received from acquisition. 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 inflows from financing activities was $36,881,100 during the nine months ended September 30, 2021. Net cash provided by financing activities during the nine months ended September 30, 2020, totaled $3,110,500.

During the nine months ended September 30, 2021, net cash provided by financing activities primarily consisted of the public offering which closed on July 2, 2021. This public offering sold 8,000,000 shares of common stock with net proceeds of $37,118,100.

During the nine months ended September 30, 2020, the net cash provided by financing activities primarily consisted of proceeds from preferred stock issuance in the amount of $3,000,000 and proceeds from a loan payable of $105,600, net of repayments.

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 nine months ended September 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 nine months ended September 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 nine months ended September 30, 2021, we used our listed Nasdaq Capital Market closing price on the grant date to determine common stock valuation.

During the nine months ended September 30, 2020, the fair value of the common stock underlying our stock-based compensation grants was determined by our Board, with input from management and third-party valuations. We believe that the Board 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 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 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 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 equity offering 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 initial public offering warrants were issued is equal to the initial public offering common stock issuance price of $12.00 per share. The fair value of our common stock when the July 2, 2021 warrants were issued is equal to the offering price of $5.00 per share.

Exercise Price. The representative warrants' exercise price to purchase common stock is $15.00 and $6.25 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. Modified retroactive transition approach will be required for operating leases existing at or entered into after the beginning of the earliest comparative period present. Though the Company is currently evaluating the potential impact of this standard on its financial position, results of operations, and cash flows, the Company expects that

adopting the new standard will result in recording a material lease liability and right-of-use asset associated with the Company's facility lease agreement and subsequent amendments thereto.

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 Interim Chief Executive Officer ("Interim CEO") and Interim Chief Financial Officer ("Interim CFO") (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. 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 Interim CEO and Interim CFO, we evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2021. Based on this evaluation of our disclosure controls and procedures, our management, including our Interim CEO and Interim CFO, have concluded that our disclosure controls and procedures were not effective as of September 30, 2021 because of the material weaknesses in our internal control over financial reporting described below.

Material Weaknesses

Internal control over financial reporting

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.

In addition, during the quarter ended September 30, 2021 and in connection with the Internal Review, we identified a material weakness in our internal control over financial reporting because we did not have a control to appropriately communicate relevant information from the FDA to appropriate parties on a timely basis. This material weakness resulted in our failure to timely disclose the June 16 and 17, 2021 FDA Communications.

As a remedial measure to address the Company's material weakness in internal control over financial reporting as a result of the Internal Review, on January 10, 2022, the Board approved the formation of a Disclosure Committee comprised of certain members of the Company's management including (i) its Chief Executive Officer; (ii) the executive in charge of overseeing submissions of any nature to the FDA; (iii) its Chief Financial Officer; (iv) its General Counsel, if any; (v) its Controller; (vi) any other finance executive overseeing financial disclosures; (vii) the executive in charge of investor relations, if any; and (viii) such other employees as the Chief Financial Officer, who serves as chairman of the Disclosure Committee, may invite from time to time. The Disclosure Committee shall be responsible for preparing and reviewing all corporate disclosures made by the Company to its security holders, the Securities and Exchange Commission and/or the broader investment community to ensure that such disclosures (i) shall be accurate and complete; (ii) shall fairly present, in all material respects, the Company's financial condition, results of operations and cash flows; and (iii) shall be made on a timely basis in accordance with all applicable requirements of (A) the Exchange Act and the rules and regulations promulgated thereunder, (B) the Securities Act of 1933, as amended and the rules and regulations promulgated thereunder (C) the Nasdaq Stock Market or such other stock exchange on which the Company's securities may be traded and (D) any other applicable laws or legal requirements.

Our management is monitoring these material weaknesses and will continue to evaluate whether the remedial actions initiated by the Company will remediate these material weaknesses.

Changes in Internal Control over Financial Reporting

There were 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 September 30, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We note that the signing officers included on the certifications in Exhibit 31.1, 31.2, 32.1, and 32.2 have changed as of the report date. The Company's Chief Financial Officer resigned and has been replaced by the Company's Interim Chief Financial Officer. The Company's Chief Executive Officer was terminated and has been replaced by the Company's Interim Chief Executive Officer. We will evaluate the remedial actions being taken to remediate our material weaknesses when we complete our evaluation of the internal control over financial reporting for the year ended December 31, 2021.

Except as disclosed above, there have been no other changes in our internal control over financial reporting for the quarter ended September 30, 2021.

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.

On March 22, 2021, Jason Terrell ("Terrell"), a former consultant for and director of the Company, commenced an action against us in the Court of Chancery of the State of Delaware, C.A. No. 2021-0248-MTZ (the "Action"). In the Action, Terrell seeks a declaratory judgment that we are obligated to issue him (i) options to purchase 500,000 shares of

our common stock at a price of $0.50 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 500,005 shares of our common stock at a price of $0.17 per share pursuant to an alleged January 2017 non-employee director options agreement. In his complaint, Terrell also claimed that, pursuant to our operative certificate of incorporation, he is entitled to indemnification from us for attorneys' fees and costs he incurs in connection with the Action because the Action arises in connection with his position as a former director.

We dispute Terrell's claims and allegations in the Action and intend to vigorously defend against them. On May 21, 2021, we filed a motion to dismiss Terrell's claims in the actions with prejudice, arguing that (i) Terrell's options-related claims fail because his 2014 and January 2017 agreements were explicitly superseded by a later options agreement, under which Terrell relinquished his prior options; and (ii) Terrell is not entitled to indemnification because the Action relates to contracts between the Company and Terrell in his personal capacity, and not in connection with any activities or duties of Terrell in his official capacity as former director. In response to the motion, filed on June 21, 2021, Terrell withdrew his claim for indemnification, but opposed the portion seeking dismissal of his declaratory judgment claim. The motion was fully briefed with the filing of our reply brief on July 7, 2021.

Oral argument was held before the Vice Chancellor on October 20, 2021. During oral argument, the Vice Chancellor invited the parties to submit supplemental letter briefs on the question of whether the Court of Chancery even had the authority to adjudicate the Action in light of the delegation of authority in Terrell's most recent stock option agreement with the Company (the "SOA") to our Compensation Committee to resolve all disputes regarding the interpretation of the SOA. The parties submitted simultaneous supplemental letters briefs on this issue on November 15, 2021. On January 20, 2022, the Vice Chancellor issued her decision on our motion to dismiss, ruling that the Action is stayed until the Compensation Committee itself resolves whether it has sole authority to resolve the parties' contract interpretation dispute.

The parties are currently in discussions to coordinate submissions and/or presentations to the Compensation Committee. In the interim, as noted, the Action is stayed and no further proceedings are taking place.

Sabby Volatility Warrant Master Fund Ltd., et al. v. Kiromic BioPharma, Inc. et al., Case No. 22-cv-1927 (SDNY). On March 7, 2022, entities related to Sabby Management LLC (the "Sabby Entities") and Empery Asset Management, LP (the "Empery Entities") filed a complaint in the District Court for the Southern District of New York alleging claims against the Company and certain current and former officers and directors of Kiromic BioPharma, Inc. ("Kiromic" or the "Company") for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock through the Company's public offering that closed on July 2, 2021. The plaintiffs seek unspecified damages; rescission to the extent they still hold Kiromic securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. The Company expects to vigorously defend against this action. The Company has evaluated that it is reasonably possible that the Sabby Entities' and Empery Entities' claims may result in an estimated loss ranging between $0 and $8,100,000. Similarly, the Company has evaluated that it is reasonably possible that other unasserted claims in future litigation and losses may occur. However, the Company is unable to estimate any possible range of loss attributed to other unasserted claims at this time.

In addition to the above, several class action plaintiff law firms have issued press releases announcing that the firms are investigating securities law claims on behalf of stockholders of the Company. These press releases were in response to an approximately 15% decline in the Company's stock price on July 16, 2021, the date we had first announced we had received comments from the FDA on our two INDs, resulting in clinical holds. If claims are ultimately made pursuant to these investigations or otherwise, we intend to defend ourselves vigorously, but are unable to predict the outcome of any such litigation. Even if we are successful, securities litigation is costly to defend and would likely divert management's attention away from the business. To the extent that we are subject to a legal proceeding, it could have a material adverse impact on us.

We are not currently party to any other legal proceedings that we believe could have a material adverse effect on our business, operating results or financial condition.

ITEM 1A. RISK FACTORS.

In evaluating us and our common stock, in addition to the risk factors below, we urge you to carefully consider the risks and other information in this Quarterly Report on Form 10-Q, as well as the risk factors disclosed in Item 1A. of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 ("2020 Form 10-K"), and filed with the SEC on March 31, 2021. Any of the risks discussed in this Quarterly Report on Form 10-Q or any of the risks disclosed in Item 1A. of Part I of our 2020 Form 10-K, as well as additional risks and uncertainties not currently known to us or that we currently deem immaterial, could materially and adversely affect our financial position, results of operations, and cash flows.

We will need substantial additional funding to develop our product candidates and conduct our future operations and to repay our outstanding debt obligations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business operations.

We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to continue funding our operations, including our continuing substantial research and development expenses. We do not currently believe that our cash balance will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital from accessible sources of financing in the near future. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations on terms acceptable to us, or at all;
- our perceived capital needs with respect to our development programs, and any delays in, adverse events and excessive costs of such programs beyond what we currently anticipate;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our product candidates to market and the cost of such arrangements at the time;
- the cost of manufacturing our product candidates, including compliance with good manufacturing practices applicable to our product candidates;
- expenses related to the establishment of sales and marketing capabilities for product candidates awaiting approval or products that have been approved;
- competing technological and market developments; and
- our ability to introduce and sell new products.

The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts.

We have secured capital historically from equity offerings. To obtain additional capital, we may pursue debt and/or equity offering programs, strategic corporate partnerships, state and federal development programs, licensing arrangements, and sales of assets. We cannot be certain that additional capital will be available on terms acceptable to us, or at all. If we are unsuccessful in our efforts to raise any such additional capital (as a result of any securities law claims regarding past disclosure, the inability to retain key employees, the existence of significant costs related to litigation and/or investigations, or other reasons), we may be required to take actions that could materially and adversely harm our business, including a possible significant reduction in our research, development and administrative operations (including reduction of our employee base), the surrender of our rights to some technologies or product opportunities, delay of our clinical trials or regulatory and reimbursement efforts, or curtailment or cessation of operations.

Depending on the type and the terms of any financing we pursue, stockholders' rights and the value of their investment in our common stock could be reduced. A financing could involve one or more types of securities including common stock, convertible debt or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be prior to the rights of stockholders until the debt is paid. Interest on these debt securities would increase costs and negatively impact operating results. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be negatively impacted.

We may be subject to securities laws claims regarding past disclosures.

We may be subject to additional claims for rescission (under which a successful claimant would have the right to receive the total amount paid for his or her shares, plus interest and less any income earned on the shares, in exchange for surrender of the shares), damages (under which a successful claimant would have the right to receive the total amount paid for his or her shares, plus interest and less any income earned on the shares, in exchange for surrender of the shares) or other securities law claims resulting from our failure to timely disclose that the Company had received communications from the FDA on June 16 and June 17, 2021 that the FDA was placing the Company's IND applications that the Company submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively, on clinical hold (the "June 16 and 17, 2021 FDA Communications").

On July 2, 2021, we consummated a public offering of $40 million of our common stock. Neither the Registration Statement on Form S-1 with respect to this offering that was filed on June 25, 2021 nor the final prospectus dated June 29, 2021 with respect to this offering contained any disclosure with respect to the June 16 and 17, 2021 FDA Communications. Our Form S-1 and final prospectus for the offering stated the following with respect to our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates: "These products are in the pre-IND stage of the FDA clinical trial process. We are currently going through the IND enabling trials process for these product candidates and we expect that first in human dosing in Phase I of clinical trials will commence in the third quarter of 2021." Anyone who purchased shares of our common stock in the offering and anyone who purchased or sold shares of our common stock in the public market after June 16, 2021 could claim that they were misled by our failure to disclose the clinical hold on studies under the INDs for these product candidates and that they suffered damages. As described in Item 1. above, on March 7, 2022, certain shareholders who had purchased shares of our common stock in the Company's public offering that closed on July 2, 2021 filed a complaint against the Company and certain our current and former officers and directors for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock in the offering. The plaintiffs seek unspecified damages; rescission to the extent they still hold Kiromic securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. We expect to vigorously defend against this action. We have evaluated that it is reasonably possible that the Sabby Entities' and Empery Entities' claims may result in an estimated loss ranging between $0 and $8,100,000. Similarly, we have evaluated that it is reasonably possible that other unasserted claims in future litigation and losses may occur. However, we are unable to estimate any possible range of loss attributed to other unasserted claims at this time. Even if we are successful in defending against this litigation or any other unasserted claims, securities litigation is costly to defend and would likely divert management's attention away from the business.

In addition to the above, several class action plaintiff law firms have issued press releases announcing that the firms are investigating securities law claims on behalf of stockholders of the Company. These press releases were in response to an approximately 15% decline in the Company's stock price on July 16, 2021, the date we had first announced we had received comments from the FDA on our two INDs. If claims are ultimately made pursuant to these investigations or otherwise, we intend to defend ourselves vigorously, but are unable to predict the outcome of any such litigation. Even if we are successful, securities litigation is costly to defend and would likely divert management's attention away from the business.

We had ineffective disclosure controls and procedures during the third quarter of 2021 and earlier periods, which resulted in our failure to disclose certain information, which could result in further potential exposure to litigation and could adversely affect our ability to raise capital in the future.

We have determined that our disclosure controls and procedures were not effective as of September 30, 2021. Our disclosure controls and procedures were ineffective due to the existence of a material weakness resulting from internal communication deficiencies surrounding our failure to timely disclose the June 16 and 17, 2021 FDA Communications as further described in Part 1 Item 4. We had previously determined that our disclosure controls and procedures were not effective as of June 30, 2021 due to the existence of material weaknesses in our internal control over financial reporting. We made the same determination in earlier periods as well. 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.

In addition, there were deficiencies in our disclosure controls and procedures over the identification of information for disclosure during our second and third quarters of 2021. Specifically, there was a deficiency in the disclosure controls and procedures in place to ensure that information related to the June 16 and 17, 2021 FDA Communications was appropriately elevated and evaluated to allow timely decisions regarding required disclosure.

A Special Committee of our Board has made several recommendations to improve the effectiveness of the Company's disclosure controls and procedures, which recommendations were accepted and adopted by our Board. The recommendations that have been adopted include among other things: (i) the appointment of an interim CEO who has received training in appropriate disclosure controls and procedures and who will be responsible for supervising our disclosure controls and procedures, (ii) the establishment of a Disclosure Committee of our management, and (iii) the appointment of two additional independent directors to our Board. However, the fact that we experienced ineffective disclosure controls could result in further potential exposure to litigation and could adversely affect our ability to raise funds in the future.

Failure to meet the continued listing requirements of the Nasdaq Stock Market, LLC ("Nasdaq") could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital.

On November 18, 2021, we received a written notice (the "Notice") from the Listing Qualifications Department of The Nasdaq Stock Market ("Nasdaq") advising us that we were not in compliance with Nasdaq's continued listing requirements under the Nasdaq Listing Rule 5250(c)(1) (the "Rule") as a result our failure to file our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 in a timely manner. The Rule requires listed companies to timely file all required periodic reports with the Securities and Exchange Commission.

On January 18, 2022, we submitted to Nasdaq a plan of compliance to regain compliance with the Rule. On February 28, 2022 we submitted an updated plan of compliance letter to Nasdaq to regain compliance with the Rule. If Nasdaq accepts our plan, then Nasdaq may grant an exception of up to 180 calendar days from the due date of the Form 10-Q, or until May 16, 2022, to regain compliance. However, there can be no assurance that Nasdaq will accept our plan to regain compliance or that we will be able to regain compliance within any extension period granted by Nasdaq. If Nasdaq does not accept our plan, then we will have the opportunity to appeal that decision to a Nasdaq hearings panel.

If we fail to comply with Nasdaq's continued listing requirements, including the Rule, our common stock will be subject to delisting. If that were to occur, our common stock would be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock. This would adversely affect the ability of investors to trade our common stock and would adversely affect the value of our common stock. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our common stock. The delisting of our common stock from Nasdaq would also adversely affect our ability to complete future financings.

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

Not required.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

On or about August 17 and 23, 2021, Tony Tontat, who at the time was the Chief Financial Officer and a member of the Board, submitted substantially identical reports (the "Complaints") through our complaint hotline. These Complaints, alleged, among other topics, risks associated with our public disclosures in our securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the U.S. Food and Drug Administration's ("FDA") authorization of our investigational new drug ("IND") applications and (ii) the anticipated timing of human clinical trials. These Complaints were subsequently submitted to the Audit Committee of the Board.

After receiving the Complaints, the Audit Committee recommended that the Board form, and the Board did in turn form, a Special Committee comprised of three independent directors (Messrs. Americo Cicchetti, Michael Nagel, and Jerry Schneider (until his resignation from the Board on December 3, 2021 due to personal reasons)) (the "Special Committee") to review the Complaints and other related issues (the "Internal Review"). The Special Committee retained Sidley Austin LLP as independent counsel to assist it in conducting the Internal Review, and Sidley Austin in turn engaged AlixPartners LLP to assist with the Internal Review.

On February 2, 2022, following the conclusion of the Internal Review, the Special Committee reported the results of its Internal Review to the Board. The Board approved certain actions to address the fact that we had received communications from the FDA on June 16 and June 17, 2021 that the FDA was placing our IND applications that we submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively, on clinical hold (the "June 16 and 17, 2021 FDA Communications"). On July 13, 2021, we received the FDA's formal clinical hold letters, which asked us to address key components regarding the chemical, manufacturing, and control components of the IND applications. On July 16, 2021, we issued a press release disclosing that it had received comments from the FDA on our two INDs, but did not use the term "clinical hold." On August 13, 2021, we issued a press release announcing that these INDs were placed on clinical hold. We did not disclose the June 16 and 17, 2021 FDA Communications in (i) our Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"); or (ii) our Form 10-Q for the fiscal quarter ended June 30, 2021 that was filed with the Securities and Exchange Commission on August 13, 2021. We consummated a public offering of $40 million of our common stock pursuant to the Registration Statement on July 2, 2021.

In the course of the Internal Review, the Special Committee also identified that Mr. Tontat submitted incorrect information regarding his educational background to us. Specifically, although Mr. Tontat represented to us that he held a BA in Economics from Harvard University, it was determined that he had actually received an ALB, a degree conferred by the Harvard Extension School. We have implemented changes to our vetting process for prospective director and officer candidates including the implementation of thorough background checks to verify background information provided by such candidates.

Remediation Actions resulting from the Internal Review

1. The Board approved the inclusion of certain Risk Factors for inclusion in this Quarterly Report on Form 10-Q for its fiscal quarter ended September 30, 2021. See Item 4. Controls and Procedures for more information.

2. On January 10, 2022, the Board approved the formation of a Disclosure Committee comprised of certain members of the management including (i) its Chief Executive Officer; (ii) the executive in charge of overseeing submissions of any nature to the FDA; (iii) its Chief Financial Officer; (iv) its General Counsel, if any; (v) its Controller, if any; (vi) any other finance executive overseeing financial disclosures; (vii) the executive in charge of investor relations, if any; and (viii) such other employees as the Chief Financial Officer, who serves as chairman of the Disclosure Committee, may invite from time to time. The Disclosure Committee shall be responsible for preparing and reviewing all corporate disclosures made by us to our security holders, the Securities and Exchange Commission and/or the broader investment community to ensure that such disclosures (i) shall be accurate and complete; (ii) shall fairly present, in all material respects, our financial condition, results of operations and cash flows; and (iii) shall be made on a timely basis in accordance with all

applicable requirements of (A) the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder, (B) the Securities Act of 1933, as amended and the rules and regulations promulgated thereunder (C) the Nasdaq Stock Market or such other stock exchange on which the our securities may be traded and (D) any other applicable laws or legal requirements. The Board adopted and approved a Disclosure Committee Charter.

3. The Board terminated Maurizio Chiriva-Internati as Chief Executive Officer for cause on January 27, 2022, after the Special Committee's Internal Review found evidence of conduct that the Board believed was inconsistent with the company policies. Under the terms of the Executive Employment Agreement between Dr. Chiriva and the Company effective as of July 1, 2020, as amended October 21, 2021, as the result of the termination of his employment, Dr. Chiriva also is deemed to have resigned as a Director on the Board effective as of January 27, 2022.

4. The Board named Pietro Bersani as Interim Chief Executive Officer, effective as of January 27, 2022. A search for a permanent Chief Executive Officer will be commenced with the assistance of an executive recruiter. Mr. Bersani has resigned from all Committees of the Board.

5. The Board named independent Director Michael Nagel as Chairperson of the Board, effective as of January 27, 2022.

6. The Board approved the appointment of Frank Tirelli as a member of the Board to fill a vacancy, effective as of January 28, 2022. The Board has determined that Mr. Tirelli is "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). Mr. Tirelli has been named Chairperson of the Audit Committee effective January 28, 2022. He was also nominated and appointed as a member of the Nominating and Corporate Governance Committee effective March 1, 2022. Mr. Tirelli was nominated by our Nominating and Corporate Governance Committee of the Board after a thorough review of all his background, relevant experience, and professional and personal reputations.

7. On February 10, 2022, we and Dr. Scott Dahlbeck ("Dr. Dahlbeck") entered into a Modification to Employment Agreement dated as of February 9, 2022 (the "Dahlbeck Agreement"). The Dahlbeck Agreement amends and supersedes certain terms of the Employment Agreement dated as of January 1, 2020, between the Company and Dr. Dahlbeck. Pursuant to the Dahlbeck Agreement, effective as of February 9, 2022, Dr. Dahlbeck's title was changed to Chief of Staff, and he ceased to be our Chief Medical Officer and Head of Clinical.

8. On February 10, 2022, we and Mr. Gianluca Rotino ("Mr. Rotino") entered into a Transition and Consulting Agreement dated as of February 9, 2022 (the "Rotino Agreement"). Pursuant to the terms of the Rotino Agreement, effective as of February 9, 2022, Mr. Rotino's employment as our Chief Strategy and Innovation Officer terminated and the Company retained Mr. Rotino to provide consulting services to the Company for a period of nine months (or until November 9, 2022). Notwithstanding the foregoing, the Rotino Agreement may be terminated by either us or Mr. Rotino upon 30 days' prior written notice, except no such prior notice shall be required in the event we terminate the Rotino Agreement for cause.

   Under the terms of the Executive Employment Agreement between Mr. Rotino and the Company effective as of July 1, 2020, as amended October 21, 2020, as the result of the termination of Mr. Rotino's employment, Mr. Rotino is deemed to have resigned as a member of the Board effective as of February 9, 2022.

9. The Board approved the appointment of Karen Reeves as a member of the Board to fill a vacancy, effective as of February 14, 2022. The Board has determined that Dr. Reeves is "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). Dr. Reeves was nominated and appointed to be the Nominating and Corporate Governance Committee Chairperson and a member of the Compensation Committee effective March 1,

2022. Dr. Reeves was nominated by our Nominating and Corporate Governance Committee of the Board after a thorough review of all her background, relevant experience, and professional and personal reputations.

ITEM 6. EXHIBITS.

See Exhibit Index.

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
10.1	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)
10.2	Executive Employment Agreement by and between the Company and Pietro Bersani, effective as of January 27, 2022 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 2, 2022)
10.3	Confidential Information, Inventions, Non-Solicitation and Non-Competition Agreement by and between the Company and Pietro Bersani effective as of January 27, 2022 (incorporated by reference to Exhibit 10.2 to Form 8-K filed on February 2, 2022)
10.4	Indemnification Agreement by and between the Company and Pietro Bersani effective as of January 27, 2022 (incorporated by reference to Exhibit 10.3 to Form 8-K filed on February 2, 2022)
10.5	Transition and Consulting Agreement effective as of February 9, 2022, by and between Kiromic BioPharma, Inc. and Gianluca Rotino (incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 16, 2022)
10.6	Modification to Employment Agreement effective as of February 9, 2022, by and between Kiromic BioPharma, Inc. and Scott Dahlbeck (incorporated by reference to Exhibit 10.2 to Form 8-K filed on February 16, 2022)
10.7	Executive Employment Agreement effective as of February 14, 2022, by and between Kiromic BioPharma, Inc. and Daniel Clark (incorporated by reference to Exhibit 10.3 to Form 8-K filed on February 16, 2022)
10.8	Confidential Information, Inventions, Non-Solicitation, and Non-Competition Agreement effective as of February 14, 2022, between Kiromic BioPharma, Inc. and Daniel Clark (incorporated by reference to Exhibit 10.4 to Form 8-K filed on February 16, 2022)
10.9	Indemnification Agreement effective as of February 14, 2022, by and between Kiromic BioPharma, Inc. and Daniel Clark (incorporated by reference to Exhibit 10.5 to Form 8-K filed on February 16, 2022)
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
99.1	Disclosure Committee Charter (incorporated by reference to Exhibit 99.1 to Form 8-K filed on February 2, 2022)
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: March 11, 2022

KIROMIC BIOPHARMA, INC.

/s/ Pietro Bersani

Name: Pietro Bersani

Title: Interim Chief Executive Officer

(Principal Executive Officer)

/s/ Daniel Clark

Name: Daniel Clark

Title: Interim Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Pietro Bersani, 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: March 11, 2022

/s/ Pietro Bersani
Pietro Bersani
Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Daniel Clark, 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: March 11, 2022

/s/ Daniel Clark

Daniel Clark
Interim 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 Interim 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 September 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 March 11, 2022.

/s/ Pietro Bersani
Pietro Bersani
Interim 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 Interim 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 September 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 March 11, 2022.

/s/ Daniel Clark
Daniel Clark
Interim 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.