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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 March 31, 2022

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 May 13, 2022, there were 15,669,340 shares of the registrant's common stock outstanding.

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Note Regarding Forward-Looking Statements

Various statements made in this Quarterly Report on Form 10-Q are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, 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.

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as “may," "could," "will," "should," "would," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "potential," "project" or "continue".

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements:

- the extent to which the COVID-19 pandemic impacts our business, our customers’ businesses, the medical community and the global economy;
- the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data;
- our expectations regarding the timing and clinical development of our product candidates;
- our ability to achieve profitable operations and access to needed capital;
- fluctuations in our operating results;
- the success of current and future license and collaboration agreements
- our dependence on contract research organizations, vendors and investigators;
- effects of competition and other developments affecting development of products;
- market acceptance of our products;
- protection of intellectual property and avoiding intellectual property infringement;
- product liability; and
- other factors described in our filings with the SEC.

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove

inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 15,123,100	$ 25,353,900
Accounts receivable	—	16,200
Prepaid expenses and other current assets	1,607,900	1,699,400
Total current assets	16,731,000	27,069,500
Property and equipment, net	6,900,400	3,629,000
Operating lease right-of-use asset	2,227,300	—
Other assets	31,100	31,100
Total Assets	$ 25,889,800	$ 30,729,600
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 2,302,600	$ 2,214,300
Accrued expenses and other current liabilities	1,036,600	741,000
Note payable	285,700	454,500
Operating lease liability - short term	480,300	—
Total current liabilities	4,105,200	3,409,800
Deferred rent	5,500	—
Operating lease liability - long term	1,747,000	—
Total Liabilities	5,857,700	3,409,800
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Common stock, $0.001 par value: 300,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 15,585,587 shares and 15,488,516 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	9,300	9,300
Additional paid-in capital	94,607,100	94,527,000
Accumulated deficit	(74,584,300)	(67,216,500)
Total Stockholders' Equity	20,032,100	27,319,800
Total Liabilities and Stockholders' Equity	$ 25,889,800	$ 30,729,600

See accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 2,925,800	$ 1,885,600
General and administrative	4,439,200	2,071,000
Total operating expenses	7,365,000	3,956,600
Loss from operations	(7,365,000)	(3,956,600)
Other income (expense)		
Gain on loan extinguishment	—	105,800
Interest expense	(2,800)	(3,700)
Total other income (expense)	(2,800)	102,100
Net loss	$ (7,367,800)	$ (3,854,500)
Net loss per share, basic and diluted	$ (0.48)	$ (0.53)
Weighted average common shares outstanding, basic and diluted	15,542,444	7,332,999

See accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended March 31, 2022				
	Common Stock		Additional Paid-In	Accumulated	
	Number of Shares	Amount	Capital	Deficit	Total
Balance January 1, 2022	15,488,516	$ 9,300	$ 94,527,000	$ (67,216,500)	$ 27,319,800
Common stock discount amortization	—	—	85,100	—	85,100
Warrants underlying common stock issuance	—	—	(85,100)	—	(85,100)
Released restricted stock units	97,071	—	—	—	—
Stock compensation expense	—	—	80,100	—	80,100
Net loss	—	—	—	(7,367,800)	(7,367,800)
Balance at March 31, 2022	15,585,587	$ 9,300	$ 94,607,100	$ (74,584,300)	$ 20,032,100

See accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended March 31, 2021				
	Common Stock				
	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
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

See accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (7,367,800)	$ (3,854,500)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	182,800	95,600
Stock compensation expense	80,100	945,200
Gain on loan extinguishment	—	(105,800)
Changes in operating assets and liabilities		
Accounts receivable	16,200	—
Prepaid expenses and other current assets	91,500	75,400
Operating lease right-of-use asset	(2,227,300)	—
Accounts payable	(882,800)	273,600
Accrued expenses and other current liabilities	295,600	(65,400)
Deferred rent	5,500	—
Operating lease liability	2,227,300	—
Net cash used for operating activities	(7,578,900)	(2,635,900)
Cash flows from investing activities:		
Purchases of property and equipment	(2,483,100)	(44,700)
Net cash used for investing activities	(2,483,100)	(44,700)
Cash flows from financing activities:		
Repayments of note payable	(168,800)	(134,600)
Net cash used for financing activities	(168,800)	(134,600)
Net change in cash and cash equivalents	(10,230,800)	(2,815,200)
Cash and cash equivalents:		
Beginning of year	25,353,900	10,150,500
End of period	$ 15,123,100	$ 7,335,300
Supplemental disclosures of non-cash investing and financing activities:		
Accounts payable and accruals for property and equipment	$ 971,100	$ 264,400
Cash paid for interest on note payable	$ 2,800	$ 3,700

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.

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.

The Company is developing its brand of CAR-T cell product candidates known as ALEXIS. The two product candidates are called ALEXIS-PRO-1 and ALEXIS-ISO-1. ALEXIS-PRO-1 is an allogeneic gamma delta chimeric T cell therapy product candidate targeting PD-L1. ALEXIS-ISO-1 is an allogenic gamma delta CAR-T cell therapy product candidate targeting Isomesothelin (the isoform of Mesothelin). These are designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells. We filed two investigational new drug ("IND") applications in May 2021 for ALEXIS-PRO-1 and ALEXIS-ISO-1. The Food and Drug Administration ("FDA") placed these applications under a clinical hold in June 2021. 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. Those components included tracing of all reagents used in manufacturing, flow chart of manufacturing processes, and certificate of analysis. The Company is currently working on addressing 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 $7,578,900 for the three months ended March 31, 2022, and an accumulated deficit of $74,584,300 as of March 31, 2022. 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**.**

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 March 31, 2022 and December 31, 2021, 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.

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

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

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

Internal Use Software Development Costs—The Company capitalizes certain costs incurred to develop internal use software. All costs incurred that relate to planning and post-implementation phases of development are expensed as incurred. Costs incurred in the development and implementation phases are capitalized and amortized over the estimated life of the software, generally five years. The Company did not capitalize any software development costs during the three months ended March 31, 2022 and 2021.

Goodwill— In connection with the InSilico Solutions, LLC ("InSilico") 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 assessed events and circumstances as of December 31, 2021 which was primarily driven by a reduced stock price as of December 31, 2021. The carrying value of the Company's assets was in excess of the market value of equity as of December 31, 2021. After analyzing this quantitative circumstance along with other qualitative considerations, the Company's management determined that an impairment of the entire value of the goodwill was appropriate. Accordingly, the Company incurred an impairment expense on the statement of operations totaling $430,000 during the year ended December 31, 2021. Since the Company records a full valuation allowance to offset any deferred tax assets, the Company does not believe this impairment would result in any material tax impact.

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 ended March 31, 2022 and 2021.

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.

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 months ended March 31, 2022 and 2021.

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. The Company has issued grants of nonvested stock options and restricted stock units under the 2017 Plan and 2021 Plan.

The vesting conditions for stock options and restricted stock units include annual vesting, monthly vesting, and fully vesting upon grant date. 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.

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 months ended March 31, 2022 and 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. 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, the Company has adopted Topic 842 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. The Company notes that adopting the new standard resulted in recording a lease liability and right-of-use asset associated with the Company's facility lease agreement and subsequent amendments thereto totaling $2,067,000 and $2,063,400, respectively as of January 1, 2022.

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, and restricted stock units 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 March 31,	
	2022	2021
Net loss	$ (7,367,800)	$ (3,854,500)
Less: initial public offering Common Stock discount amortization	(24,700)	(24,700)
Less: public offering Common Stock discount amortization	(60,400)	—
Net loss attributable to common shareholders, basic and diluted	$ (7,452,900)	$ (3,879,200)
Weighted average common shares outstanding, basic and diluted	15,542,444	7,332,999
Net loss per common share, basic and diluted	$ (0.48)	$ (0.53)

For the three months ended March 31, 2022 and 2021, potentially dilutive securities excluded from the computations of diluted weighted-average shares of common stock outstanding were:

	March 31, 2022	March 31, 2021
Stock options	—	677
Restricted stock units	—	32,000
Total	—	32,677

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of March 31, 2022 and December 31, 2021:

	March 31, 2022	December 31, 2021
Equipment	$ 1,651,800	$ 1,593,100
Leasehold improvements	2,936,200	1,464,700
Office furniture, fixtures, and equipment	109,500	16,600
Software	359,500	359,500
Construction in progress	3,057,700	1,226,600
	8,114,700	4,660,500
Less: Accumulated depreciation	(1,214,300)	(1,031,500)
Total	$ 6,900,400	$ 3,629,000

Depreciation expense was $182,800 and $95,600 for the three months ended March 31, 2022 and 2021, 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 March 31, 2022 and December 31, 2021:

	March 31, 2022	December 31, 2021
Accrued consulting and outside services	$ 742,900	$ 467,100
Accrued compensation	293,700	273,900
Total	$ 1,036,600	$ 741,000

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 December 31, 2021, this financing arrangement was paid in its entirety.

In November 2021, the Company entered into a financing arrangement for 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 March 31, 2022 and December 31, 2021, the remaining payable balance on the financed amount was $285,700 and $454,500, respectively.

8. COMMITMENTS AND CONTINGENCIES

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 March 31, 2022 and December 31, 2021, 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. The Company did not renew this agreement as of March 31, 2022 and there are no further estimated payments associated with the agreement.

Legal Proceedings— On March 22, 2021, Jason Terrell (“Terrell”), a former consultant former 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 the Company is obligated to issue him (i) options to purchase 500,000 shares of 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 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 the 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.

The Company disputes Terrell’s claims and allegations in the Action and intends to vigorously defend against them. On May 21, 2021, the Company 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 the Company's 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 the Company's 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.

Subsequently, the parties agreed upon a process for coordinating submissions and/or presentations to the Compensation Committee. The parties made their respective written submissions to the Compensation Committee on March 31, 2022 and are awaiting the Compensation Committee's determination(s).

In the interim, as noted, the Action is stayed and no further proceedings are taking place.

In a separate matter, 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 the Company's complaint hotline. These Complaints, alleged, among other topics, risks associated with the Company's public disclosures in securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the FDA authorization of the 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 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, 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 parties have agreed that the Defendants' shall respond to the complaint on June 30, 2022. 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.

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

On July 26, 2021, the Company completed its previously announced acquisition of 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 determined 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. 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
Goodwill (a)		430,000
Other current liabilities		(1,000)
Fair value of net assets acquired		540,000

(a) 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.

The Company assessed events and circumstances as of December 31, 2021 which was primarily driven by a reduced stock price as of December 31, 2021. The carrying value of the Company's assets was in excess of the market value of equity as of December 31, 2021. After analyzing this quantitative circumstance along with other qualitative considerations, the Company's management determined that an impairment of the entire value of the goodwill was appropriate. Accordingly, the Company recorded impairment expense of $430,000 during the year ended December 31, 2021.

10. LEASES

The Company adopted FASB ASU No. 2016-02, Leases (Topic 842) on January 1, 2022, using the modified retrospective method, in which it did not restate prior periods. Upon adoption, the Company elected the package of practical expedients permitted under the transition guidance within Topic 842 which, among other things, allowed the Company to carry forward the historical lease classification.

In our implementation of ASU No. 2016-02 the Company elected to discount lease obligations using our incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of lease payments. The Company's incremental borrowing rate represents the rate of interest that it would have to pay to borrow over a similar term an amount equal to the lease payments in a similar economic environment. The Company considers publicly available data for instruments with similar terms and characteristics when determining its incremental borrowing rates. In addition, we elected the practical expedient to account for the lease and non-lease components on a combined basis. The Company intends to use the full lease term under the existing lease agreement as the lease term, which is currently set to expire on April 30, 2026. As of March 31, 2022, the Company is not able to determine if any renewal options will be exercised.

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

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

Two further amendments were executed in 2021. The agreements commenced on November 1, 2021, and December 1, 2021 under an operating lease agreement that is noncancelable from commencement until May 1, 2024. The amended lease agreement adds approximately 3,684 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.

An amendment to the lease agreement was executed in January 2022 and commenced May 1, 2022. The amendment will add approximately 9,352 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. In year one and two monthly rent is $4,800 per month, in year three and four monthly rent is $4,896 per month, and in year five monthly rent is $5,000 per month.

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 following table indicates the balance sheet line items that include the right-of-use assets and lease liabilities for our operating lease:

	March 31, 2022
	Operating lease
Right-of-Use Asset	
Operating lease	$ 2,227,300
Total right-of use asset	2,227,300
Lease Liabilities	
Operating lease - short term	$ (480,300)
Operating lease - long term	(1,747,000)
Deferred rent	(5,500)
Total lease liabilities	(2,232,800)

For the three months ended March 31, 2022, the components of lease expense were as follows:

		2022
Operating lease cost allocated to research and development expense	$	82,300
Operating lease cost allocated to general and administrative expense		68,100
Total lease expense	$	150,400
Weighted-average remaining lease term		4.08
Weighted-average discount rate		7.12 %

As of March 31, 2022 the maturities of the Company's operating lease liabilities were as follows:

Maturity of Lease Liabilities		Operating lease
2022	$	465,300
2023		626,100
2024		628,900
2025		634,600
2026		212,500
Total lease payments		2,567,400
Less: imputed interest		(334,600)
Present value of lease payments		2,232,800

The Company maintains a month to month lease in Arlington, VA, which is considered a short term lease. The Company elected to exclude this lease from the determination of the right-of-use asset and lease liability, as permitted under ASC 842. The Company will recognize the lease payments in profit or loss in the statement of operations on a straight-line basis over the term of the lease.

Under ASC 840, rent expense recognized under the leases was $69,000 for the three months ended March 31, 2021.

Future minimum lease payments under noncancellable operating leases were:

		As of December 31, 2021
2022	$	616,157
2023		624,825
2024		523,939
Total lease payments		1,764,921

11. STOCKHOLDERS' EQUITY

As of March 31, 2022 and December 31, 2021, 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 March 31, 2022 and December 31, 2021, 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.

On July 2, 2021, the Company received net proceeds of $37,118,100 from its public offering, after deducting underwriting discounts and commissions of $2,494,900 and other offering expenses of $457,000 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 months ended March 31:

	2022	2021
Common Stock		
Balance at January 1,	$ 48,264,300	$ 11,975,400
Common stock initial public offering discount amortization	24,700	24,700
Common stock public offering discount amortization	60,400	—
Balance at March 31,	$ 48,349,400	$ 12,000,100

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.

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 880,785 shares and 433,895 shares available for issuance as of March 31, 2022, and December 31, 2021, respectively.

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 March 31, 2022.

These warrants were equity classified. As of March 31, 2022 and December 31, 2021, the warrant fair values of $232,600 and $257,300, 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 (the "Additional 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 Additional Underwriters' Warrants have a five-year term and are not exercisable prior to January 2, 2022. All of the Additional Underwriters' Warrants were outstanding at March 31, 2022.

These warrants were equity classified. As of March 31, 2022 and December 31, 2021, the fair value of the warrants was $868,900 and $929,300, respectively, 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 %

12. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan— Stock Options

The Black-Scholes option-pricing model has been used previously to estimate the fair value of stock options. However, there were no options granted during the three months ended March 31, 2022 and 2021.

The following table summarizes the activity for all stock options outstanding at March 31 under the 2017 Plan:

	2022		2021	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	380,909	$ 10.03	489,718	$ 10.03
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled and forfeited	(42,037)	9.19	(57,149)	17.88
Balance at March 31	338,872	$ 8.49	432,569	$ 8.99
Options exercisable at March 31:	332,674	$ 8.44	408,306	$ 8.75
Weighted average grant date fair value for options granted and expected to be vested during the period:		$ —		$ —

The following table summarizes additional information about stock options outstanding and exercisable at March 31, 2022 and 2021 under the 2017 Plan:

	Options Outstanding				Options Exercisable		
As of March 31,	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
2022	338,872	5.76	8.49	—	332,674	8.44	—
2021	432,569	6.72	8.99	839,700	408,306	8.75	269,514

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 ended March 31, 2022 and 2021 as follows:

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 49,000	$ 19,000
General and administrative	8,000	102,000
Total	$ 57,000	$ 121,000

On August 20, 2020, the board of directors canceled and terminated 15,792 stock options, granted during the quarter ended June 30, 2020 to four non-employees. Thereafter, on August 20, 2020, the board of directors granted 21,112 stock options to the same individuals with a grant date fair value of $12.81 per share. There were 3,959 stock option grants that were considered vested on the grant date. The effects of the stock option modifications resulted in $20,900 of stock compensation expense allocable to general and administrative for the three months ended March 31, 2021. Included in that amount were $9,600 of incremental compensation costs resulting from the modifications for the three months ended March 31, 2021.

As of March 31, 2022, total unrecognized stock compensation expense is $61,815 related to unvested stock options to be recognized over the remaining weighted-average vesting period of 0.79 years.

2017 Stock Incentive Plan—Restricted Stock Units

The 2017 Plan permits the Company to grant equity awards for 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 three months ended March 31, 2022 and 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 March 31 under the 2017 Plan:

	2022		2021	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year, as restated	510,851	$ 12.48	946,245	$ 12.81
Granted	—	—	6,019	9.00
Vested	(2,947)	8.71	—	—
Cancelled and forfeited	(334,271)	12.81	—	—
Nonvested RSUs at March 31,	173,633	$ 11.91	952,264	$ 12.79

Subsequent to the issuance of the December 31, 2021 consolidated financial statements, the Company identified an error related to the calculation of the number of vested shares of restricted stock units related to the Company's 2017 Equity Incentive Plan. The Company used an incorrect number of vested shares of restricted stock units for the year ended December 31, 2021. Accordingly, the Company restated the number of vested shares of restricted stock units for the year ended December 31, 2021 from 37,802 shares to 393,909 shares, and the resulting total non-vested restricted stock units at December 31, 2021 from 866,958 shares to 510,851 shares. Additionally, the weighted average grant date fair value of vested shares for the year ended December 31, 2021 was restated from $6.51 per share to $11.21 per share, and the weighted average grant date fair value for total nonvested restricted stock units as of December 31, 2021 was restated from $12.16 per share to $12.48 per share. This change did not have any impact on our earnings per share calculations, nor did it have any impact on any previous disclosures related to potentially dilutive securities excluded from the computations of diluted weighted-average shares of common stock outstanding. The Company has evaluated the materiality of this error and concluded that it is not material to the December 31, 2021 consolidated financial statements. Further, the Company will also prospectively restate the previously reported financial information for the related error in future and annual filings for the year ending December 31, 2022.

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 months ended March 31, 2022 and 2021, as follows:

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 12,000	$ 267,700
General and administrative	(7,100)	556,600
Total	$ 4,900	$ 824,300

On August 20, 2020, the board of directors canceled and terminated 709,334 RSUs, granted during the quarter ended June 30, 2020. The cancelled RSUs were originally granted to five individuals with a grant date fair value of $12.87 per share. Thereafter, on August 20, 2020, the board of directors granted 946,245 RSUs to the same individuals with a grant date fair value of $12.81 per share. None of the RSU grants were considered vested on the grant date. The RSU grants were modified for three employees and two non-employees. The effects of the RSU modifications did not result in any stock compensation expense during the three months ended March 31, 2022. The effects of the RSU modifications resulted in $267,700 and $556,600 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three months ended March 31, 2021. Included in those amounts were incremental compensation costs of $20,400 and $44,700 of stock compensation expense allocable to research and development and general and administrative, respectively, during the three months ended March 31, 2021.

2021 Stock Incentive Plan—Restricted Stock Units

The 2021 Plan permits the Company to grant equity awards for 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 three months ended March 31, 2022, 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 March 31, 2022 under the 2021 Plan:

	2022	
	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of year	62,049	$ 5.52
Granted	—	—
Vested	—	—
Cancelled and forfeited	(2,090)	4.22
Nonvested RSUs at March 31,	59,959	$ 5.57

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 months ended March 31, 2022, as follows:

	Three Months Ended March 31,
	2022
Research and development	$ 8,300
General and administrative	9,900
Total	$ 18,200

13. INCOME TAXES

The Company's effective tax rate from continuing operations was 0% for the three months ended March 31, 2022 and 2021. The Company recorded no income tax provision for the three months ended March 31, 2022 and 2021.

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.

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.

Our Business

Overview

Kiromic BioPharma, Inc. (together with its subsidiary, "we," "us," "our" or the "Company") is an artificial intelligence ("AI") driven, end-to-end allogenic cell therapy company, currently developing the multi-indication allogeneic T cell therapy that exploits the natural potency of Gamma Delta T cells ("GDTs") to target solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and good manufacturing practices ("GMP") manufacturing, which we believe will allow us to leverage a new framework for the next generation of cell therapies. We also have new technologies in development that we believe will support our end-to-end approach.

We are developing our Chimeric Antigen T cell ("CAR-T cell") platform known as ALEXIS. Our two product candidates are called ALEXIS-PRO-1 and ALEXIS-ISO-1. ALEXIS-PRO-1 is our allogeneic gamma delta chimeric T cell therapy product candidate targeting PD-L1. ALEXIS-ISO-1 is our allogenic gamma delta CAR-T cell therapy product candidate targeting Isomesothelin (the isoform of Mesothelin). These are designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells. We filed two Investigational New Drug ("IND") applications in May 2021 for ALEXIS-PRO-1 and ALEXIS-ISO-1. The IND applications for these trial candidates are currently on a clinical hold as of June 2021. In placing the clinical hold, the FDA 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 currently working on addressing the FDA's comments. Accordingly, for ALEXIS-PRO-1, we expect the clinical hold will be lifted in the second half of 2022 allowing us to begin the activation process for the clinical trial by the end of the last quarter of 2022. For ALEXIS-ISO-1, we expect to begin the activation process for the clinical trial by the end of the last quarter of 2023.

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.

Recent Developments

Going Concern

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.

Clinical Update

On May 10, 2022, the Company announced it reaffirmed its intent to submit an amended IND for ALEXIS-PRO-1 during the second half of 2022. The Company also announced ongoing progress toward the implementation of a current good manufacturing practice mammalian master cell bank, which will provide a GMP-grade retroviral vector for GDT engineering.

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 its periodic reports. See Part II, Item 1A. Risk Factors for further 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 until the earliest of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering, which was October 15, 2020, (b) the date in which our total annual gross revenues exceed $1.07 billion, or (c) the date in which 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 (ii) 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 Phase 1/2 clinical trials for our ALEXIS-PRO-1 and ALEXIS-ISO-1 trial candidates and continue to discover and develop additional 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 March 31, 2022 and 2021

The following table sets forth key components of our results of operations for the three months ended March 31, 2022 and 2021.

	Three Months Ended March 31,		Increase (Decrease)	
	2022	2021	$	%
Operating expenses:				
Research and development	$ 2,925,800	$ 1,885,600	$ 1,040,200	55.17 %
General and administrative	4,439,200	2,071,000	2,368,200	114.35 %
Total operating expenses	7,365,000	3,956,600	3,408,400	86.14 %
Loss from operations	(7,365,000)	(3,956,600)	3,408,400	86.14 %
Other income (expense)				
Gain on loan extinguishment	—	105,800	(105,800)	100.00 %
Interest expense	(2,800)	(3,700)	900	(24.32)%
Total other income (expense)	(2,800)	102,100	(104,900)	102.74 %
Net loss	$ (7,367,800)	$ (3,854,500)	$ 3,513,300	91.15 %

Research and development expenses. Our research and development expenses increased by $1,040,200, or 55.17%, to $2,925,800 for the three months ended March 31, 2022, from $1,885,600 for the three months ended March 31, 2021. The following table summarizes our research and development expenses by product candidate or development program:

	Three Months Ended March 31,		Increase (Decrease)	
	2022	2021	$	%
Direct research and development expenses by product candidate:				
ALEXIS-PRO-1	$ 229,300	$ 26,000	$ 203,300	781.92 %
ALEXIS-ISO-1	67,700	484,700	(417,000)	(86.03)%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	1,303,700	855,900	447,800	52.32 %
Laboratory supplies and services	330,800	120,700	210,100	174.07 %
Outsourced research and development	405,400	150,000	255,400	170.27 %
Laboratory equipment and maintenance	156,800	32,400	124,400	383.95 %
Facility-related costs	330,500	155,800	174,700	112.13 %
Intellectual Property	94,000	60,000	34,000	56.67 %
Other research and development costs	7,600	100	7,500	7,500.00 %
Total research and development expenses	$ 2,925,800	$ 1,885,600	$ 1,040,200	55.17 %

As illustrated above, the increase in research and development expenses primarily resulted from (i) a $447,800 increase in employee related costs, which primarily included a $709,600 increase in wages, benefits and payroll taxes, offset by reduced stock compensation expenses of $257,400 attributable to research and development employees; (ii) a $255,400 increase in outsourced research and development costs, which primarily included a $141,500 increase in regulatory consulting fees, and a $73,600 increase in research studies; (iii) a $210,100 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 (iv) a $203,300 increase in ALEXIS-PRO-1 direct research and development costs, which was mainly driven by increased disposables and consumables for GDT manufacturing, in-vitro, and in-vivo experimentation costs.

These cost increases were primarily incurred to support GDT manufacturing as well as experimentation and validation of our product candidates.

1. Augmented our research and development team: in the three months ended March 31, 2022 and 2021, our average headcount increased to 39 employees from 16 employees allocable to research and development and clinical trials preparation.

2. ALEXIS-PRO-1 Manufacturing and Experimentation: $203,300 increase in spending during the three months ended March 31, 2022, from manufacturing expanded GDTs in the recently expanded GMP facilities.

3. Increased regulatory consulting costs: in the three months ended March 31, 2022, we incurred an increase of $141,500 in regulatory and chemical manufacturing and control consulting fees compared to the same three months in 2021 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 $2,368,200, or 114.35%, to $4,439,200 for the three months ended March 31, 2022, from $2,071,000 for the three months ended March 31, 2021.

During the three months ended March 31, 2022, the increase primarily resulted from an increase in professional services of $1,613,700, and employee related expenses of $1,090,900.

The increase in professional services expenses was primarily driven by an increase of $1,492,900 in legal expenses, $80,200 from corporate finance professional fees, and $40,600 from other professional services during the three months ended March 31, 2022, compared to the same period in the prior year. We incurred significant legal expenses and accounting professional fees related to the Internal Review. Between October 1, 2021 and March 31, 2022, we incurred $4,089,600 in legal fees and other professional services directly attributed to the Internal Review and related matters. During that same period, we incurred $680,700 in accounting professional fees directly related to the Internal Review. During the three months ended March 31, 2022, we incurred $941,800 in legal fees and other professional services directly attributed to the Internal Review and related matters. During that same period, we incurred $253,500 in accounting professional fees directly related to the internal review.

Employee related expenses were impacted by increases to headcount, and recruiting. During the three months March 31, 2022 and 2021, the headcount for employees allocated to general and administrative purposes increased to 25.5 employees from 6.5 employees, respectively. In addition, the changes in headcount generated $146,400 in increased recruiting fees.

Gain on loan extinguishment. Gain on loan extinguishment was $0 and $105,800 for the three months ended March 31, 2022 and 2021, respectively. During the year ended December 31, 2020, we applied for forgiveness of the SBA Loan in accordance with the terms of the CARES Act. On February 16, 2021, the SBA granted forgiveness of the SBA Loan and all applicable interest. On the date of forgiveness, the principal and accrued interest totaled $105,800.

Interest expense. Interest expense was an expense of $2,800 and $3,700 for the three months ended March 31, 2022 and 2021, respectively. The increase is entirely driven by cash paid for interest attributed to the financing arrangement for our Director and Officer Insurance policy. 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 March 31, 2021, the remaining payable balance on the financed amount was $227,800.

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 March 31, 2022, the remaining payable balance on the financed amount was $285,700.

Net loss. As a result of the cumulative effect of the factors described above, our net loss increased to $7,019,400 during the three months ended March 31, 2022, compared to $3,854,500 during the three months ended March 31, 2021.

Liquidity and Capital Resources

As of March 31, 2022, we had cash and cash equivalents of $15,123,100. As of December 31, 2021, we had cash and cash equivalents of $25,353,900. As of April 30, 2022, we had cash and cash equivalents of $11,942,300 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.

We have known material contractual obligations which will require cash to meet their requirements. These applicable obligations include our facility lease agreement, our employment contracts, and our financing arrangement for our Director and Officer Insurance Policy. We also plan to deploy cash for other research and development and general and administrative operating expenses. Our ability to continue meeting these contractual obligations will be reliant upon our ability to secure significant additional capital funding.

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 first quarter of 2022 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, 2021. 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:

	Three Months Ended March 31,	
	2022	**2021**
Net cash used in operating activities	$ (7,578,900)	$ (2,635,900)
Net cash used in investing activities	(2,483,100)	(44,700)
Net cash provided by financing activities	(168,800)	(134,600)
Net increase in cash and cash equivalents	(10,230,800)	(2,815,200)
Cash and cash equivalents at beginning of the period	25,353,900	10,150,500
Cash and cash equivalents at end of the period	15,123,100	7,335,300

Cash flows from operating activities

Net cash used in operating activities was $7,578,900 for the three months ended March 31, 2022, as compared to $2,635,900 for three months ended March 31, 2021. In the three months ended March 31, 2022, the primary cash outflows were from the net loss of $7,367,800 and outflows from accounts payable of $882,800. These cash outflows were partly offset by accrued expenses and current liabilities of $295,600, and depreciation of $182,800. Net cash used in operating activities increased by a total of $4,943,000 period-over-period. The main driver for the increase is the change in net loss to $7,367,800 during the three months ended March 31, 2022, compared to $3,854,500 during the three months ended March 31, 2021. In addition, stock compensation expense was $80,100 and $945,200 during the three months ended March 31, 2022 and 2021, respectively. We primarily used cash to augment our headcount, develop our ALEXIS-PRO-1 product candidate, and pay for legal and professional fees. See “Results of Operations” above for further details.

Cash flows from investing activities

Net cash used for in investing activities was $2,483,100 for the three months ended March 31, 2022, as compared to $44,700 for the three months ended March 31, 2021. Our net cash used in investing activities consisted of purchases of property and equipment. This increase was primarily driven by 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

During the three months ended March 31, 2022 and 2021, we paid $168,800 and $134,600 towards our financing arrangement for our Director and Officer Insurance policy, respectively.

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 three months ended March 31, 2022 and 2021.

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 three months ended March 31, 2022 and 2021, 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 three months ended March 31, 2022 and 2021, we used our listed Nasdaq Capital Market closing price on the grant date to determine common stock valuation.

Warrants Underlying Shares of Equity Offering Common Stock— We record warrants to purchase shares of common stock underlying our shares of IPO common stock and July 2021 offering common stock ("the equity offerings") in accordance with ASC 470, *Debt with conversion and other options*. The fair value of the warrants was estimated on each 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. 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 CEO and 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 March 31, 2022. Based on this evaluation of our disclosure controls and procedures, our management, including our CEO and CFO, have concluded that our disclosure controls and procedures were not effective as of March 31, 2022 because of the material weaknesses in our internal control over financial reporting described below.

Changes in Internal Control over Financial Reporting

As disclosed under Item 9A., Controls and Procedures in our Annual Report on Form 10-K for the year ended December 31, 2021, we identified material weaknesses in our internal control over financial reporting because we (i) do not have a formal process for period end financial closing and reporting; (ii) we have insufficient resources to conduct an effective monitoring and oversight function independent from our operations; and (iii) we did not have a control to appropriately communicate relevant information from the FDA to appropriate parties on a timely basis. These material weaknesses resulted in an increased risk of material misstatement in the financial statements, and in our failure to timely disclose the June 16 and 17, 2021 FDA Communications.

We believe that we are addressing the material weaknesses identified in connection with the audit of our financial statements for the year ended December 31, 2021 and prior periods 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; and
- 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.

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 is 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. However, our management concluded that these material weaknesses still existed as of March 31, 2022. In order to consider these material weaknesses to be fully remediated, we believe additional time is needed to demonstrate effectiveness of the remediation.

Except as disclosed above, there have been no other changes in our internal control over financial reporting for the quarter ended March 31, 2022.

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.

Dr. Terrell Claim

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.

Subsequently, the parties agreed upon a process for coordinating submissions and/or presentations to the Compensation Committee. The parties made their respective written submissions to the Compensation Committee on March 31, 2022 and are awaiting the Compensation Committee's determination(s).

In the interim, as noted, the Action is stayed and no further proceedings are taking place.

Sabby and Empery Claim

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 parties have agreed that the Defendants' shall respond to the complaint on June 30, 2022. 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.

There have been no material changes to the risk factors previously disclosed in Part I, "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on April 8, 2022.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None

ITEM 6. EXHIBITS.

Exhibit No.	Description of Exhibit
3.1	Fourth Amended and Restated Certificate of Incorporation of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on October 21, 2020)
3.2	Second Amended and Restated Bylaws of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1/A filed on October 6, 2020)
10.1	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)
10.2	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)
10.3	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)
10.4	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)
10.5	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)
10.6	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)
10.7	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)
10.8	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)
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

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the Company specifically incorporates it by reference.

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: May 13, 2022

KIROMIC BIOPHARMA, INC.

/s/ Pietro Bersani

Name: Pietro Bersani

Title: Chief Executive Officer

(Principal Executive Officer)

/s/ Daniel Clark

Name: Daniel Clark

Title: 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: May 13, 2022

/s/ Pietro Bersani

Pietro Bersani
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: May 13, 2022

/s/ Daniel Clark
Daniel Clark
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

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

1. The Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 (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 May 13, 2022.

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

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

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

Exhibit 32.2

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

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

1. The Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 (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 May 13, 2022.

/s/ Daniel Clark
Daniel Clark
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.