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: 001-38210

Krystal Biotech, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**82-1080209**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

2100 Wharton Street, Suite 701
Pittsburgh, Pennsylvania 15203
(Address of principal executive offices and zip code)

(412) 586-5830
(Registrant's telephone number, including area code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	KRYS	NASDAQ Capital 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, 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 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 April 29, 2022, there were 25,635,138 shares of the registrant's common stock issued and outstanding.

Krystal Biotech, Inc.
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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

Krystal Biotech, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except shares and per share data)	(unaudited) March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 269,303	$ 341,246
Short-term investments	165,329	96,850
Prepaid expenses and other current assets	3,366	4,171
Total current assets	437,998	442,267
Property and equipment, net	136,927	112,355
Long-term investments	33,339	64,371
Right-of-use assets	8,453	7,228
Other non-current assets	157	74
Total assets	$ 616,874	$ 626,295
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 8,209	$ 8,398
Current portion of lease liability	1,411	1,041
Accrued expenses and other current liabilities	50,817	16,297
Total current liabilities	60,437	25,736
Lease liability	7,883	6,983
Total liabilities	68,320	32,719
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock; $0.00001 par value; 20,000,000 shares authorized at March 31, 2022 (unaudited) and December 31, 2021; 2,061,773 shares issued, and no shares outstanding at March 31, 2022 (unaudited) and December 31, 2021	—	—
Common stock; $0.00001 par value; 80,000,000 shares authorized at March 31, 2022 (unaudited) and December 31, 2021; 25,199,081 shares issued and outstanding at March 31, 2022 (unaudited); and 25,207,985 shares issued and outstanding at December 31, 2021	—	—
Additional paid-in capital	740,500	734,523
Accumulated other comprehensive expense	(1,197)	(163)
Accumulated deficit	(190,749)	(140,784)
Total stockholders' equity	548,554	593,576
Total liabilities and stockholders' equity	$ 616,874	$ 626,295

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

Krystal Biotech, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

(In thousands, except share and per share data)	Three Months Ended March 31, 2022	2021
Expenses		
Research and development	$ 9,314	$ 6,201
General and administrative	15,908	8,152
Litigation settlement	25,000	—
Total operating expenses	50,222	14,353
Loss from operations	(50,222)	(14,353)
Other Income (Expense)		
Interest and other income, net	257	33
Interest expense	—	(1,492)
Net loss	$ (49,965)	(15,812)
Unrealized loss on available-for-sale securities and other	(1,034)	(3)
Comprehensive loss	$ (50,999)	$ (15,815)
Net loss per common share: Basic and diluted	$ (1.99)	$ (0.74)
Weighted-average common shares outstanding: Basic and diluted	25,114,453	21,253,508

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

Krystal Biotech, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)

(In thousands, except shares)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Expense	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2022	25,207,985	$ —	$ 734,523	$ (163)	$ (140,784)	$ 593,576
Issuance of common stock, net	1,475	—	55	—	—	55
Restricted stock surrendered for taxes	(10,379)	—	(649)	—	—	(649)
Stock-based compensation expense	—	—	6,571	—	—	6,571
Unrealized loss on investments and other	—	—	—	(1,034)	—	(1,034)
Net loss	—	—	—	—	(49,965)	(49,965)
Balances at March 31, 2022	25,199,081	$ —	$ 740,500	$ (1,197)	$ (190,749)	$ 548,554

(In thousands, except shares)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Expense	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2021	19,714,220	$ —	$ 363,292	$ 6	$ (71,214)	$ 292,084
Issuance of common stock, net	2,489,837	—	152,033	—	—	152,033
Stock-based compensation expense	—	—	2,350	—	—	2,350
Unrealized loss on investments and other	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(15,812)	(15,812)
Balances at March 31, 2021	22,204,057	$ —	$ 517,675	$ 3	$ (87,026)	$ 430,652

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

Krystal Biotech, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

(In thousands)	Three Months Ended March 31, 2022	2021
Operating Activities		
Net loss	$ (49,965)	$ (15,812)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,015	536
Stock-based compensation expense	6,430	2,313
Non-cash interest expense	—	1,492
Other, net	(135)	12
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	820	1,312
Other non-current assets	9	—
Lease liability	(126)	(77)
Accounts payable	(554)	294
Accrued expenses and other current liabilities	2,013	276
Accrued legal settlement	25,000	—
Net cash used in operating activities	(15,493)	(9,654)
Investing Activities		
Purchases of property and equipment	(17,191)	(2,473)
Purchases of investments	(62,754)	—
Proceeds from maturities of investments	24,037	1,726
Net cash used in investing activities	(55,908)	(747)
Financing Activities		
Issuance of common stock, net	107	152,264
Taxes paid related to settlement of restricted stock awards	(649)	—
Repayment of ASTRA build to suit liability	—	(7,960)
Net cash provided by (used in) financing activities	(542)	144,304
Net increase (decrease) in cash and cash equivalents	(71,943)	133,903
Cash and cash equivalents at beginning of period	341,246	268,269
Cash and cash equivalents at end of period	$ 269,303	$ 402,172
Supplemental Disclosures of Non-Cash Investing and Financing Activities		
Unpaid purchases of property and equipment	$ 14,507	$ 2,615
Initial recognition of right-of-use assets	$ 1,394	$ —
Unpaid offering costs	$ 24	$ 214

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

Krystal Biotech, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization

Krystal Biotech, Inc. (the “Company,” or “we” or other similar pronouns) commenced operations on April 15, 2016. On March 31, 2017, the Company converted from a California limited liability company to a Delaware C-corporation, and changed its name from Krystal Biotech LLC to Krystal Biotech, Inc. On June 19, 2018, the Company incorporated Krystal Australia Pty Ltd., an Australian proprietary limited company, a wholly-owned subsidiary, for the purpose of undertaking preclinical and clinical studies in Australia. On April 24, 2019, the Company incorporated Jeune Aesthetics, Inc., formerly known as Jeune, Inc. ("Jeune"), in Delaware, a wholly-owned subsidiary, for the purpose of undertaking preclinical and clinical studies for aesthetic skin conditions. On January 7, 2022, the Company incorporated Krystal Biotech Switzerland GmbH, for the purpose of establishing initial operations in Europe for the development and commercialization of Krystal's pipeline.

We are a clinical stage biotechnology company leading the field of redosable gene delivery. Using our patented platform that is based on engineered herpes simplex virus type 1 ("HSV-1"), we create vectors that efficiently deliver therapeutic transgenes to cells of interest in multiple organ systems. The cell’s own machinery then transcribes and translates the encoded effector to treat or prevent disease. We formulate our vectors for non-invasive or minimally invasive routes of administration at a doctor’s office or potentially in the patient’s home by a healthcare professional. Our goal is to develop easy to use medicines to dramatically improve the lives of patients living with debilitating diseases. Our innovative technology platform is supported by in-house, commercial scale current good manufacturing practices ("cGMP") manufacturing capabilities.

Liquidity

As of March 31, 2022, the Company had an accumulated deficit of $190.7 million. With the net proceeds raised from its public and private securities offerings the Company believes that its cash, cash equivalents and short-term investments of approximately $434.6 million as of March 31, 2022 will be sufficient to allow the Company to fund its planned operations for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. As the Company continues to incur losses, a transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and the achievement of a level of revenues adequate to support the Company’s cost structure. The Company may never achieve profitability and unless and until it does, the Company will continue to need to raise additional capital or obtain financing from other sources. Management intends to fund future operations through the sale of equity and debt financings and may also seek additional capital through arrangements with strategic partners or other sources. There can be no assurance that additional funding will be available on terms acceptable to the Company, if at all.

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to the failure of product candidates in clinical and preclinical studies, the development of competing product candidates or other technological innovations by competitors, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to commercialize product candidates.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (“GAAP”), as found in the Accounting Standards Codification (“ASC”), the Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”), and the rules and regulations of the US Securities and Exchange Commission (“SEC”). In the opinion of management, all adjustments, which consist of all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended March 31, 2022 and 2021, are reflected in the interim condensed consolidated financial statements. All intercompany balances and transactions have been eliminated in consolidation. Certain prior period amounts have been reclassified to conform to the current period presentation. The reclassified amounts have no impact on the Company’s previously reported financial position or results of operation.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These unaudited interim condensed financial statements should be read in conjunction with the Company’s audited consolidated financial statements and the notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on February 28, 2022.

Risks and Uncertainties

The novel coronavirus ("COVID-19") pandemic has resulted, and is likely to continue to result, in significant national and global economic uncertainty and may adversely affect our business. The Company is continuing to actively monitor the impact of the COVID-19 pandemic and the related effects on its financial condition, liquidity, operations, suppliers, industry, and workforce. However, the full extent, consequences, and duration of the COVID-19 pandemic and the resulting impact on the Company cannot currently be predicted. The Company will continue to evaluate the impact that these events could have on the operations, financial position, and the results of operations and cash flows during fiscal year 2022.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the condensed consolidated financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements. Estimates are used in the following areas including stock-based compensation expense, accrued expenses, the fair value of financial instruments, the incremental borrowing rate for lease liabilities, and the valuation allowance included in the deferred income tax calculation.

Segment and Geographical Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company and the Company’s chief operating decision maker view the Company’s operations and manage its business in one operating segment, which is the business of developing and commercializing pharmaceuticals.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to credit risk consist of cash, cash equivalents and investments. The Company’s policy is to invest its cash, cash equivalents and investments in money market funds, certificates of deposit, corporate bonds, commercial paper, government agency securities and various other bank deposit accounts. The counterparties to the agreements relating to the Company’s investments consist of financial institutions of high credit standing. The Company is exposed to credit risk in the event of default by the financial institutions to the extent amounts recorded on the balance sheets are in excess of insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no financial instruments with off-balance sheet risk of loss.

Cash, Cash Equivalents and Investments

Cash and cash equivalents consist of money market funds and bank deposits. Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase.

Investments with maturities of greater than 90 days but less than one year are classified as short-term investments on the consolidated balance sheets and consist of commercial paper, corporate bonds, and government agency securities. Investments with maturities of greater than one year are classified as long-term investments on the consolidated balance sheets and consist of corporate bonds and government agency securities. Accrued interest on corporate bonds and government agency securities are also classified as short-term investments.

As our entire investment portfolio is considered available for use in current operations, we classify all investments as available-for-sale securities. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in accumulated other comprehensive loss, which is a separate component of stockholders’ equity in the consolidated balance sheets.

Fair Value of Financial Instruments

Fair value is defined as 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. There is a three-level hierarchy that prioritizes the inputs used in determining fair value by their reliability and preferred use, as follows:

- *Level 1*— Valuations based on quoted prices in active markets for identical assets or liabilities.
- *Level 2*— Valuations based on quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data.
- *Level 3*— Valuations based on inputs that are both significant to the fair value measurement and unobservable.

To the extent that a valuation is based on models or inputs that are less observable, or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized within Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

There have been no significant changes to the valuation methods utilized by the Company during the periods presented. There have been no transfers between Level 1, Level 2, and Level 3 in any periods presented.

The carrying amounts of financial instruments consisting of cash and cash equivalents, investments, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities included in the Company's financial statements, are reasonable estimates of fair value, primarily due to their short maturities. Marketable securities are classified as long-term investments if the Company has the ability and intent to hold them and such holding period is longer than one year. The Company classifies all of its investments as available-for-sale.

Our available-for-sale, short-term and long-term investments, which consist of, commercial paper, corporate bonds, and government agency securities are considered to be Level 2 valuations. The fair value of Level 2 financial assets is determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data, such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis.

Property and Equipment, net

Property and equipment, net, is stated at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred, while costs of major additions and betterments are capitalized. Upon disposal, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

Computer equipment and software	3 - 7 years
Lab equipment	3 - 7 years
Furniture and fixtures	3 - 7 years
Leasehold improvement	lesser of remaining useful life or remaining lease term

Construction in progress ("CIP") is not depreciated until the asset is placed in service.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. The Company has not recognized any impairment losses for the three months ended March 31, 2022 and 2021.

Leases

The Company accounts for its lease agreements in accordance with FASB ASC Topic 842, Leases ("ASC 842"). Right-of-use lease assets represent our right to use an underlying asset during the lease term and the lease obligations represent our commitment to make lease payments arising from the lease. Right-of-use lease assets and obligations are recognized based on the present value of remaining lease payments over the lease term. As the Company's lease agreements do not provide an implicit rate and as the Company does not have any external borrowings, we have used an estimated incremental borrowing rate based on the information available at lease commencement in determining the present value of lease payments. Operating lease expense is recognized on a straight-line basis over the lease term. Variable lease expense is recognized in the period in which the obligation for the payment is incurred. In addition, the Company also has made an accounting policy election to exclude leases with an initial term of twelve months or less from its balance sheet and to account for lease and non-lease components of its operating leases as a single component.

For lease arrangements where it has been determined that the Company has control over an asset that is under construction and is thus considered the accounting owner of the asset during the construction period, the Company records a construction in progress asset and corresponding financial obligation on the condensed consolidated balance sheet. Once the construction is complete, an assessment is performed to determine whether the lease meets certain "sale-leaseback" criteria. If the sale-leaseback criteria are determined to be met, the Company will remove the asset and related financial obligation from the condensed consolidated balance sheet and treat the lease as either an operating or finance lease based on our assessment of the guidance. If, upon completion of construction, the project does not meet the "sale-leaseback" criteria, the lease will be treated as a financing obligation and the Company will depreciate the asset over its estimated useful life for financial reporting purposes once the asset has been placed into service.

Research and Development Expenses

Research and development costs are charged to expense as incurred in performing research and development activities. These costs include employee compensation costs, facilities and overhead, preclinical and clinical activities, related clinical manufacturing costs, contract management services, regulatory and other related costs.

The Company estimates contract research and clinical trials materials manufacturing expenses based on the services performed pursuant to contracts with research organizations and manufacturing organizations that manufacture materials used in the Company's ongoing preclinical and clinical studies. Non-refundable advanced payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. These estimates are based on communications with the third party service providers and the Company's estimates of accrued expenses using information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

Stock-Based Compensation Expense

The Company applies the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718, *Compensation—Stock Compensation* ("ASC 718"), to account for stock-based compensation. Compensation costs related to stock options granted is based on the estimated fair value of the awards on the date of grant.

ASC 718 requires all stock-based payments, including grants of stock options and restricted stock, to be recognized in the statements of operations based on their grant-date fair values. Compensation expense is recognized on a straight-line basis based on the grant-date fair value over the associated service period of the award, which is generally the vesting term.

The Company estimates the fair value of its stock options using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including: (i) the expected stock price volatility; (ii) the expected term of the award; (iii) the risk-free interest rate; and (iv) expected dividends. Once the Company's own sufficient historical volatility data was obtained, the Company eliminated the use of a representative peer group and uses only its own historical volatility data in its estimate of expected volatility.

The Company estimates the expected term of its stock options using the "simplified" method, whereby the expected term equals the arithmetic mean of the vesting term and the original contractual term of the option. The risk-free interest rates are based on US Treasury securities with a maturity date commensurate with the expected term of the associated award. The

Company has never paid and does not expect to pay dividends in the foreseeable future. The Company accounts for forfeitures as they occur. Stock-based compensation expense recognized in the financial statements is based on awards for which service conditions are expected to be satisfied.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions from non-owner sources. Unrealized gains or losses on available-for-sale securities is a component of other comprehensive gains or losses and is presented net of taxes. We have not recorded any reclassifications from other comprehensive gains or losses to net loss during any period presented.

Recent Accounting Pronouncements

ASU No. 2020-08, Codification Improvements to Subtopic 310-20, Receivables - Nonrefundable Fees and Other Costs

In October 2020, the FASB issued ASU 2020-08, *Codification Improvements to Subtopic 310-20, Receivables - Nonrefundable Fees and Other Costs* ("ASU 2020-08") to provide further clarification and update the previously issued guidance in ASU 2017-08, *Receivables - Nonrefundable Fees and Other Costs (Subtopic 310-20: Premium Amortization on Purchased Callable Debt Securities)* ("ASU 2017-08"). ASU 2017-08 shortened the amortization period for certain callable debt securities purchased at a premium by requiring that the premium be amortized to the earliest call date. ASU 2020-08 requires that at each reporting period, to the extent that the amortized cost of an individual callable debt security exceeds the amount repayable by the issuer at the next call date, the excess premium shall be amortized to the next call date. The new standard was effective beginning January 1, 2021 and should be applied on a prospective basis as of the beginning of the period of adoption for existing or newly purchased callable debt securities. The adoption of ASU 2020-08 did not have a material impact on the Company's financial position or results of operations upon adoption.

3. Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of shares of common stock and common share equivalents outstanding for the period. Common share equivalents consist of common stock issuable upon exercise of stock options and vesting of restricted stock awards. There were 3,226,962 and 1,423,540 common share equivalents outstanding as of March 31, 2022 and 2021, respectively, in the form of stock options and unvested restricted stock awards, that have been excluded from the calculation of diluted net loss per common share as their effect would be anti-dilutive for all periods presented.

	Three Months Ended March 31,	
	2022	2021
(In thousands, except shares and per share data)	**(Unaudited)**	
Numerator:		
Net loss per common share	$ (49,965)	$ (15,812)
Denominator:		
Weighted-average basic and diluted common shares	25,114,453	21,253,508
Basic and diluted net loss per common share	$ (1.99)	$ (0.74)

4. Fair Value Instruments

The following tables show the Company's cash, cash equivalents and available-for-sale securities by significant investment category as of March 31, 2022 and December 31, 2021, respectively (in thousands):

	March 31, 2022 (unaudited)						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities [1]	Long-term Marketable Securities [2]
Level 1:							
Cash and cash equivalents	$ 269,303	$ —	$ —	$ 269,303	$ 269,303	$ —	$ —
Subtotal	269,303	—	—	269,303	269,303	—	—
Level 2:							
Commercial paper	39,476	—	(37)	39,439	—	39,439	—
Corporate bonds	106,741	2	(724)	106,019	—	81,961	24,058
U.S. government agency securities	53,650	—	(440)	53,210	—	43,929	9,281
Subtotal	199,867	2	(1,201)	198,668	—	165,329	33,339
Total	$ 469,170	$ 2	$ (1,201)	$ 467,971	$ 269,303	$ 165,329	$ 33,339

	December 31, 2021						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities [1]	Long-term Marketable Securities [2]
Level 1:							
Cash and cash equivalents	$ 341,246	$ —	$ —	$ 341,246	$ 341,246	$ —	$ —
Subtotal	341,246	—	—	341,246	341,246	—	—
Level 2:							
Commercial paper	40,469	1	(4)	40,466	—	40,466	—
Corporate bonds	83,300	10	(114)	83,196	—	35,768	47,428
U.S. government agency securities	37,621	—	(62)	37,559	—	20,616	16,943
Subtotal	161,390	11	(180)	161,221	—	96,850	64,371
Total	$ 502,636	$ 11	$ (180)	$ 502,467	$ 341,246	$ 96,850	$ 64,371

(1) The Company's short-term marketable securities mature in one year or less.
(2) The Company's long-term marketable securities mature between one year and two years.

See Note 2 to these unaudited condensed consolidated financial statements for additional discussion regarding the Company's fair value measurements.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	March 31, 2022	December 31, 2021
	(Unaudited)	
Construction in progress	$ 128,933	$ 104,340
Leasehold improvements	5,736	5,723
Furniture and fixtures	900	891
Computer equipment and software	96	85
Laboratory and manufacturing equipment	5,938	5,530
Total property and equipment	141,603	116,569
Accumulated depreciation and amortization	(4,676)	(4,214)
Property and equipment, net	$ 136,927	$ 112,355

Depreciation expense was $462 thousand and $438 thousand for the three months ended March 31, 2022 and 2021, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
	(Unaudited)	
Accrued preclinical and clinical expenses	$ 2,647	$ 1,602
Accrued professional fees	4,168	2,011
Accrued payroll and benefits	1,560	2,882
Accrued taxes	149	83
Accrued construction in progress	17,097	9,606
Accrued financing costs	54	26
Accrued litigation settlement	25,000	—
Other current liabilities	142	87
Total	$ 50,817	$ 16,297

6. Commitments and Contingencies

Significant Contracts and Agreements

Lease Agreements

On May 26, 2016, the Company signed an operating lease for laboratory and office space that commenced in June 2016 and expired on October 31, 2017 (the “2016 Lease”). The 2016 Lease has been amended several times to increase the area leased, which currently consists of approximately 47,000 square feet and includes the commercial scale cGMP-compliant manufacturing facility, ANCORIS. As a result of the lease amendments, the lease expiration date was extended to October 31, 2031.

On December 26, 2019, we entered into a lease agreement for our second commercial gene therapy facility ("ASTRA") in the Pittsburgh, Pennsylvania area ("ASTRA lease") with Northfield I, LLC (the "Landlord", "Northfield", or "Lessor") with

an initial lease term that expired on October 31, 2035. The ASTRA lease contained an option ("Purchase Option") to purchase the building, related improvements and take corresponding assignment of the Landlord's rights under its existing Ground Lease (the "Ground Lease"). A cash contribution in the amount of $2.4 million was paid to escrow on January 21, 2020. The contribution was intended to reduce the amount of the building construction costs and had the effect of reducing the base rental rate of the lease and as such, was recorded as prepaid rent in the consolidated balance sheet at the time of payment.

On October 5, 2020, the Company was provided with notice that the initial delivery conditions of the building had been met, including completion of the building shell, interior slab, and exterior doors, and on October 15, 2020, the Company gave the Landlord notice of its intent to purchase ASTRA for approximately $9.4 million, subject to the parties entering into a commercially reasonable purchase and sale agreement. As a result of the Company's ability to exercise its option to purchase ASTRA, the Company obtained control over the construction in progress of ASTRA as of October 5, 2020. The Company recorded a $10.0 million CIP asset and a corresponding build to suit lease liability related to the costs incurred by the Landlord, offset by the previous cash contribution of $2.4 million.

On January 29, 2021, the Company entered into a Purchase and Sale Agreement ("PSA") for ASTRA with Northfield related to the purchase option exercised by the Company on October 15, 2020, for a purchase price of $9.4 million. The Company held approximately $1.5 million on deposit with Northfield under the existing lease agreement and applied this deposit as a credit against the purchase price at closing. On February 1, 2021, Northfield delivered the space as substantially complete and made the space available for access by the Company, thus triggering lease commencement. As a result, the Company concluded that this transaction did not qualify for sale-leaseback accounting because it did not meet the definition of a sale. As control did not transfer to the Lessor at lease commencement, the transaction continued to be accounted for as construction in progress and a financing obligation. On March 5, 2021, the purchase closed and the Company determined that reclassification of the construction in progress to buildings and leasehold improvements was not appropriate as the interior of the building was not yet ready for its intended use. The building continues to be held under construction in progress as of March 31, 2022. The interior of the building is currently under construction and is expected to be completed and validated in 2022. From construction completion to the closing of the purchase, the Company recognized interest expense to accrete the financial obligation to a balance that equaled the cash consideration that was paid upon the close of purchase. For more information about the expected construction costs associated with ASTRA, see "ASTRA Contractual Obligations" below.

As part of the transaction, the Company also became the accounting owner of the Ground Lease, due to obtaining control over ASTRA, and recorded the applicable operating right-of-use asset and corresponding lease liability as of October 5, 2020. When the PSA was finalized, the Company took assignment of the Lessor's Ground Lease, in accordance with the Purchase Option, of which lease payments are based on annual payments of $82 thousand, and are subject to a cumulative 10% escalation clause every 5 years through 2071.

On December 15, 2021, the Company entered into a 3 year lease agreement for our Boston, Massachusetts office (the "Boston Lease") location that commenced in January 2022 and expires in January 2025.

As of March 31, 2022, future minimum commitments under the Company’s operating leases were as follows (in thousands):

		Operating Leases
2022 (remaining nine months)	$	1,115
2023		1,510
2024		1,539
2025		1,277
2026		1,277
Thereafter		12,063
Future minimum operating lease payments	$	18,781
Less: Interest		9,487
Present value of lease liability	$	9,294

Supplemental condensed consolidated balance sheet information related to leases is as follows:

	(unaudited) March 31, 2022		December 31, 2021	
Operating leases:				
Right-of-use assets	$ 8,453		$ 7,228	
Current portion of lease liability	1,411		1,041	
Lease liability	7,883		6,983	
Total lease liability	$ 9,294		$ 8,024	
Weighted average remaining lease term, in years		13.0		14.4
Weighted average discount rate	9.3	%	9.5	%

The Company recorded operating lease costs of $409 thousand and $218 thousand for the three months ended March 31, 2022 and 2021, respectively, and variable lease costs of $49 thousand and $37 thousand for the three months ended March 31, 2022 and 2021, respectively.

Agreements with Contract Manufacturing Organizations and Contract Research Organizations

The Company enters into various agreements in the normal course of business with Contract Research Organizations ("CROs"), Contract Manufacturing Organizations ("CMOs") and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. The agreements with CMOs relate to the manufacturing of sterile gel that is mixed with in-house produced vectors as part of the final drug product applied in certain of our clinical trials. These agreements may also include research and development activities, storage, packaging, labeling, and/or testing of our preclinical and clinical-stage products. The Company is obligated to make milestone payments under certain of these agreements. The estimated remaining commitment as of March 31, 2022 under these agreements is approximately $3.1 million. The Company may also be responsible for the payment of a monthly service fee for project management services for the duration of any agreements. The Company has incurred expenses under these agreements of $1.8 million for each of the three months ended March 31, 2022 and 2021.

Commercial Preparedness Activities

The Company has contracted with various third parties to facilitate, coordinate and perform agreed upon commercial preparedness and market research activities relating to our lead product candidate. These contracts typically call for the payment of fees for services upon the achievement of certain milestones. The estimated remaining commitment as of March 31, 2022 is $4.3 million. The Company has incurred expenses under these activities of $3.1 million and $1.3 million for the three months ended March 31, 2022 and 2021, respectively.

ASTRA Contractual Obligations

The Company has contracted with various third parties to construct our second cGMP facility, ASTRA. Additionally, we have entered into various non-cancellable purchase agreements for long-lead materials to help avoid potential schedule disruptions or material shortages. These contracts typically call for the payment of fees for services or materials upon the achievement of certain milestones. The estimated remaining commitment as of March 31, 2022 is $20.2 million. The Company has included costs incurred to-date associated with ASTRA within construction in progress as of March 31, 2022.

On June 30, 2021, the Company entered into a Standard Form of Contract for Construction and the corresponding General Conditions of the Contract for Construction (collectively, the “Agreement”) with The Whiting-Turner Contracting Company (“Whiting-Turner”), pursuant to which Whiting-Turner is constructing and managing the construction of ASTRA. Subject to certain conditions in the Agreement, the Company will pay Whiting-Turner a contract price consisting of the cost of work plus a fee equal to 1.75% of the cost of work.

Effective September 13, 2021, the Company entered into a guaranteed maximum price amendment (the "Amendment") to the Agreement to set forth the guaranteed maximum price, as well as the date by which Whiting-Turner is to achieve Substantial Completion (as defined in the Agreement). Under the Amendment, the guaranteed maximum price to be paid by the Company is $82.3 million, subject to certain additions and deductions by change orders as provided by the Agreement. Whiting-Turner’s work under the Agreement represents a portion of the work necessary to complete construction

of the ASTRA facility and, therefore the date of Substantial Completion of Whiting-Turner's work under the Agreement does not equate to the date of completion of ASTRA. The guaranteed maximum price under the Agreement constitutes only a portion of the total estimated cost of building and equipping ASTRA.

Legal Proceedings

On May 1, 2020, a complaint was filed against us in the United States District Court for the Western District of Pennsylvania by PeriphaGen, Inc. ("PeriphaGen"), which also named our Chief Executive Officer and President, R&D, Krish Krishnan and Suma Krishnan, respectively. The complaint alleged breach of contract and misappropriation of trade secrets, which secrets the plaintiff asserted were used to develop our product candidates, including the vector backbones, and our STAR-D platform. We answered the complaint on June 26, 2020 by denying the allegations and brought a counterclaim asking the court to declare that we did not misappropriate PeriphaGen's trade secrets or confidential information, and to further declare that we are the rightful and sole owner of our product candidates and STAR-D platform. In addition, we filed a third-party complaint against two principals of PeriphaGen, James Wechuck and David Krisky, alleging breach of contract and seeking contribution and indemnification from them in the event PeriphaGen is awarded damages.

On March 9, 2022, the court officially ordered the parties to attend mediation on March 11, 2022. During the course of the mediation process, the parties were able to exchange information, allowing the parties to value their positions. On March 12, 2022, we entered into a binding term sheet. In consideration of settling the dispute, the acquisition of certain PeriphaGen assets, and the grant of a license by PeriphaGen for dermatological applications, Krystal made a payment of $25.0 million on April 28, 2022. Upon approval of Krystal's first product by the U.S. Food and Drug Administration ("FDA"), Krystal will pay an additional $12.5 million, followed by three additional $12.5 million contingent milestone payments upon reaching $100.0 million in total cumulative sales, $200.0 million in total cumulative sales and $300.0 million in total cumulative sales. As defined in the settlement agreement, cumulative sales shall include all revenue from sales of Krystal products by Krystal and its affiliates and licensees, as reported by Krystal in its annual Form 10-K filings. If all milestones are achieved, the total consideration for settling the dispute, acquiring certain assets, and granting of a license from PeriphaGen will be $75.0 million.

The final settlement agreement was signed on April 28, 2022, and, because we deemed settlement to be probable as of the balance sheet date, we have recorded an accrued liability equal to the settlement of $25.0 million under accrued expenses and other current liabilities on the condensed consolidated balance sheet and under litigation settlement expense on the condensed consolidated statements of operations. The additional contingent milestone payments were not deemed probable due to uncertainty in the achievement of these milestones as of March 31, 2022, and therefore no additional accrual has been recorded.

The Company has received $768 thousand of insurance proceeds during the three months ended March 31, 2022 and we have recorded an additional $301 thousand as a receivable within prepaid expenses and other current assets on the condensed consolidated balance sheet as management determined that the amount was probable of collection relating to legal defense costs and expenses associated with the PeriphaGen litigation. The reimbursements have been recorded as an offset to our legal fees included in general and administrative expenses on the condensed consolidated statements of operations and within operating activities on the condensed consolidated statements of cash flows.

7. Capitalization

Sale of Common Stock

On December 3, 2021, the Company completed a public offering of 2,866,667 shares of its common stock, including 200,000 shares purchased by the underwriters, at $75.00 per share. Net proceeds to the Company from the offering were $201.9 million after deducting underwriting discounts and commissions of approximately $12.9 million, and other offering expenses payable by the Company of $227 thousand.

On February 1, 2021, the Company completed a public offering of 2,211,538 shares of its common stock, including 288,461 shares purchased by the underwriters, at $65.00 per share. Net proceeds to the Company from the offering were $134.9 million after deducting underwriting discounts and commissions of approximately $8.6 million, and other offering expenses payable by the Company of $198 thousand.

On December 31, 2020, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") with respect to an at-the-market equity offering program ("ATM Program"), under which Cowen will act as the Company's agent and/or principal and may issue and sell from time to time, during the term of the Sales Agreement, shares of our common stock, having an aggregate offering price up to $150.0 million ("Placement Shares"). Related offering expenses payable by the Company were $172 thousand. The issuance and sale of the Placement Shares by the Company under the Sales Agreement will be made pursuant to the Company's effective "shelf" registration statement on Form

S-3. During the three months ended March 31, 2021, 262,500 shares of common stock were issued pursuant to the ATM Program at a weighted average price of $66.50 per share for net proceeds of $16.9 million after deducting underwriting discounts and commissions of approximately $524 thousand, resulting in a remaining $132.5 million available for issuance under the ATM Program.

8. Stock-Based Compensation

Stock Options

Options granted to employees vest ratably over four-year periods and stock options granted to directors of the company vest ratably over one year to four-year periods. Stock options have a life of ten years.

The Company granted 1,179,500 and 502,450 stock options to employees and directors of the Company during the three months ended March 31, 2022 and 2021, respectively.

The following table summarizes the Company's stock option activity:

	Stock Options Outstanding	Weighted-average Exercise Price	Weighted-average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands) [1]
Outstanding at December 31, 2021	2,043,179	$ 57.00	9.0	$ 31,331
Granted	1,179,500	$ 62.53		
Exercised	(1,475)	$ 37.34		
Cancelled or forfeited	(68,342)	$ 61.24		
Expired	—	$ —		
Outstanding at March 31, 2022	3,152,862	$ 58.99	9.1	$ 30,364
Exercisable at March 31, 2022	439,954	$ 44.52	7.6	$ 10,929

(1) Aggregate intrinsic value represents the difference between the closing stock price of our common stock on March 31, 2022 and the exercise price of outstanding in-the-money options.

The total intrinsic value (the amount by which the fair market value exceeds the exercise price) of stock options exercised during the three months ended March 31, 2022 and 2021 was $36 thousand and $808 thousand, respectively.

The weighted-average grant-date fair value per share of options granted to employees and directors during the three months ended March 31, 2022 and 2021 was $43.09 and $50.04, respectively.

There was $101.1 million of unrecognized stock-based compensation expense related to employees' and directors' option awards that is expected to be recognized over a weighted-average period of 3.4 years as of March 31, 2022.

The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards in the condensed consolidated statements of operations for the three months ended March 31, 2022 and 2021 as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
	(unaudited)	
Research and development	$ 1,368	$ 516
General and administrative	4,582	1,615
Total stock-based compensation	$ 5,950	$ 2,131

We capitalize the portion of stock-based compensation that relates to work performed on the construction of new buildings. There was $141 thousand and $37 thousand of stock-based compensation that was capitalized in the three months ended March 31, 2022 and 2021, respectively.

The Company recorded stock-based compensation expense of $6.0 million and $2.1 million for the three months ended March 31, 2022 and 2021, respectively. The fair value of options was estimated at the date of grant using the Black-Scholes valuation model with the following weighted-average assumptions for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	2021
Expected stock price volatility	78 %	73 %
Expected term of the award (years)	6.24	6.22
Risk-free interest rate	1.79 %	1.00 %
Weighted average exercise price	$ 62.53	$ 77.46
Forfeiture rate	— %	— %

Restricted Stock Awards

Restricted stock awards ("RSAs") granted to employees vest ratably over a four-year period. The Company granted zero and 98,800 RSAs to employees of the Company during the three months ended March 31, 2022 and 2021, respectively.

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested RSAs as of December 31, 2021	98,800	$ 78.89
Granted	—	$ —
Vested	(14,321)	$ 78.89
Forfeited	(10,379)	$ 78.89
Non-vested RSAs as of March 31, 2022	74,100	$ 78.89

There was $5.7 million of unrecognized stock-based compensation expense related to employees' awards that is expected to be recognized over a weighted-average period of 2.9 years as of March 31, 2022.

The Company recorded stock-based compensation expense related to RSAs of $480 thousand and $182 thousand for the three months ended March 31, 2022 and 2021, respectively, within general and administrative expenses in the accompanying condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2022	2021
	(unaudited)	
General and administrative	$ 480	$ 182
Total stock-based compensation	$ 480	$ 182

Shares remaining available for grant under the Company's stock incentive plan were 1,028,815, with a sublimit for incentive stock options of 26,546, at March 31, 2022.

9. Subsequent Events

On April 28, 2022, the Company entered into a final settlement agreement and paid PeriphaGen an upfront payment of $25.0 million for: (i) the resolution of all claims in the trade secret litigation with PeriphaGen, Inc.; (ii) the acquisition of certain PeriphaGen assets, and (iii) the grant of a license by PeriphaGen for dermatological applications.

On April 5, 2022, pursuant to an inbound request, the Company issued and sold 434,782 shares of common stock at a weighted average price of $69.00 per share, under it's ATM Program, for net proceeds of $29.1 million after deducting underwriting discounts and commissions.

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

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed consolidated financial statements and related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on February 28, 2022.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or similar expressions and the negatives of those terms. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Some of such factors include, but are not limited to:

- the initiation, timing, cost, progress and results, of our research and development activities, preclinical studies and clinical trials for B-VEC (previously "KB103" and now known as Vyjuvek™), KB105, KB104, KB407, KB408, KB301, KB303, and any other product candidates;
- the continuing impact that the COVID-19 pandemic and measures implemented to prevent its spread may have on our business operations, access to capital, research and development activities, and preclinical and clinical trials for our product candidates;
- the timing, scope or results of regulatory filings and approvals, including timing of final US Food and Drug Administration ("FDA"), marketing and other regulatory approval of our product candidates;
- our ability to achieve certain accelerated or orphan drug designations from the FDA;
- changes in our estimates regarding the potential market opportunity for B-VEC, KB105, KB104, KB407, KB408, KB301, KB303 and any other product candidates;
- our ability to raise capital to fund our operations;
- increased costs associated with our research and development programs for our product candidates;
- our general and administrative expenses;
- risks related to our ability to successfully develop and commercialize our product candidates, including B-VEC, KB105, KB104, KB407, KB408, KB301, KB303 and our other product candidates;
- our ability to identify and develop new product candidates;
- our ability to identify, recruit and retain key personnel;
- risks related to our marketing and manufacturing capabilities and strategy;
- our business model, strategic plans for our business, product candidates and technology;
- the cost of building a medical affairs and commercial organization including a sales force in anticipation of commercialization of B-VEC and any additional product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates and gene therapy, in general;
- our competitive position and the success of competing therapies;
- our intellectual property position and our ability to protect and enforce our intellectual property;
- our financial performance;
- our ability to establish and maintain collaborations or obtain additional funding;
- our estimates regarding expenses, future revenue, capital requirements and needs for or ability to obtain additional financing;

- our ability to successfully avoid or resolve any litigation, intellectual property or other claims, that may be brought against us;
- global economic conditions; and
- the impact of changes in laws and regulations.

Forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in other filings we make with the SEC from time to time. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Quarterly Report. You should read this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Throughout this Form 10-Q, unless the context requires otherwise, all references to "Krystal," "the Company," we," "our," "us" or similar terms refer to Krystal Biotech, Inc., together with its consolidated subsidiaries.

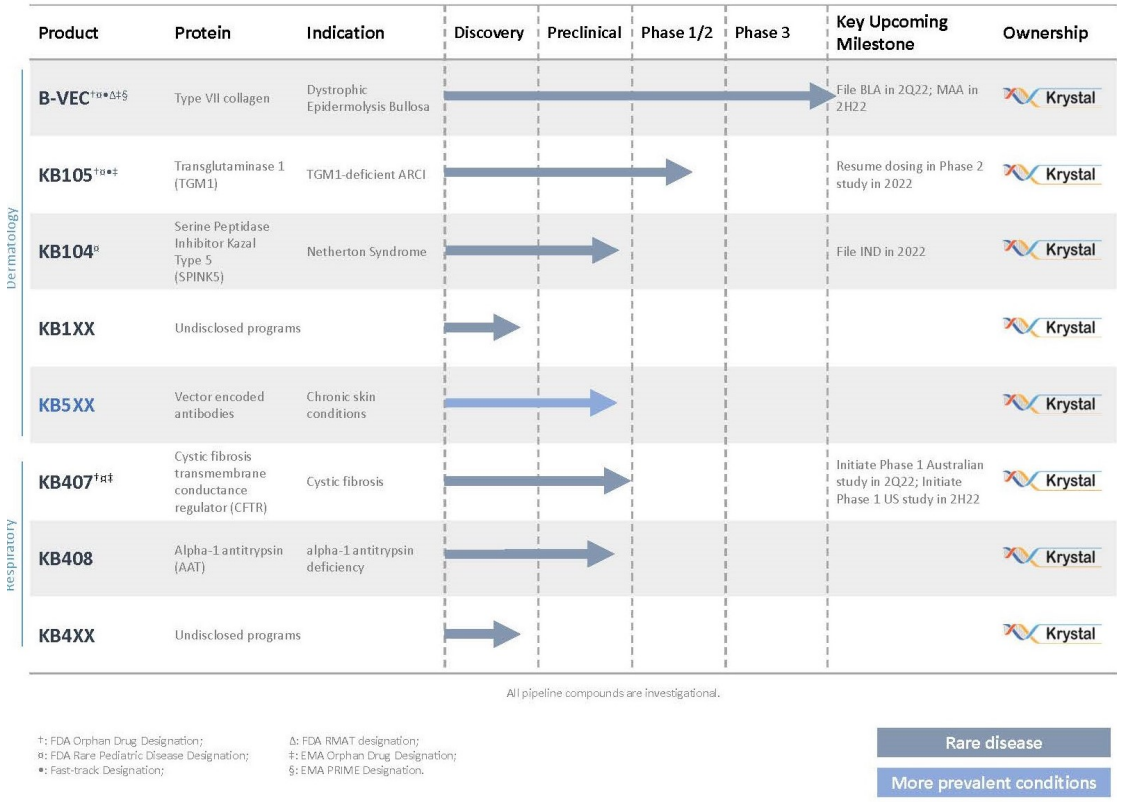
Overview

We are a clinical stage biotechnology company leading the field of redosable gene delivery. Using our patented platform that is based on engineered HSV-1, we create vectors that efficiently deliver therapeutic transgenes to cells of interest in multiple organ systems. The cell's own machinery then transcribes and translates the encoded effector to treat or prevent disease. We formulate our vectors for non-invasive or minimally invasive routes of administration at a healthcare professional's office or potentially in the patient's home by a healthcare professional. Our goal is to develop easy-to-use medicines to dramatically improve the lives of patients living with rare diseases and chronic conditions. Our innovative technology platform is supported by in-house, commercial scale cGMP manufacturing capabilities.

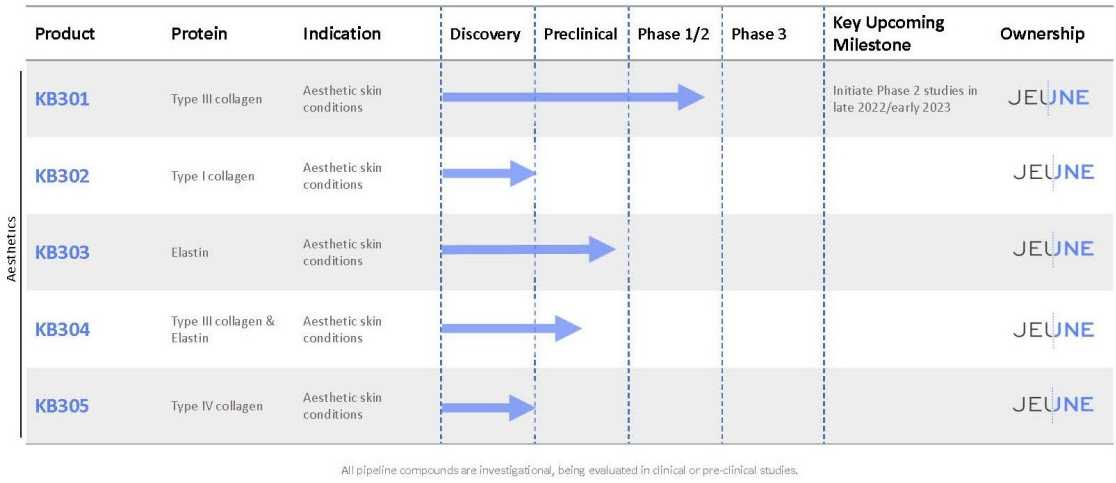
Our Product Candidates

The following table summarizes information regarding our product candidates in various stages of clinical and preclinical development:

Krystal Biotech Pipeline



Jeune Aesthetics Pipeline



There can be no assurance that the upcoming milestones will be met on the expected timeline or at all.

Pipeline Highlights and Recent Developments

B-VEC is a topical gel containing our novel vector designed to deliver two copies of the *COL7A1* transgene for the treatment of dystrophic epidermolysis bullosa ("dystrophic EB"), a serious rare skin disease caused by missing or mutated type VII collagen protein ("COL7"). Our randomized, double-blind, placebo-controlled GEM-3 pivotal study was designed to evaluate topical B-VEC as compared to placebo in dystrophic EB patients. Following public announcement of topline data from the GEM-3 study trial on November 29, 2021, we presented more detailed results at the 2022 American Academy of Dermatology Annual Meeting on March 26, 2022. We expect to file a BLA with the FDA in 2Q 2022, and an MAA with the EMA in 2H 2022. On March 28, 2022, we announced that detailed results from the Phase 1 and 2 study of B-VEC were published in *Nature Medicine*. During 2Q 2021, we began enrolling patients into an open label extension ("OLE") study, including patients who participated in the Phase 3 study, as well as new participants who meet all enrollment criteria. Based on the feedback from the FDA following their review of our human factors validation study report, we announced on April 11, 2022 our plan to offer dystrophic EB patients enrolled in the GEM-3 OLE, the opportunity to be dosed in their homes by a healthcare professional.

KB105 is a topical gel containing our novel vector designed to deliver two copies of the *TGM1* transgene for the treatment of TGM1-deficient autosomal recessive congenital ichthyosis ("TGM1-ARCI"), a serious rare skin disorder caused by missing or mutated TGM1 protein. A randomized, placebo-controlled Phase 1/2 study is ongoing. On July 1, 2021, we announced data from the fourth patient dosed in the trial, showing repeat topical KB105 dosing continued to be well tolerated with no adverse events or evidence of immune response. We plan to resume dosing in the KB105 Phase 2 study later this year.

KB407 is an inhaled (nebulized) formulation of our novel vector designed to deliver two copies of the full-length *CFTR* transgene for the treatment of cystic fibrosis, a serious rare lung disease caused by missing or mutated cystic fibrosis transmembrane conductance regulator ("CFTR") protein. On September 29, 2021, we announced that the Bellberry Human Research Ethics Committee in Australia granted approval to conduct a Phase 1 clinical study of inhaled KB407 in patients with cystic fibrosis, and trial initiation is anticipated in 2Q 2022. We plan to submit an IND and initiate a Phase 1 trial in the U.S. in 2H 2022.

KB104 is a topical gel formulation of our novel vector designed to deliver two copies of the *SPINK5* transgene for the treatment of Netherton Syndrome, a debilitating autosomal recessive skin disorder caused by missing or mutated SPINK5 protein. We expect to initiate a Phase 1 clinical study in 2022.

We have several other product candidates in various stages of preclinical development as reflected in the chart above.

We are also leveraging the ability of our platform to deliver proteins of interest to cells in the skin in the context of aesthetic medicine via our wholly-owned subsidiary Jeune Aesthetics, Inc ("Jeune"). A Summary description of Jeune’s key product candidate and its status is as follows:

KB301 is a solution formulation of our novel vector for intradermal injection designed to deliver two copies of the *COL3A1* transgene to address signs of aging or damaged skin caused by declining levels of, or damaged proteins within the extracellular matrix, including type III collagen. A Phase 1 study is currently ongoing. On March 22, 2022, we announced positive proof-of-concept efficacy data from Cohort 2 of the PEARL-1 study of KB301. We plan to initiate a Phase 2 trial in 4Q 2022 or early 2023.

Jeune has several other aesthetic medicine product candidates in various stages of preclinical development as reflected in the chart above.

Business Highlights and Recent Developments

- On January 18, 2022, we announced that Jing Marantz, MD, PhD, MBA had resigned from the Board of Directors to accept the position as Chief Business Officer with the Company and E. Rand Sutherland was appointed as a member of the Board of Directors to fill the vacancy.
- On March 15, 2022, we announced that we had reached a binding term sheet with PeriphaGen, Inc. ("PeriphaGen") to resolve all claims in the trade secret litigation filed by PeriphaGen on May 20, 2020.

COVID-19 Update

The COVID-19 pandemic has prompted governments and businesses across the globe to take unprecedented measures, such as restrictions on travel and business operations, temporary closures of businesses, and quarantines. For example, in an effort to slow the spread of the virus, The Commonwealth of Pennsylvania where the Company's primary offices, laboratory and manufacturing spaces are located, enacted stay-at-home orders, and sweeping restrictions to travel were initiated by corporations and governments. Although these restrictions have been lifted, it is not known at this time whether they will be reestablished or the extent to which the Company will be impacted. The degree of the pandemic's effect on the Company's clinical, operational and financial performance will depend on future developments, including additional protective measures that may be implemented by governmental authorities or the Company to protect its employees, or by investigators, caregivers or patients to minimize exposure, all of which are uncertain and difficult to predict. To date the impact of the pandemic on our business and clinical trials in the U.S. has been minimal and the increased vaccination rates in the U.S. are encouraging. We will continue to assess the potential impact of the pandemic on our business and operations, including our supply chain and preclinical and clinical trial activities. Outside of the U.S., we have experienced pandemic-related delays in clinical trial initiation in Australia, and we will continue to closely monitor this rapidly evolving situation. For additional information regarding the impact of the coronavirus pandemic, please see "Risk Factor - Business interruptions resulting from the COVID-19 outbreak or similar public health crises could cause a disruption of the development efforts of our product candidates and adversely impact our business." in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Financial Overview

Revenue

We currently have no approved products for commercial marketing or sale and have not generated any revenue from the sale of products or other sources to date. In the future, we may generate revenue from product sales, royalties on product sales, or license fees, milestones, or other upfront payments if we enter into any collaborations or license agreements. We expect that our future revenue will fluctuate from quarter to quarter for many reasons, including the uncertain timing and amount of any such payments and sales.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred to advance our preclinical and clinical candidates, which include:

- expenses incurred under agreements with contract manufacturing organizations, consultants and other vendors that conduct our preclinical activities;
- costs of acquiring, developing and manufacturing clinical trial materials and lab supplies;
- facility costs, depreciation and other expenses, which include direct expenses for rent and maintenance of facilities and other supplies; and
- payroll related expenses, including stock-based compensation expense.

We expense internal research and development costs to operations as incurred. We expense third party costs for research and development activities, such as the manufacturing of preclinical and clinical materials, based on an evaluation of the progress to completion of specific tasks such as manufacturing of drug substance, fill/finish and stability testing, which is provided to us by our vendors.

We expect our research and development expenses will increase as we continue the manufacturing of preclinical and clinical materials and manage the clinical trials of, and seek regulatory approval for, our product candidates and expand our product portfolio. In the near term, we expect that our research and development expenses will increase as we continue our open label extension ("OLE") study for B-VEC, resume dosing with KB105 Phase 2 clinical trial, initiate Phase 2 trial for KB301, initiate Phase 1 trial for KB407, and incur preclinical expenses for our other product candidates. Due to the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration, costs and timing of clinical trials, and, as a result, the actual costs to complete clinical trials may exceed the expected costs.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and other related costs, including stock-based compensation for personnel in our executive, commercial, business development and other administrative functions. General

and administrative expenses also include professional fees associated with corporate and intellectual property-related legal expenses, consulting and accounting services, facility-related costs and expenses associated with obtaining and maintaining patents. Other general and administrative costs include stock-based compensation and travel expenses.

We anticipate that our general and administrative expenses will increase in the future to support the continued research and development of our product candidates and to operate as a public company. These increases will likely include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants, lawyers and accountants, among other expenses. Additionally, if and when we believe a regulatory approval of our first product candidate appears likely, we anticipate that we will increase our salary and personnel costs and other expenses as a result of our preparation for commercial operations.

ASTRA Capital Expenditures

On March 5, 2021, we closed on the purchase of the building that was constructed to house our second cGMP facility, ASTRA. We are currently in the process of constructing the interior build-out of this facility and we have entered into a contract with Whiting-Turner who will manage the construction of ASTRA. Further, we have entered into various non-cancellable purchase agreements for long-lead materials to help avoid potential schedule disruptions or material shortages. These contracts typically call for the payment of fees for services or materials upon the achievement of certain milestones. We expect to continue to incur significant capital expenditures related to ASTRA as we construct and validate this facility, which is expected to be completed in 2022.

Interest Income

Interest income consists primarily of income earned from our cash, cash equivalents and investments.

Interest Expense

Interest expense consists primarily of non-cash interest expense recognized to accrete the build to suit financial obligation to a balance that equaled the cash consideration that was paid upon the close of the purchase of ASTRA.

Critical Accounting Policies, Significant Judgments and Estimates

There have been no significant changes during the three months ended March 31, 2022 to our critical accounting policies, significant judgments and estimates as disclosed in our management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Results of Operations

Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31,		
	2022	2021	Change
(In thousands)	**(unaudited)**		
Expenses			
Research and development	$ 9,314	$ 6,201	$ 3,113
General and administrative	15,908	8,152	7,756
Litigation settlement	25,000	—	25,000
Total operating expenses	50,222	14,353	35,869
Loss from operations	(50,222)	(14,353)	(35,869)
Other Income (Expense)			
Interest and other income, net	257	33	224
Interest expense	—	(1,492)	1,492
Net loss	$ (49,965)	$ (15,812)	$ (34,153)

Research and Development Expenses

Research and development expenses increased $3.1 million in the three months ended March 31, 2022 compared to the three months ended March 31, 2021. Higher research and development expenses were due to an increase in preclinical, clinical and pre-commercial manufacturing activities of $1.3 million, payroll related expenses of $1.6 million, which were primarily driven by an increase in headcount to support overall growth, and includes an $848 thousand increase in stock-based compensation, and other research and development expenses of $320 thousand, primarily due to software related costs and rent. These increases were partially offset by a decrease in travel related activities of approximately $86 thousand.

General and Administrative Expenses

General and administrative expenses increased $7.8 million in the three months ended March 31, 2022 as compared to the three months ended March 31, 2021. Higher general and administrative spending was due largely to increases in payroll related expenses of approximately $5.9 million, which was primarily driven by an increase in headcount to personnel in our executive, commercial, business development and other administrative functions to support overall growth, and includes a $3.3 million increase in stock-based compensation, commercial preparedness expenses of approximately $1.0 million, medical affairs costs of $162 thousand, software related costs of $130 thousand, business development costs of $166 thousand, and other administrative expenses of $526 thousand, primarily due to rent and taxes. These increases were offset by a decrease in legal and professional fees of approximately $92 thousand, which includes $509 thousand of insurance proceeds.

Litigation settlement

Litigation settlement expenses increased $25.0 million in the three months ended March 31, 2022 as compared to the three months ended March 31, 2021 and consisted of the settlement of litigation with PeriphaGen. See "Legal Proceedings" in Note 6 of the notes to condensed consolidated financial statements included in this Form 10-Q for more information.

Other Income (Expense)

Interest and other income for the three months ended March 31, 2022 and 2021 was $257 thousand and $33 thousand, respectively, and consisted of interest and dividend income earned from our cash, cash equivalents and investments.

Interest expense for the three months ended March 31, 2022 and 2021 was zero and $1.5 million, respectively, and related to accretion of the financial obligation for the build to suit lease liability during the three months ended March 31, 2021 to a balance that equaled the purchase consideration for ASTRA.

Liquidity and Capital Resources

Overview

At March 31, 2022, our cash, cash equivalents and short-term investments balance was approximately $434.6 million. Since operations began, we have incurred operating losses. Our net losses were $50.0 million and $15.8 million for the three months ended March 31, 2022 and 2021, respectively. At March 31, 2022, we had an accumulated deficit of $190.7 million. With the net proceeds raised from our previous public and private securities offerings and our ability to issue additional shares under our current ATM program, the Company believes that our cash, cash equivalents and short-term investments as of March 31, 2022 will be sufficient to allow the Company to fund operations for at least 12 months from the filing date of this Form 10-Q.

As the Company continues to incur losses, a transition to profitability is dependent upon the successful development, approval and commercialization of our product candidates and the achievement of a level of revenues adequate to support the Company's cost structure. Furthermore, we expect to incur increasing costs associated with operating as a public company, meeting financial controls, satisfying regulatory and quality standards, maintaining product and clinical trials, and furthering our efforts around our current and future product candidates. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital or obtain financing from other sources.

Costs related to clinical trials can be unpredictable and therefore there can be no guarantee that we will have sufficient capital to fund our continued clinical studies of B-VEC, KB105, KB301 or our planned preclinical studies for our other product candidates, or our operations. Further, we do not expect to generate any product revenues until 4Q 2022, at the earliest, assuming we receive marketing approval for B-VEC on the schedule we currently contemplate. While we are in the process of building out our internal vector manufacturing capacity, some of our manufacturing activities will be contracted out to third parties. Additionally, we currently utilize third-party contract research organizations to carry out our clinical development activities. As we seek to obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses as we prepare for product sales, marketing, manufacturing, and distribution. Our funds may not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for or commercially launch B-VEC, KB105, KB301 or any other product candidate. Accordingly, to obtain marketing approval for and to commercialize these or any other product candidates, we may be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, if at all. Our failure to raise capital when needed could have a negative effect on our financial condition and our ability to pursue our business strategy.

Operating Capital Requirements

Our primary uses of capital are, and we expect will continue to be for the near future, compensation and related expenses, manufacturing costs for preclinical and clinical materials, third party clinical trial research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs. In order to complete the process of obtaining regulatory approval for any of our product candidates and to build the sales, manufacturing, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timeline and cost of our OLE study for B-VEC;
- the progress, timing and costs of our ongoing Phase 1/2 clinical trials for KB105;
- the progress, results and costs of our Phase 2 clinical trials for KB301;
- the progress, timing and costs of manufacturing of B-VEC;
- the continued development and the filing on an IND application for future product candidates;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for any other product candidates that we may pursue in the future, if any;
- the costs of maintaining our own commercial-scale cGMP manufacturing facilities;
- the outcome, timing and costs of seeking regulatory approvals;

- the costs associated with the manufacturing process development and evaluation of third-party manufacturers;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, in the event we receive marketing approval for our current and future product candidates;
- the extent to which the costs of our product candidates, if approved, will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors;
- the costs of commercialization activities for our current and future product candidates if we receive marketing approval for such product candidates we may develop, including the costs and timing of establishing product sales, medical affairs, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, if any, revenue received from commercial sale of our current and future product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements;
- our current license agreements remaining in effect and our achievement of milestones under those agreements;
- our ability to establish and maintain collaborations and licenses on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

We may need to obtain substantial additional funding in order to receive regulatory approval and to commercialize our product candidates. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely affect our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development or commercialization of our product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to our product candidates that we otherwise would seek to develop or commercialize ourselves.

Sources and Uses of Cash

The following table summarizes our sources and uses of cash (in thousands):

	Three Months Ended March 31,	
	2022	**2021**
	(unaudited)	
Net cash used in operating activities	$ (15,493)	$ (9,654)
Net cash used in investing activities	(55,908)	(747)
Net cash provided (used in) by financing activities	(542)	144,304
Net increase (decrease) in cash	$ (71,943)	$ 133,903

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2022 was $15.5 million and consisted primarily of a net loss of $50.0 million adjusted for non-cash items primarily of depreciation and amortization and stock-based compensation expense of $7.3 million, and increases in net operating liabilities of approximately $27.2 million which includes an increase in accrued legal settlement of $25.0 million.

Net cash used in operating activities for the three months ended March 31, 2021 was $9.7 million and consisted primarily of a net loss of $15.8 million adjusted for non-cash items primarily of depreciation and amortization and stock-based compensation expense of approximately $2.8 million and build to suit interest expense of $1.5 million, as well as decreases in net operating assets of approximately $1.8 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2022 was $55.9 million and consisted primarily of expenditures of $17.2 million on the build-out of our ASTRA facility, leasehold improvement of new office space, and purchases of computer and laboratory equipment, $62.8 million on the purchase of short-term and long-term investments, partially offset by proceeds of $24.0 million received from the maturities of short-term investments.

Net cash used in investing activities for the three months ended March 31, 2021 was $747 thousand and consisted primarily of expenditures of $2.5 million on the build-out of our ASTRA facility, leasehold improvement of new office space, and purchase of computer and laboratory equipment, partially offset by proceeds of $1.7 million received from the maturities of short-term investments.

Financing Activities

Net cash used by financing activities for the three months ended March 31, 2022 was $542 thousand and consisted primarily of proceeds of $107 thousand received from exercises of stock options and offset by $649 thousand used for the employee tax withholding payment for settlement of vested restricted stock awards.

Net cash provided by financing activities for the three months ended March 31, 2021 was $144.3 million and consisted primarily of proceeds of $152.3 million received from our ATM Program, a public offering, and exercises of stock options, partially offset by $8.0 million used for the purchase of the ASTRA building.

On February 1, 2021 the Company completed a public offering of 2,211,538 shares of its common stock at $65.00 per share. Net proceeds to the Company from the offering were $134.9 million after deducting underwriting discounts and commissions of approximately $8.6 million and other offering expenses of approximately $198 thousand.

During the three months ended March 31, 2021, pursuant to the ATM Program the Company issued 262,500 shares of common stock at a weighted average price of $66.50 per share for net proceeds of $16.9 million after deducting underwriting discounts and commissions of approximately $524 thousand. The Company also incurred $172 thousand of other offering expenses related to the ATM Program.

For the three months ended March 31, 2021, the Company received proceeds of $346 thousand from the exercise of stock options.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Contractual Obligations

There have been no material changes to our contractual obligations as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 other than as described in Note 6 “Commitments and Contingencies” of our condensed consolidated financial statements on this Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Qualitative and Quantitative Disclosures About Market Risk

We had cash, cash equivalents and short-term investments of $434.6 million at March 31, 2022, which consist primarily of money market, bank deposits, commercial paper, corporate bonds, and government agency securities. The investments in these financial instruments are made in accordance with an investment policy which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the

financial instruments in which we invest could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and short and long-term investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations or our financial position would be materially affected by an immediate change of 10% in interest rates.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash, cash equivalents and short-term investments have a significant risk of default or illiquidity. While we believe our cash, cash equivalents and short-term investments do not contain excessive risk, we cannot provide absolute assurance that any investments we make in the future will not be subject to adverse changes in market value. Our cash, cash equivalents and short and long-term investments are recorded at fair value.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Chief Accounting Officer, with the participation of other members of the Company's management, have evaluated the effectiveness of the Company's "disclosure controls and procedures" (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act")) as of the end of the period covered by this quarterly report, and our Chief Executive Officer and our Chief Accounting Officer have concluded that our disclosure controls and procedures are effective based on their evaluation of these controls and procedures as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15.

Changes in Internal Control over Financial Reporting

In 2021, we implemented a new enterprise resource planning software, Microsoft Dynamics D365 ("Dynamics"), as part of a plan to integrate and upgrade our systems and processes. The implementation of this software is scheduled to continue in phases over a number of years. As the phased implementation of this system occurs, we expect certain changes to our processes and procedures which, in turn, will result in changes to our internal control over financial reporting. We expect Dynamics to strengthen our internal financial controls by automating a number of accounting and reporting processes and activities, thereby decreasing the number of manual processes previously required. Management will continue to evaluate and monitor our internal controls as processes and procedures in each of the affected areas evolve.

Other than as discussed above, no change in our internal control over financial reporting occurred during the quarter ended March 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information set forth under the heading “Legal Proceedings” in Note 6 of the notes to condensed consolidated financial statements included in Item 1 of Part I of this Form 10-Q is incorporated by reference in response to this item.

Item 1A. Risk Factors.

As disclosed in "Summary Risk Factors" and "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on February 28, 2022, there are a number of risks and uncertainties that may have a material effect on the operating results of our business and our financial condition. There have been no material changes from the risk factors previously disclosed in such filing.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	
31.1	Certification of Periodic Report by Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Periodic Report by Chief Accounting Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Accounting Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Inline XBRL (Extensible Business Reporting Language). The following materials from this Quarterly Report on Form 10-Q for the period ended March 31, 2022, formatted in Inline XBRL: (i) consolidated balance sheets of Krystal Biotech, Inc., (ii) consolidated statements of operations of Krystal Biotech, Inc., (iii) consolidated statements of comprehensive income/(loss) of Krystal Biotech, Inc., (iv) consolidated statements of changes in equity of Krystal Biotech, Inc., (v) consolidated statements of cash flows of Krystal Biotech, Inc. and (vi) notes to consolidated financial statements of Krystal Biotech, Inc. The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL

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.

KRYSTAL BIOTECH, INC.
(Registrant)

Date: May 9, 2022	By:	/s/ Krish S. Krishnan
		Krish S. Krishnan President and Chief Executive Officer (Principal executive officer)
	By:	/s/ Kathryn A. Romano
		Kathryn A. Romano Chief Accounting Officer (Principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Krish S. Krishnan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Krystal Biotech, 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 Condensed 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)) 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. 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

   c. 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 9, 2022

By: /s/ Krish S. Krishnan
Krish S. Krishnan
President and Chief Executive Officer

Exhibit 32.1

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

I, Krish S. Krishnan, Chief Executive Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Quarterly Report on Form 10-Q for the three months ended March 31, 2022, (the "Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition and results of operations of Krystal Biotech, Inc.

Date: May 9, 2022

By: /s/ Krish S. Krishnan
Krish S. Krishnan
President and Chief Executive Officer

I, Kathryn A. Romano, Chief Accounting Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Quarterly Report on Form 10-Q for the three months ended March 31, 2022, (the "Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition and results of operations of Krystal Biotech, Inc.

Date: May 9, 2022

By: /s/ Kathryn A. Romano
Kathryn A. Romano
Chief Accounting Officer

Exhibit 31.2

CERTIFICATION OF CHIEF ACCOUNTING OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kathryn A. Romano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Krystal Biotech, 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 Condensed 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) 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. 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

   c. 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 9, 2022

By: /s/ Kathryn A. Romano
Kathryn A. Romano
Chief Accounting Officer