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, 2019

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)

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 ☒

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

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

As of April 30, 2019, the registrant had 14,443,569 shares of common stock, $0.00001 par value per share, outstanding.

Krystal Biotech, Inc.
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ITEM 1.

Krystal Biotech, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except shares and per share data)	March 31, 2019 (unaudited)	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 98,013	$ 103,670
Short-term investments	8,617	8,091
Prepaid and other current assets	1,264	889
Total current assets	107,894	112,650
Property and equipment, net	4,354	3,014
Right-of-use asset	3,001	—
Other noncurrent assets	455	452
Total assets	$ 115,704	$ 116,116
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,126	$ 888
Current portion of lease liability	418	—
Accrued expenses and other current liabilities	1,698	1,708
Total current liabilities	3,242	2,596
Lease liability	2,976	—
Other noncurrent liabilities	—	294
Total liabilities	6,218	2,890
Commitments and contingencies (Note 5)		
Stockholders' equity		
Preferred stock; $0.00001 par value; 20,000,000 shares authorized at March 31, 2019 (unaudited) and December 31, 2018; 2,061,773 shares issued, and no shares outstanding at March 31, 2019 (unaudited) and December 31, 2018	—	—
Common stock; $0.00001 par value; 80,000,000 shares authorized at March 31, 2019 (unaudited) and December 31, 2018; 14,443,569 and 14,428,916 shares issued and outstanding at March 31, 2019 (unaudited) and December 31, 2018, respectively	—	—
Additional paid-in capital	133,540	133,183
Accumulated other comprehensive income	16	2
Accumulated deficit	(24,070)	(19,959)
Total stockholders' equity	109,486	113,226
Total liabilities and stockholders' equity	$ 115,704	$ 116,116

The accompanying notes are an integral part of these 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, 2019	2018
Expenses		
Research and development	$ 3,167	$ 1,520
General and administrative	1,527	757
Total operating expenses	4,694	2,277
Loss from operations	(4,694)	(2,277)
Other Expense		
Interest and other income, net	583	127
Total interest and other income, net	583	127
Net loss	(4,111)	(2,150)
Unrealized gain on available-for-sale securities	14	—
Comprehensive loss	(4,097)	(2,150)
Net loss attributable to common stockholders per share: Basic and diluted	$ (0.29)	$ (0.21)
Weighted-average common shares outstanding: Basic and diluted	14,417,649	10,307,379

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

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

(In thousands, except shares)	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at January 1, 2019	—	$ —	14,428,916	$ —	$ 133,183	$ 2	$ (19,959)	$ 113,226
Issuance of common stock	—	—	14,653	—	44	—	—	44
Stock-based compensation expense	—	—	—	—	313	—	—	313
Unrealized gain on investments	—	—	—	—	—	14	—	14
Net loss	—	—	—	—	—	—	(4,111)	(4,111)
Balances at March 31, 2019	—	$ —	14,443,569	$ —	$ 133,540	$ 16	$ (24,070)	$ 109,486
Balances at January 1, 2018	—	$ —	10,307,247	$ —	$ 58,544	$ —	$ (9,070)	$ 49,474
Issuance of common stock	—	—	2,368	—	10	—	—	10
Stock-based compensation expense	—	—	—	—	65	—	—	65
Net loss	—	—	—	—	—	—	(2,150)	(2,150)
Balances at March 31, 2018	—	$ —	10,309,615	$ —	$ 58,619	$ —	$ (11,220)	$ 47,399

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

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

(In thousands)	Three Months Ended March 31, 2019	2018
Operating Activities		
Net loss	$ (4,111)	$ (2,150)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	132	18
Stock-based compensation expense	313	65
Decrease in		
Prepaids and other current assets	(352)	(118)
Accounts payable	583	(104)
Accrued expenses and other current liabilities	153	(80)
Amortization of right-of-use asset	67	—
Net cash used in operating activities	(3,215)	(2,369)
Investing Activities		
Purchases of property and equipment	(1,707)	—
Purchases of short-term investments	(512)	—
Purchases of other noncurrent assets	(263)	—
Net cash used in investing activities	(2,482)	—
Financing Activities		
Issuance of common stock, net	40	6
Issuance of preferred stock and preferred units	—	—
Net cash provided by financing activities	40	6
Net decrease in cash and cash equivalents	(5,657)	(2,363)
Cash and cash equivalents at beginning of period	103,670	49,591
Cash and cash equivalents at end of period	$ 98,013	$ 47,228
Supplemental Disclosures of Non-Cash Investing and Financing Activities		
Unpaid purchase of property and equipment	$ 375	$ —
Unpaid deferred offering costs	$ 155	$ 1
Initial recognition of right-of-use assets	$ 3,394	$ —

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

Krystal Biotech, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)
(In thousands, except per share data)

1. Organization

Krystal Biotech, Inc. and its consolidated subsidiary (the "Company," or "we" or other similar pronouns) commenced operations in April 2016. In March 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, for the purposes of undertaking preclinical and clinical studies in Australia.

We are a gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from skin diseases. We have developed a proprietary gene therapy platform that consists of an engineered, patented (issued and pending), viral vector based on modified herpes simplex virus 1, or HSV-1, and skin-optimized gene transfer technology, to develop off-the-shelf treatments for skin diseases for which we believe there are no known effective treatments.

Our lead product candidate, KB103, seeks to use topical gene therapy to treat dystrophic epidermolysis bullosa, or DEB, a rare and severe genetic disease, for which there is currently no approved treatment. In May 2018, we commenced a Phase 1/2 clinical study of KB103, a first-in-class topical gene therapy for the treatment of DEB, at Stanford University. We announced positive interim results from this clinical study on October 15, 2018. The clinical results to date on the two patients met all primary efficacy and safety endpoints in topically administered KB103 wounds.

Liquidity and Risks

As of March 31, 2019, the Company had an accumulated deficit of $24.1 million. With the net proceeds raised upon the close of its initial public offering ("IPO") in September 2017, a private placement in August 2018, a secondary public offering in October 2018, an "at-the-market" equity offering program ("ATM Facility) in March 2019, as described in Note 6 "Capitalization", the Company believes that its cash, cash equivalents and short-term investments of approximately $106.6 million as of March 31, 2019 will be sufficient to allow the Company to fund its 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 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. There can be no assurances 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, development of technological innovations by its competitors, risks of failure of clinical studies, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to transition from preclinical manufacturing to commercial production of products.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and follow the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. In the opinion of management, the condensed consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair statement of the Company's condensed consolidated financial information. The results of operations for the three-month period ended March 31, 2019 are not necessarily indicative of the results to be expected for the full year or any other future period. The condensed consolidated balance sheet as of December 31, 2018 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete consolidated financial statements.

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 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, among others: stock-based compensation expense, accrued research and development expenses, the fair value of financial instruments, and the valuation allowance included in deferred income taxes calculations.

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 short-term investments. The Company's policy is to invest its cash and cash equivalents in money market funds and various 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 of amounts recorded on the balance sheets which may be 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 Short-Term 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 condensed consolidated balance sheets and consist of U.S. Treasury bills and certificates of deposit. Accrued interest on U.S. Treasury bills and certificates of deposit 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 and as current assets. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in accumulated other comprehensive gain or loss, which is a separate component of stockholders' equity in the condensed consolidated balance sheets.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurement and Disclosures*, established a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the financial instrument based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the financial instrument and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported or disclosed fair value of the financial instruments and is not a measure of the investment credit quality. Fair value measurements are classified and disclosed in one of the following three categories:

- *Level 1*—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- *Level 2*—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- *Level 3*—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and are 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 changes to the valuation methods utilized by the Company during the periods presented. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the periods presented.

The carrying amounts of financial instruments consisting of cash and cash equivalents, 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.

Our available-for-sale short-term investments, which consist of US Treasury bills and certificates of deposit, are considered to be level 2. 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 years
Lab equipment	3-7 years
Furniture and fixtures	3 years
Leasehold improvements	remaining life of lease

Construction-in-progress 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. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value. The Company has not recognized any impairment losses through March 31, 2019.

Leases

We have entered into a lease agreement for our laboratory and office space. As described below under "Recent Accounting Standards," we adopted ASU 2016-02 – Leases (Topic 842) ("ASU 2016-02") as of January 1, 2019. Pursuant to ASU 2016-02, all of our leases outstanding on January 1, 2019 continued to be classified as operating leases. With the adoption of ASU 2016-02, we recorded an operating lease right-of-use asset and an operating lease liability on our balance sheet. Right-of-use lease assets represent our right to use the underlying asset during the lease term and the lease obligation represents our commitment to make lease payments arising from the lease. Right-of-use lease assets and obligations were recognized based on the present value of remaining lease payments over the lease term. As the Company's leases do not provide an implicit rate, we have used an estimated incremental borrowing rate based on the information available at our adoption date in determining the present value of lease payments. Operating lease expense is recognized on a straight-line basis over the lease term. Variable lease costs such as common area costs and other operating costs are expensed as incurred. For all lease agreements we combine lease and non-lease components. Leases with an initial term of 12 months or less are not recorded on the balance sheet.

Prior to our adoption of ASU 2016-02, when our lease agreements contained tenant improvement allowances and rent escalation clauses, we recorded a deferred rent asset or liability equal to the difference between the rent expense and the future minimum lease payments due. The lease expense related to operating leases was recognized on a straight-line basis in the statements of operations over the term of each lease. In cases where the lessor granted us leasehold improvement allowances that reduced our lease expense, we capitalized the improvements as incurred and recognized deferred rent, which was amortized over the shorter of the lease term or the expected useful life of the improvements.

Research and Development Expenses

Research and development costs are charged to expense as incurred in performing research and development activities. The costs include employee compensation costs, facilities and overhead, preclinical activities and related clinical manufacturing costs, 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 and manufacturing organizations that manufacture materials used in the Company's ongoing preclinical studies. Nonrefundable 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 accounts for its stock-based compensation awards to employees and directors in accordance with FASB ASC Topic 718, *Compensation-Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock, to be recognized in the statements of operations based on their grant-date fair values. Compensation expense related to awards to employees 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. Beginning in the first quarter of 2019, the Company adopted ASU 2018-07 - Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which no longer required non-employee stock options to be periodically revalued. The adoption of this amended guidance did not have a material effect on our condensed consolidated financial statements. Prior to the first quarter of 2019, share-based payments issued to non-employees were recorded at their fair values and were periodically revalued as the equity instruments vest and were recognized as expense over the related service period in accordance with the provisions of ASC 718 and ASC Topic 505, *Equity,* and were expensed ratably over 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; (iv) expected dividends; and (v) the estimated fair value of its common stock on the measurement date. Due to the lack of sufficient history and trading volume of its Common Stock and a lack of Company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company computes historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. Due to the lack of Company-specific historical option activity, the Company has estimated the expected term of its employee 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. Beginning in the first quarter of 2019, the expected term of non-employee stock options also used the "simplified" method. Prior to the first quarter of 2019, the expected term for non-employee awards was the remaining contractual term of the option. The risk-free interest rates are based on the U.S. 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 is also required to estimate forfeitures at the time of grant and to revise those estimates in subsequent periods if actual forfeitures differ from its estimates. Beginning in the first quarter of 2019, the Company used historical data to estimate forfeitures and recorded stock-based compensation expense only for those awards that were expected to vest. Prior to the first quarter of 2019, the forfeiture rate was estimated to be zero. To the extent that actual forfeitures differ from the Company's estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive loss in the financial statements in the period in which they are recognized. Net loss and other comprehensive income or loss are reported, net of their related tax effect, to arrive at a comprehensive loss.

Recent Accounting Pronouncements

In August 2018, the SEC issued a final rule to simplify certain disclosure requirements. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. In August and September 2018, further amendments were issued to provide implementation guidance on adoption of the SEC rule and transition guidance for the new interim stockholders' equity disclosure. We adopted this amended guidance in the first quarter of 2019. The adoption of this amended guidance resulted in us disclosing the Condensed Consolidated Statements of Stockholders' Equity for the three months ending March 31, 2018 and 2019.

In August 2018, the FASB issued ASU 2018-13 - Fair Value Measurement (Topic 820) ("ASU 2018-13") which removes, modifies and adds disclosure requirements on fair value measurements. ASU 2018-13 removes disclosure requirements for transfers between Level 1 and Level 2 measurements and valuation processes for Level 3 measurements but adds new disclosure requirements including changes in unrealized gains/losses in other comprehensive income related to recurring Level 3 measurements. The amended guidance is effective for us commencing in the first quarter of 2020. Certain aspects may be applied prospectively while other aspects may be applied retrospectively upon the effective date. Early adoption is permitted. We are in the process of evaluating the effect of this guidance on our consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07 - Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations. The amended guidance is effective for us commencing in the first quarter of 2019. The adoption of this amended guidance did not have a material effect on our condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02 - Leases (Topic 842) ("ASU 2016-02"), which replaces the existing lease accounting standards. The new standard requires a dual approach for lessee accounting under which a lessee would account for leases as finance (also referred to as capital) leases or operating leases. Both finance leases and operating leases with terms longer than 12 months will result in the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases the lessee would recognize interest expense and amortization of the right-of-use asset and for operating leases the lessee would recognize straight-line total lease expense. In July 2018, further amendments were issued to clarify how to apply certain aspects of the amended lease guidance and to address certain implementation issues. ASU 2016-02 is effective for the Company beginning in the first quarter of 2019. The Company generally does not finance purchases of equipment but does lease office and lab facilities. The adoption of this amended guidance resulted in $3.0 million of right-of-use asset and $3.4 million of lease liability being recognized on the condensed consolidated balance sheet as of March 31, 2019.

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. There were 443,362 and 233,464 common stock equivalents outstanding as of March 31, 2019 and 2018, respectively, in the form of stock options and unvested restricted stock awards, that have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect would be anti-dilutive for all periods presented.

	Three Months Ended March 31,	
	2019	2018
(In thousands, except shares, units, per share and per unit data)	(Unaudited)	
Numerator:		
Net loss applicable to common stockholders and members	$ (4,111)	$ (2,150)
Denominator:		
Weighted-average basic and diluted common shares and common units	14,417,649	10,307,379
Basic and diluted net loss per common share and common unit	$ (0.29)	$ (0.21)

4. Balance Sheet Components

Property and Equipment, Net

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

	March 31, 2019	December 31, 2018
	(Unaudited)	
Construction-in-progress	309	2,259
Leasehold improvements	2,171	3
Furniture & fixtures	99	99
Computer equipment and software	48	40
Laboratory equipment	2,025	779
Total property and equipment	4,652	3,180
Accumulated depreciation and amortization	(298)	(166)
Property and equipment, net	$ 4,354	$ 3,014

Depreciation expense was $132 thousand and $18 thousand for the three months ended March 31, 2019 and 2018, respectively.

Accrued Expenses and Other Current Liabilities

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

	March 31, 2019	December 31, 2018
	(Unaudited)	
Accrued pre-clinical expenses	$ 675	$ 537
Accrued professional fees	159	41
Accrued payroll and benefits	256	348
Accrued taxes	50	154
Accrued construction in progress	330	589
Other current liabilities	646	39
Total	$ 2,116	$ 1,708

5. Commitments and Contingencies

Significant Contracts and Agreements

Lease Agreement

In May 2016, the Company signed an operating lease for laboratory and office space that commenced in June 2016 (the "2016 Lease"). The 2016 Lease was amended to increase the area leased to approximately 31,000 square feet and to extend the expiration date to February 28, 2027. As mentioned above in "Recent Accounting Pronouncements" in Note 2, the adoption of ASU 2016-02 on January 1, 2019 for the 2016 Lease, as amended, resulted in a $3.0 million of right-of-use asset and $3.4 million of lease liability being recognized on the condensed consolidated balance sheet as of March 31, 2019.

The Company's future minimum operating lease payments from the 2016 Lease, as amended, were as follows (in thousands):

	Operating Leases
2019 (remaining nine months)	$ 321
2020	515
2021	592
2022	604
2023	616
Thereafter	2,033
Future minimum operating lease payments	$ 4,681
Less: Interest	1,287
Present value of lease liability	$ 3,394
Current portion of lease liability	418
Long-term portion of lease liability	2,976

The Company recorded $125 thousand and $31 thousand in rent expense for the three months ended March 31, 2019 and 2018, respectively.

Clinical Supply Agreement

The Company has entered into various product manufacturing and clinical supply agreements with Contract Manufacturing Organizations ("CMOs"). The product manufacturing and clinical supply agreements provide the terms and conditions under which the CMOs will formulate, fill, inspect, package, label and test our products, KB103 and KB105 for clinical supply. The Company is obligated to make milestone payments. Additionally, certain raw materials, supplies, outsourced testing and other services for the purposes of batch production will be invoiced separately by the CMOs. The estimated remaining commitment as of March 31, 2019 under these agreements for the manufacturing of our drug product is approximately $2.2 million. The Company is also responsible for the payment of a monthly service fee for project management services for the duration of the arrangement. The Company has incurred expenses under these agreements of $803 thousand and $801 thousand for the three months ended March 31, 2019 and 2018, respectively.

6. Capitalization

Sale of Common Stock

On November 1, 2017, the Company entered into a stock purchase agreement (the "Agreement") with the Epidermolysis Bullosa Medical Research Foundation, a California not-for-profit corporation ("EBMRF"), and EB Research Partnership, Inc., a New York not-for-profit corporation ("EBRP" and together with EBMRF, the "Purchasers"), pursuant to which the Company issued and sold to the Purchasers an aggregate of 70,000 shares of the Company's common stock, par value $0.00001 per share, for a purchase price of $11.00 per share, resulting in aggregate gross proceeds to the Company of $770,000 (the "Transaction"). The proceeds are to be used exclusively to complete the research plan pursuant to the Agreement. There are redemption features whereby the Company shall repurchase all or a portion of the shares at a purchase price of $11.00 per share or the closing trading price of the common stock on the redemption request date, whichever is higher, should the Company not commence work on or before September 1, 2018 or cease commercially reasonable efforts. The Company did commence work prior to September 1, 2018. As the Company does not intend to cease commercially reasonable efforts, the remaining redemption feature is within the control of the Company and consequently the issued common stock is classified as permanent equity. The offer, sale and issuance of the shares of the Company under the Agreement are exempt from registration pursuant to Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act of 1933, as amended. The Transaction closed on November 2, 2017.

ATM Facility

On March 12, 2019, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen") to issue and sell shares of the Company's common stock of up to $50.0 million in gross proceeds, from time to time during the term of the sales agreement, through an "at-the-market" equity offering program under which Cowen will act as the Company's agent and/or principal ("ATM Facility). The ATM Facility provides that Cowen will be entitled to compensation for its services in an amount of 3.00% of the gross proceeds of any shares sold under the ATM Facility. The Company has no obligation to sell any shares under the ATM Facility and may at any time suspend solicitation and offers under the sales agreement. As of March 31, 2019, the Company has not sold any shares under the ATM Facility.

Shares Outstanding

There were 14,443,569 and 14,428,916 shares of common stock outstanding at March 31, 2019 and December 31, 2018, respectively. No shares of preferred stock were outstanding at March 31, 2019 or December 31, 2018.

7. Stock-Based Compensation

On September 5, 2017, the Board approved the establishment of the Krystal Biotech, Inc. 2017 IPO Plan (the "2017 IPO Plan"), which was adopted prior to the effectiveness of our registration statement on Form S-1 relating to our IPO. Under the 2017 IPO Plan, the Company may grant incentive stock options, non-qualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, and stock grants to purchase up to 900,000 shares of the Company's Common Stock.

The Company granted 67,500 and 55,000 stock options to employees and directors of the Company during the three months ended March 31, 2019 and 2018, respectively. Options granted to employees vest ratably over a four-year period and options granted to directors of the company vest ratably between one and four-year periods. Options have a life of ten years. Commencing in the first quarter of 2019, the accounting treatment for stock options granted to non-employees was aligned with the accounting for employee stock options upon the adoption of ASU 2018-07 as described in Note 2 "Summary of Significant Accounting Policies". Prior to the first quarter of 2019, stock options granted to non-employees were accounted for using the fair value method of accounting, and are periodically revalued as the options vest, and recognized as expense over the related service period.

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)
Balance at December 31, 2018	357,089	$ 8.73	8.8	$ 4,302
Granted	67,500	$ 23.87		
Exercised	(14,653)	$ 2.75		
Cancelled or forfeited	(9,000)	$ 18.71		
Balance at March 31, 2019	400,936	$ 11.28	8.8	$ 8,670
Exercisable at March 31, 2019	93,468	$ 5.82	8.2	$ 2,531
Vested at March 31, 2019	112,364	$ 5.30	8.2	$ 3,102

(1) Aggregate intrinsic value represents the difference between the closing stock price of our common stock on March 31, 2019 and the exercise price of outstanding in-the-money options.

Options for 14,653 shares of our common stock with an intrinsic value of $442 thousand were exercised during the three months ended March 31, 2019.

The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards to employees and non-employees in the condensed consolidated statements of operations for the three months ended March 31, 2019 and 2018 as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 117	$ 46
General and administrative	87	19
Total stock-based compensation	$ 204	$ 65

Stock Options Granted to Employees. The Company recorded stock-based compensation expense related to employee's and board member's stock options of $185 thousand and $61 thousand for the three months ended March 31, 2019 and 2018, respectively. The fair value of options granted to employees 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, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
Expected stock price volatility	71%	80%
Expected term of the award (years)	6.25	6.25
Risk-free interest rate	2.46%	2.71%
Forfeiture Rate	10.00%	0.00%
Expected dividend yield	0%	0%

The weighted-average grant-date fair value per share of options granted to employees during the three months ended March 31, 2019 was $15.51.

There was $1.5 million of unrecognized stock-based compensation expense related to employees' awards that is expected to be recognized over a weighted-average period of 2.88 years as of March 31, 2019.

Stock Options Granted to Non-Employees. The Company recorded stock-based compensation expense related to non-employees' stock options of $19 thousand and $4 thousand for the three months ended March 31, 2019 ad 2018, respectively.

Restricted Stock Awards. The Company granted 26,213 and 16,213 restricted stock awards ("RSA"s) on June 1, 2018 to our Chief Executive Officer and Chief Operating Officer, respectively. The RSAs vest ratably over a one-year period. 31,818 shares of RSAs had vested as of March 31, 2019. The RSAs, including the unvested portion, are considered issued and outstanding as of March 31, 2019. The fair value of each restricted stock was $10.30 reflecting the closing price of our common stock on the grant date. The Company recorded stock-based compensation expense related to RSAs of $109 thousand and $0 for the three months ended March 31, 2019 and 2018, respectively within general and administrative expenses in the accompanying condensed consolidated statements of operations. As of March 31, 2019, there was $73 thousand of unrecognized stock-based compensation expense related to RSAs that is expected to be recognized over a weighted-average period of 2 months.

Stock options and restricted stock awards available for grant were 623,074 at March 31, 2019.

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 elsewhere 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, 2018, as filed with the SEC, on March 12, 2019.

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, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and the negative and plural forms of these words and similar expressions are intended to identify forward-looking statements.

Overview

We are a clinical stage gene therapy company currently dedicated to developing and commercializing novel treatments for patients suffering from dermatological skin diseases. We have developed a proprietary gene therapy platform that consists of a patented engineered viral vector based on herpes simplex virus 1, or HSV-1, and skin-optimized gene transfer technology, to develop off-the-shelf treatments for dermatological diseases for which we believe there are no known effective treatments. We are initially using the platform to develop treatments for rare or orphan dermatological indications caused by the absence of or a mutation in a single gene, and plan to leverage our platform in the future to expand our pipeline to include other dermatological indications and skin conditions.

Our lead clinical product candidate, KB103 (bercolagene telserpavec) is our proprietary gene therapy candidate therapy for the treatment of dystrophic epidermolysis bullosa, or DEB, a rare and severe genetic disease, for which there is currently no approved treatment. DEB affects the skin and mucosal tissues and is caused by one or more mutations in a gene called COL7A1, which is responsible for the production of protein type VII collagen, or COL7, that forms anchoring fibrils that bind the dermis, or inner layer of the skin, to the epidermis, or outer layer of the skin. Based on information from DEBRA International, a worldwide alliance of patient support groups for epidermolysis bullosa, or EB, of which DEB is a subset, we believe there may be as many as 52,000 cases worldwide who suffer from DEB. We estimate that there are approximately 3500 diagnosed DEB patients in the United States. There is currently no approved cure for DEB and current treatment for DEB is limited to palliative care estimated to cost between $200,000 and $400,000 annually per patient in the United States.

We are currently in Phase 2 of a Phase 1/2 clinical study of KB103 (GEM-1 study), a first-in-class topical gene therapy for the treatment of DEB. The trial commenced in May 2018 at Stanford University, and we announced positive interim results from this clinical study on two patients in October 2018. The clinical results to date on the two patients met all primary efficacy (presence of functional protein type VII collagen expression, observation of NC1 and NC2 reactive anchoring fibrils and continued expression following repeat administration) and safety endpoints (no adverse events, inflammation or irritation) in topically administered KB103 wounds. We anticipate announcing top-line data from full study enrollment of six (6) patients in the KB103 Phase 1/2 trial in the first half of 2019. If successful, we anticipate commencing pivotal Phase 3 clinical trials for KB103 in the second half of 2019.

The FDA and the European Medicines Agency, or EMA, have each granted KB103 orphan drug designation for the treatment of DEB, and the FDA has granted KB103 fast track designation and rare pediatric designation for the treatment of DEB.

In March 2019, the EMA granted PRIority MEdicines, or PRIME, eligibility for KB103 to treat DEB. The PRIME designation is awarded by the EMA to promising medicines that target an unmet medical need. These medicines are considered priority medicines by the EMA. The PRIME designation is awarded by the EMA to promising medicines that target an unmet medical need. These medicines are considered priority medicines by the EMA. To be eligible and accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data coupled with non-clinical data. Through PRIME, the EMA offers enhanced support to medicine developers including early interaction and dialogue, and a pathway for accelerated evaluation by the agency. The program is intended to optimize development plans and

expedite the review and approval process so that these medicines may reach patients as early as possible. To be eligible for PRIME, medicines must target an unmet medical need and show potential benefit for patients based on early clinical data coupled with non-clinical data.

Our second pipeline candidate, KB105, is currently in preclinical development for treatment of patients with deficient autosomal recessive congenital ichthyosis, or ARCI, which is associated with transglutaminase 1, or TGM-1. There are currently no treatments for this disease that affects approximately 20,000 patients worldwide. We anticipate filing an Initial New Drug, or IND, application for KB105 in the second half of 2019. The FDA has granted KB103 orphan drug designation and rare pediatric designation for the treatment of ARCI. We have several other product candidates in various stages of preclinical development.

In March 2019, we had the official inauguration of Ancoris, our commercial scale current good manufacturing practice or cGMP-compliant facility, following the completion of a manufacturing trial run of KB103. We intend to use our cGMP manufacturing process for all clinical and commercial production of KB103. Although we anticipate that our manufacturing facility will be primary production site to meet project clinical and commercial demand, we will continue to evaluate, and will pursue as needed, additional internal sources of manufacturing capacity, potential third parties to provide multiple long-term supply alternatives to meet commercial demand in the event that KB103 receives marketing approval and for our other pipeline programs. We continue to utilize our internal process development group and work with third parties in order to evaluate and develop manufacturing process improvements that may increase the productivity and efficiency of our manufacturing process.

On March 12, 2019, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen") to issue and sell shares of the Company's common stock of up to $50.0 million in gross proceeds, from time to time during the term of the sales agreement, through an "at-the-market" equity offering program under which Cowen will act as the Company's agent and/or principal ("ATM Facility). The ATM Facility provides that Cowen will be entitled to compensation for its services in an amount of 3.00% of the gross proceeds of any shares sold under the ATM Facility. The Company has no obligation to sell any shares under the ATM Facility and may at any time suspend solicitation and offers under the sales agreement. As of March 31, 2019, the Company has not sold any shares under the ATM Facility.

At March 31, 2019, our cash, cash equivalents and short-term investments balance was approximately $106.6 million. Since operations began, we have incurred operating losses. Our net losses were $4.1 million and $2.2 million for the quarters ended March 31, 2019 and 2018, respectively. At March 31, 2019, we had an accumulated deficit of $24.1 million. We expect to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We will need to generate significant revenue to achieve profitability, and we may never generate revenue or enough revenue to achieve profitability.

We commenced operations in April 2016. In March 2017, we converted from a California limited liability company to a Delaware C-corporation, and changed our name from Krystal Biotech, LLC to Krystal Biotech, Inc. On June 19, 2018, we incorporated Krystal Australia Pty Ltd, an Australian proprietary limited company, for the purposes of undertaking preclinical and clinical studies in Australia. To date, our operations have been focused on organizing and staffing our company, developing our proprietary platform, identifying potential product candidates, undertaking preclinical studies and clinical trials, and developing an in-house cGMP facility.

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 KB103 and planned preclinical studies for our other product candidates, or our operations. Our funds may not be sufficient to enable us to conduct pivotal clinical trials for, seek marketing approval for or commercially launch KB103 or any other product candidate, including KB105. Accordingly, to obtain marketing approval for and to commercialize this 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.

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, if any, 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, or CMOs, consultants and other vendors that conduct our preclinical activities;
- costs of acquiring, developing and manufacturing clinical trial materials and lab supplies; and
- facility costs, depreciation and other expenses, which include direct expenses for rent and maintenance of facilities and other supplies.

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 manufacture 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 conduct our ongoing Phase 1/2 clinical trial for KB103 and ongoing preclinical trials for KB105. Due to the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration, costs and timing of this clinical trial, and, as a result, the actual costs to complete this planned clinical trial may exceed the expected costs.

General and Administrative Expenses

General and administrative expenses consist principally of professional fees associated with corporate and intellectual property legal expenses, consulting and accounting services and facility-related costs. 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.

Interest Income

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

Critical Accounting Policies, Significant Judgments and Estimates

There have been no significant changes during the three months ended March 31, 2019 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, 2018.

Results of Operations

Three Months Ended March 31, 2019 and 2018

(In thousands)	Three Months Ended March 31, 2019	2018	Change
	(unaudited)		
Expenses			
Research and development	$ 3,167	$ 1,520	$ 1,647
General and administrative	1,527	757	770
Total operating expenses	4,694	2,277	2,417
Loss from operations	(4,694)	(2,277)	(2,417)
Other Expense			
Interest and other income (expense), net	583	127	456
Total interest and other income (expense), net	583	127	456
Net loss applicable to stockholders	$ (4,111)	$ (2,150)	$ (1,961)

Research and Development Expenses

Research and development expenses increased $1.6 million in the three months ended March 31, 2019 as compared to the three months ended March 31, 2018. Higher research and development expenses were due largely to increases in payroll, employee benefits and stock-based compensation of $608 thousand, lab supplies of $649 thousand, and other research and development expenses of $391 thousand.

General and Administrative Expenses

General and administrative expenses increased $770 thousand in the three months ended March 31, 2019 as compared to the three months ended March 31, 2018. Higher general and administrative spending was due largely to increases in payroll, employee benefits and stock-based compensation costs of $551 thousand, insurance expenses of $17 thousand as a result of being a public company, and other administrative costs of $202 thousand.

Interest and Other Income

Interest and other income for the three months ended March 31, 2019 and 2018 was $583 thousand $127 thousand, respectively and consisted of interest income earned from our cash, cash equivalents and short-term investments.

Liquidity and Capital Resources

Overview

As of March 31, 2019, we had an accumulated deficit of $24.1 million.

On March 12, 2019, the Company entered into an “at-the-market” equity offering program (“ATM Facility”) to issue and sell shares of the Company’s common stock of up to $50.0 million in gross proceeds. As of March 31, 2019, the Company has not sold any shares under the ATM Facility.

With the net proceeds raised upon the close of our initial public offering (“IPO”) in September 2017, a private placement in August 2018, a secondary public offering in October 2018, an “at-the-market” equity offering program (“ATM Facility) in March 2019, the Company believes that its cash, cash equivalents and short-term investments of approximately $106.6 million as of March 31, 2019 will be sufficient to allow the Company to fund its 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 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. There can be no assurances that additional funding will be available on terms acceptable to the Company, if at all.

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.

We believe that our available funds will be sufficient to enable us to obtain clinical data from our Phase 1/2 clinical trial for KB103 and to initiate Phase 1/2 clinical trials for KB105. We expect that these funds will not be sufficient to enable us to seek marketing approval for or commercialize any of our product candidates.

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 timing and costs of our ongoing Phase 1/2 clinical trial for KB103;
- the progress, timing and costs of manufacturing of KB103 for clinical trials;
- the timing and costs of filing an IND for KB105 and commencing Phase 1/2 clinical trials for KB105;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the costs of establishing and maintaining our own commercial-scale cGMP manufacturing facility;
- the costs associated with the manufacturing process development and evaluation of third-party manufacturers;
- the costs of commercialization activities for KB103 and other product candidates if we receive marketing approval for KB103 or any other 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, revenue, if any, received from commercial sale of KB103 or other product candidates, should any of our product candidates receive marketing approval;
- 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 amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, 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;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our current license agreements remaining in effect and our achievement of milestones under those agreements;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- 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 expect that we will need to obtain substantial additional funding in order to receive regulatory approval and to commercialize KB103 or any other product candidates, including KB105. 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 KB103 or KB105 or our other 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 KB103 or KB105 or our other 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,	
	2019	2018
	(unaudited)	
Net cash used in operating activities	$ (3,215)	$ (2,369)
Net cash used in investing activities	(2,482)	—
Net cash provided by financing activities	40	6
Net decrease in cash	$ (5,657)	$ (2,363)

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2019 was $3.2 million and consisted primarily of a net loss of $4.1 million adjusted for non-cash items of depreciation and stock-based compensation expense of $445 thousand, and cash provided by net decreases in operating assets and liabilities of $451 thousand.

Net cash used by operating activities for the three months ended March 31, 2018 was $2.4 million and consisted primarily of a net loss of $2.2 million adjusted for non-cash items of depreciation and stock-based compensation expense of $83 thousand, and cash provided by net decreases in operating assets and liabilities of $302 thousand.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2019 was $2.5 million and consisted primarily of purchases of $512 thousand of short-term available-for-sale investment securities, expenditures of $2.0 million on the build-out of our new GMP facilities and purchases of computer and laboratory equipment.

Net cash used in investing activities for the three months ended March 31, 2018 was zero.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2019 and 2018 was $40 thousand and $6 thousand, respectively and related to proceeds received from the exercise of common stock options.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

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 year ended December 31, 2018.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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 $106.6 million at March 31, 2019, which consist primarily of U.S. Treasury bills and certificates of deposit. 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 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 and cash equivalents have 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 and cash equivalents are recorded at fair value.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Chief Financial 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 Financial 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

There were no changes in our internal control over financial reporting during the three month period covered by this Quarterly Report on Form 10-Q that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We currently are not a party to any material litigation or other material legal proceedings. We may, from time to time, be subject to legal proceedings and claims arising from the normal course of business activities.

ITEM 1A. RISK FACTORS

In addition to the information set forth in this Quarterly Report on Form 10-Q and before deciding to invest in, or retain, shares of our common stock, you also should carefully review and consider the information contained in our other reports and periodic filings that we make with the SEC, including, without limitation, the information contained under the caption Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018 and under the caption "Risk Factors" in our Prospectus Supplement as filed with the SEC on March 12, 2019. Those risk factors could materially affect our business, financial condition and results of operations. The risks that we describe in our public filings are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we presently deem to be immaterial, also may materially adversely affect our business, financial condition and results of operations.

There have been no material additions or changes in our risk factors from those previously disclosed under the caption "Risk Factors" in our Prospectus Supplement as filed with the SEC on March 12, 2019.

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

Sales of Unregistered Securities

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 Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

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

KRYSTAL BIOTECH, INC.
(Registrant)

Date: May 7, 2019

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

By: /s/ Antony A. Riley
Antony Riley
Chief Financial Officer
(Principal Accounting and Financial 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 7, 2019

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

Exhibit 31.2

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

I, Antony A. Riley, 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 7, 2019

By: /s/ Antony A. Riley
Antony A. Riley
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL 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 quarter ended March 31, 2019, (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 7, 2019

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

I, Antony A. Riley, Chief Financial 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 quarter ended March 31, 2019, (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 7, 2019

By: /s/ Antony A. Riley
Antony A. Riley
Chief Financial Officer
(Principal Accounting and Financial Officer)