

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018

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
(State or other jurisdiction of
incorporation or organization)

82-1080209
(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 (§ 229.405 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 the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

There were 14,428,916 shares of the registrant's common stock issued and outstanding as of October 31, 2018.

Krystal Biotech, Inc.
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ITEM 1.

Krystal Biotech, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except shares and per share data)	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	\$ 46,667	\$ 49,591
Short-term investments	5,627	—
Prepaid and other current assets	527	323
Total current assets	52,821	49,914
Property and equipment, net	1,632	200
Total assets	<u>\$ 54,453</u>	<u>\$ 50,114</u>
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 378	\$ 193
Accrued expenses and other current liabilities	1,538	447
Total current liabilities	1,916	640
Other noncurrent liabilities	245	—
Total liabilities	2,161	640
Commitments and contingencies (Note 5)		
Preferred stock		
Preferred stock; \$0.00001 par value; 20,000,000 shares authorized at September 30, 2018 (unaudited) and December 31, 2017; 2,061,773 shares issued, and no shares outstanding at September 30, 2018 (unaudited) and December 31, 2017	—	—
Total preferred stock	—	—
Stockholders' equity		
Common stock; \$0.00001 par value; 80,000,000 shares authorized at September 30, 2018 (unaudited) and December 31, 2017; 10,978,916 and 10,307,247 shares issued and outstanding at September 30, 2018 (unaudited) and December 31, 2017, respectively	—	—
Additional paid-in capital	68,542	58,544
Accumulated other comprehensive loss	1	—
Accumulated deficit	(16,251)	(9,070)
Total stockholders' equity	52,292	49,474
Total liabilities, preferred stock and stockholders' equity	<u>\$ 54,453</u>	<u>\$ 50,114</u>

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expenses				
Research and development	\$ 1,914	\$ 1,355	\$ 4,959	\$ 2,120
General and administrative	1,058	738	2,738	1,154
Total operating expenses	<u>2,972</u>	<u>2,093</u>	<u>7,697</u>	<u>3,274</u>
Loss from operations	(2,972)	(2,093)	(7,697)	(3,274)
Other Expense				
Interest and other income (expense), net	217	(3,180)	516	(3,253)
Total interest and other income (expense), net	<u>217</u>	<u>(3,180)</u>	<u>516</u>	<u>(3,253)</u>
Net loss applicable to stockholders and members	(2,755)	(5,273)	(7,181)	(6,527)
Unrealized gain on available-for-sale securities	3	—	1	—
Comprehensive loss	<u>(2,752)</u>	<u>(5,273)</u>	<u>(7,180)</u>	<u>(6,527)</u>
Net loss attributable to common stockholders and members per share:				
Basic and diluted	<u>\$ (0.26)</u>	<u>\$ (1.26)</u>	<u>\$ (0.69)</u>	<u>\$ (1.75)</u>
Weighted-average common shares and common units outstanding: Basic and diluted	<u>10,624,113</u>	<u>4,183,075</u>	<u>10,415,025</u>	<u>3,725,825</u>

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)	Nine Months Ended September 30,	
	2018	2017
Operating Activities		
Net loss	\$ (7,181)	\$ (6,527)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	80	9
Stock-based compensation expense	490	188
Non-cash interest expense	—	3,263
Decrease in		
Prepays and other current assets	46	198
Accounts payable	129	271
Accrued expenses and other current liabilities	481	835
Other noncurrent liabilities	28	—
Net cash used in operating activities	(5,927)	(1,763)
Investing Activities		
Purchases of property and equipment	(930)	(51)
Purchases of short-term investments	(5,626)	—
Net cash used in investing activities	(6,556)	(51)
Financing Activities		
Proceeds from the issuance of convertible promissory notes	—	1,299
Proceeds from the issuance of related party convertible promissory notes	—	1,000
Issuance of common stock, net	9,559	43,162
Issuance of preferred stock and preferred units	—	7,000
Net cash provided by financing activities	9,559	52,461
Net (decrease) increase in cash and cash equivalents	(2,924)	50,647
Cash and cash equivalents at beginning of period	49,591	1,923
Cash and cash equivalents at end of period	\$ 46,667	\$ 52,570
Supplemental Disclosures of Non-Cash Investing and Financing Activities		
Conversion of convertible promissory notes to preferred stock	\$ —	\$ 4,142
Conversion of preferred stock to common stock	\$ —	\$ 12,661
Unpaid construction-in-progress	\$ 582	\$ —
Unpaid deferred offering costs	\$ 56	\$ 1,327

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.

Liquidity and Risks

As of September 30, 2018, the Company had an accumulated deficit since inception of \$16.3 million. With the net proceeds raised upon the close of its initial public offering (“IPO”), a private placement in August 2018, as described in Financial Note 6 “Capitalization”, the Company believes that its cash, cash equivalents and short-term investments of approximately \$52.3 million as of September 30, 2018 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. Furthermore, the Company closed upon a secondary public offering in October 2018 where total proceeds net of underwriting discounts and commissions but before offering expenses payable by the Company were approximately \$64.9 million. 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 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 financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America or (“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 U.S. Securities and Exchange Commission (the “SEC”). There have been no material intercompany transactions as of the date of our Quarterly Report on this Form 10-Q.

Unaudited Condensed Consolidated Financial Information

The accompanying condensed consolidated balance sheets as of September 30, 2018, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and condensed consolidated statements of cash flows for the nine months ended September 30, 2018 and 2017, and the related information contained within the notes to the condensed consolidated financial statements are unaudited. As permitted under GAAP for interim financial information under instructions to Form 10-Q and Article 10 of Regulation S-X, certain footnotes or other financial information can be condensed or omitted. These financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these statements should be read in conjunction with the audited financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2017. The condensed consolidated financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, consisting of normal and recurring adjustments, necessary for the fair presentation of the Company’s financial position at September 30, 2018 and December 31, 2017, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, and its

cash flows for the nine months ended September 30, 2018 and 2017. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018 or any other condensed future period.

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 consists 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 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	3-5 years
Furniture and fixtures	3 years
Leasehold improvements	7-8 years

Construction-in-progress which primarily represents the buildout of our Good Manufacturing Practice ("GMP") facility is not depreciated until the facility is completed and 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 September 30, 2018.

Preferred Stock

In accordance with the guidance in FASB ASC Topic 480, *Distinguishing Liabilities from Equity*, shares of preferred stock (Note 6), were classified outside of permanent equity and within temporary equity due to their associated redemption features and liquidation preferences. There were no shares of preferred stock outstanding as of September 30, 2018 and December 31, 2017.

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. Share-based payments issued to non-employees are recorded at their fair values which are periodically revalued as the equity instruments vest and are recognized as expense over the related service period in accordance with the provisions of ASC 718 and ASC Topic 505, *Equity*, and are expensed using an accelerated attribution model. 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. The expected term for non-employee awards is 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. The Company uses historical data to estimate forfeitures and records stock-based compensation expense only for those awards that are expected to vest. 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 loss are reported, net of their related tax effect, to arrive at a comprehensive loss.

Recent Accounting Pronouncements

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the condensed consolidated balance sheets must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective 30 days after publication in the Federal Register. The final rule was not yet published in the Federal Register as of the date of this Quarterly Report on Form 10-Q. The Company is evaluating the impact of this guidance on its condensed consolidated financial statements.

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 beginning 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 condensed 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 guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. We are in the process of evaluating the effect of this guidance on our consolidated condensed financial statements and related disclosures.

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 fiscal years, and periods within those years, beginning after December 15, 2018. The Company generally does not finance purchases of equipment but it does lease office and lab facilities. We are in the process of evaluating the effect of this guidance on our consolidated condensed financial statements and related disclosures.

3. Net Loss Per Share Attributable to Common Stockholders and Members

In March 2017, the Company converted from a limited liability company to a C-corporation. Upon the conversion, each outstanding common unit and preferred unit was converted into one share of common stock and preferred stock, respectively. Common units had similar rights and characteristics of common stock issued upon the conversion. In calculating net loss per share, the Company retrospectively applied the effects of the conversion to the number of common units outstanding prior to the conversion.

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. Preferred stock and stock options are common share equivalents. There were 378,015 and 185,332 common stock equivalents outstanding as of September 30, 2018 and 2017, respectively, in the form of stock options, unvested restricted stock awards, and preferred stock in 2017, 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
(In thousands, except shares, units, per share and per unit data)	(Unaudited)			
Numerator:				
Net loss applicable to common stockholders and members	\$ (2,755)	\$ (5,273)	\$ (7,181)	\$ (6,527)
Denominator:				
Weighted-average basic and diluted common shares and common units	10,624,113	4,183,075	10,415,025	3,725,825
Basic and diluted net loss per common share and common unit	\$ (0.26)	\$ (1.26)	\$ (0.69)	\$ (1.75)

4. Balance Sheet Components

Property and Equipment, Net

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

	September 30, 2018	December 31, 2017
	(Unaudited)	
Construction-in-progress	986	—
Leasehold improvements	3	—
Furniture & fixtures	66	—
Computer equipment and software	37	11
Laboratory equipment	645	214
Total property and equipment	1,737	225
Accumulated depreciation and amortization	(105)	(25)
Property and equipment, net	\$ 1,632	\$ 200

Depreciation expense was \$38 thousand and \$80 thousand for the three and nine months ended September 30, 2018 and \$5 thousand and \$9 thousand for the three and nine months ended September 30, 2017, respectively.

Accrued Expenses and Other Current Liabilities

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

	September 30, 2018 (Unaudited)	December 31, 2017
Accrued pre-clinical expenses	\$ 252	\$ 257
Accrued professional fees	150	77
Accrued payroll and benefits	347	10
Accrued taxes	115	103
Accrued leasehold improvement liabilities	582	—
Other liabilities	92	—
Total	<u>\$ 1,538</u>	<u>\$ 447</u>

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 and expired on October 31, 2017 (the "2016 Lease"). In June 2016, the Company entered into an amendment to the 2016 Lease which amended the timing of the rent payment from one single payment to 17 equal monthly installments. In February 2017, the Company entered into a second amendment to the 2016 Lease, which extended the expiration date of the 2016 Lease to October 31, 2018. In May 2018, the Company entered into a third amendment to the 2016 Lease which further extended the expiration date of the 2016 Lease to February 28, 2026. In October 2018, the Company entered into a fourth amendment to the 2016 Lease which expanded our office and lab facilities by an additional 6,003 square feet.

The Company's future minimum operating lease payments, including the fourth amendment to the 2016 Lease, were as follows (in thousands):

	Operating Leases
2018 (remaining three months)	\$ 28
2019	337
2020	388
2021	396
2022	404
Thereafter	1,334
Future minimum operating lease payments	<u>\$ 2,887</u>

The Company recorded \$60 thousand and \$125 thousand in rent expense for the three and nine months ended September 30, 2018, and \$20 thousand and \$59 thousand for the three and nine months ended September 30, 2017, respectively.

6. Capitalization

Conversion to C-Corporation

On March 31, 2017, the Company converted from a limited liability company to a C-Corporation. Upon the conversion, all outstanding preferred units and common units were converted on a 1-to-1 basis into shares of preferred stock and common stock, respectively.

Stock Split and Increase in Authorized Shares

On September 5, 2017, in connection with our IPO, the Company's board of directors (the "Board") approved a 1-to-4.5 forward stock split, in the form of a stock dividend, of all outstanding shares of common stock and preferred stock. Except as otherwise noted, all references to share and per share amounts related to common stock, common units, preferred stock, preferred units and stock options in these condensed consolidated financial statements reflect the stock split. The par value per share of \$.00001 of our capital stock was not adjusted as a result of the stock split. Additionally, the Board approved an increase in authorized shares of common stock and preferred stock to 80,000,000 shares and 20,000,000 shares, respectively. The stock split and the increase in the number of authorized common and preferred shares occurred immediately prior to the effectiveness of our registration statement on Form S-1 (File No. 333-220085) relating to the IPO on September 19, 2017.

Initial Public Offering

On September 22, 2017, the Company completed its initial public offering of 4,554,000 shares of its common stock at a price to the public of \$10.00 per share, which includes the sale of 594,000 shares of the Company's common stock pursuant to the underwriters' full exercise of their option to purchase additional shares. The total proceeds from the offering to the Company, net of underwriting discounts and commissions of approximately \$3.2 million, were approximately \$42.3 million. After deducting offering expenses payable by the Company of approximately \$1.6 million, net proceeds to the Company were approximately \$40.7 million. Immediately prior to the closing of the IPO, all outstanding shares of the Company's preferred stock converted into 2,061,773 shares of common stock on a 1-to-1 basis.

Sale of Common Stock

On August 25, 2017, following the completion of the Sun Pharma Offering (as further described below), Daniel S. Janney, a member of our board of directors, purchased 130,590 shares of our common stock at the same price per share paid by Sun Pharma, \$7.66 per share, through an investment entity owned and controlled by a board member for a total consideration of approximately \$1.0 million.

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.

On August 16, 2018, the Company entered into a stock purchase agreement with Frazier Life Sciences for the private placement of 625,000 shares of the Company's common stock at \$16.00 per share. The private placement yielded gross proceeds of \$10.0 million and closed on August 17, 2018. Pursuant to the terms of the purchase agreement, the Company filed a registration statement with the SEC which became effective on October 12, 2018.

Shares Outstanding

There were 10,978,916 and 10,307,247 shares of common stock outstanding at September 30, 2018 and December 31, 2017, respectively. No shares of preferred stock were outstanding at September 30, 2018 or December 31, 2017.

Issuance of Preferred Stock and Conversion of Convertible Promissory Notes and Related Party Convertible Promissory Notes

On August 8, 2017, the Company issued 914,107 shares of Series A Preferred Stock to a single investor ("Sun Pharma") at a purchase price of \$7.66 per share for aggregate proceeds of approximately \$7.0 million (the "Sun Pharma

Offering”). Concurrently with the issuance of the Series A Preferred Stock, and as further described in our Annual Report on Form 10-K for the year ended December 31, 2017, previously issued convertible promissory notes plus accrued interest were automatically converted into shares of preferred stock. As the conversion price per share of preferred stock was lower than the market price of each share of preferred stock on the date of conversion, an interest expense of \$3.2 million was recorded upon conversion representing a beneficial conversion feature.

The following table outlines the conversion on August 8, 2017 of the convertible promissory notes into shares of preferred stock (in thousands except share and per share amounts):

	<u>Principal</u>	<u>Accrued Interest</u>	<u>Total</u>	<u>Conversion Price Per Share (1)</u>	<u>Shares of Series A-1</u>	<u>Shares of Series A-2</u>	<u>Fair Value Date of Conversion</u>	<u>Fair Value Series A-1</u>	<u>Fair Value Series A-2</u>	<u>Loss on Extinguishment of Convertible Promissory Notes</u>
Convertible promissory notes	\$ 2,444	\$ 72	\$ 2,516	\$ 4.14	(1) 607,743	—	\$ 7.66	\$ 4,654	\$ —	\$ (2,138)
Related party convertible promissory notes	948	32	980	\$ 4.14	(1) 236,619	—	\$ 7.66	1,812	—	(832)
Related party convertible promissory notes—June notes	750	8	758	\$ 6.13	(2) —	123,691	\$ 7.66	—	947	(189)
Total related party promissory notes	1,698	40	1,738		236,619	123,691		1,812	947	(1,021)
Total	\$ 4,142	\$ 112	\$ 4,254		844,362	123,691		\$ 6,466	\$ 947	\$ (3,159)

(1) The conversion price was determined by dividing the target valuation of \$16 million by the outstanding shares of 3,863,547 immediately prior to the issuance of the Series A on August 8, 2017.

(2) The conversion price was determined to be 80% of the \$7.66 sales price per share of the Series A shares issued on August 8, 2017.

Common Stock

The voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers and privileges of the holders of the preferred stock and are as follows:

Voting Rights. The holders of shares of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings. The Board shall be elected by vote of the Common Stock and the Preferred stock voting together as a single class on an as-converted basis.

Dividends. The holders of the common stock are entitled to receive dividends, if and when declared by the Board, and all dividends shall be paid pro rata on the common stock and the preferred stock, without preference, based on the number of shares of the common stock of the holders. From inception through September 30, 2018, no dividends have been declared or paid by the Company.

Liquidation Preference. After payment to the holders of shares of preferred stock of their liquidation preferences, the holders of the common stock are entitled to share ratably in the Company’s assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation, dissolution, winding up, consolidation or merger of the Company or upon the occurrence of a deemed liquidation event.

7. Significant Agreements

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 September 30, 2018 under these agreements for the manufacturing of our drug product is approximately \$906 thousand. 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 \$762 thousand and \$2.4 million for the three and nine months ended September 30, 2018, and \$483 thousand and \$643 thousand for the three and nine months ended September 30, 2017, respectively.

8. 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 38,500 and 174,000 stock options during the three and nine months ended September 30, 2018, respectively, to employees and directors of the Company, and 6,750 and 71,649 stock options were granted during the three and nine months ended September 30, 2017. Options granted to employees vest ratably over a four-year period and options granted to directors of the company vest ratably over one and four-year periods. Options have a life of ten years. Stock options granted to non-employees are accounted for using the fair value method of accounting, and are periodically revalued as the options vest, and are 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)
Balance at December 31, 2017	185,332	\$ 3.91	9.0	\$ 1,224
Granted	174,000	\$ 12.90		
Exercised	(4,243)	\$ 2.46		
Cancelled or forfeited	(19,500)	\$ 14.96		
Balance at September 30, 2018	<u>335,589</u>	<u>\$ 7.95</u>	<u>9.0</u>	<u>\$ 3,232</u>
Exercisable at September 30, 2018	<u>65,040</u>	<u>\$ 4.27</u>	<u>8.4</u>	<u>\$ 866</u>
Vested at September 30, 2018	<u>65,040</u>	<u>\$ 4.27</u>	<u>8.4</u>	<u>\$ 866</u>

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on September 28, 2018 and the exercise price of outstanding in-the-money options.

Options for 4,243 shares of our common stock with an intrinsic value of \$53 thousand were exercised during the nine months ended September 30, 2018. No options were exercised during 2017.

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 and nine months ended September 30, 2018 and 2017 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 86	\$ 40	\$ 209	\$ 107
General and administrative	82	14	135	81
Total stock-based compensation	\$ 168	\$ 54	\$ 344	\$ 188

Stock Options Granted to Employees. The Company recorded stock-based compensation expense related to employee's and board member's stock options of \$159 thousand and \$312 thousand for the three and nine months ended September 30, 2018, respectively, and \$47 thousand and \$78 thousand for the three and nine months ended September 30, 2017, 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 and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected stock price volatility	80%	80%	80%	80%
Expected term of the award (years)	6.25	6.25	6.25	6.25
Risk-free interest rate	2.90%	1.92%	2.77%	1.93%
Expected dividend yield	0%	0%	0%	0%

The weighted-average grant-date fair value per share of options granted to employees during the nine months ended September 30, 2018 was \$9.15.

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 3.10 years as of September 30, 2018.

Stock Options Granted to Non-Employees. Stock-based compensation expense related to stock options granted to non-employees is recognized over the related service period. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered. The Company recorded stock-based compensation expense related to non-employees' stock options of \$9 thousand and \$32 thousand for the three and nine months ended September 30, 2018, respectively, and \$7 thousand and \$110 thousand for the three and nine months ended September 30, 2017, respectively. No options were granted to non-employees in the nine months ended September 30, 2018.

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. No RSAs were granted in the three and nine months ended September 30, 2017. The RSAs vest ratably over a one-year period. 10,606 shares of RSAs had vested as of September 30, 2018. The RSAs, including the unvested portion, are considered issued and outstanding as of September 30, 2018. The fair value of each restricted stock is the closing price of our common stock on the grant date. The weighted average grant-date fair value of each restricted stock was \$10.30 in the three and nine months ended September 30, 2018. The Company recorded stock-based compensation expense related to RSAs of \$109 thousand and \$146 thousand for the three and nine months ended September 30, 2018 within general and administrative expenses in the accompanying condensed consolidated statements of operations. As of September 30, 2018, there was \$291 thousand of unrecognized stock-based compensation expense related to RSAs that is expected to be recognized over a weighted-average period of 8 months.

Stock options and restricted stock awards available for grant were 703,074 at September 30, 2018.

9. Subsequent Events

On October 23, 2018, the Company completed its secondary public offering of 3,450,000 shares of its common stock at a price to the public of \$20.00 per share, which includes the sale of 450,000 shares of the Company's common stock pursuant to the underwriters' full exercise of their option to purchase additional shares. The Chief Executive Officer and Chief Operating Officer each purchased 25,000 shares of the Company's common stock at \$20.00 per share as part of the secondary public offering. The total proceeds from the offering to the Company, net of underwriting discounts and commissions of approximately \$4.1 million, but before offering expenses payable by the Company, were approximately \$64.9 million.

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, 2017, as filed with the SEC, on March 12, 2018.

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 gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from skin diseases. We have developed a proprietary gene therapy platform, our STAR-D 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. We are initially using our STAR-D 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 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. In particular, results to date on 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.

KB103 is the first topical HSV-1 based gene therapy engineered to deliver a human collagen protein to patients suffering from DEB. 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 formation of protein type VII collagen, or COL7, that forms anchoring fibrils that bind the dermis to the epidermis. In DEB patients, the genetic defect in COL7A1 results in loss or malfunctioning of these anchoring fibrils, leading to extremely fragile skin that blisters and tears from minor friction or trauma. Those who are born with DEB are sometimes called “butterfly children”, because their skin is likened to be as fragile as the wings of a butterfly. DEB patients may suffer from open wounds, skin infections, fusion of fingers and toes, and gastrointestinal tract problems throughout their lifetime, and may eventually develop squamous cell carcinoma, a potentially fatal condition. Based on information from DEBRA International, a worldwide alliance of patient support groups for EB, of which DEB is a subset, we believe there may be as many as 125,000 patients worldwide who suffer from DEB. We estimate that there are 3,200 to 3,500 diagnosed DEB patients in the European Union, United States, Japan and Canada.

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 STAR-D platform, identifying potential product candidates, undertaking preclinical studies and clinical trials, and developing an in-house good manufacturing practice (“GMP”) facility.

On September 22, 2017, the Company completed its initial public offering (“IPO”) of 4,554,000 shares of its common stock at a price to the public of \$10.00 per share. Proceeds to the Company were \$40.7 million, net of underwriting discounts, commissions and offering expenses.

On November 1, 2017, the Company entered into a stock purchase agreement with EBMRP and EBRP pursuant to which the Company agreed to issue and sell, and the Purchasers agreed to purchase, 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.

On August 16, 2018, the Company entered into a stock purchase agreement with Frazier Life Sciences for the private placement of 625,000 shares of the Company’s common stock at \$16.00 per share. The private placement yielded gross proceeds of \$10 million and closed on August 17, 2018.

On October 23, 2018, the Company completed its secondary public offering of 3,450,000 shares of its common stock at a price to the public of \$20.00 per share, which includes the sale of 450,000 shares of the Company’s common stock pursuant to the underwriters’ full exercise of their option to purchase additional shares. The total proceeds from the offering to the Company, net of underwriting discounts and commissions of approximately \$4.1 million, but before offering expenses payable by the Company, were approximately \$64.9 million.

At September 30, 2018, our cash, cash equivalents and short-term investments balance was approximately \$52.3 million.

On November 2, 2017, the U.S. Food and Drug Administration, or the FDA, granted orphan drug designation to the Company’s lead product candidate, KB103, for the treatment of DEB. The FDA’s Office of Orphan Drug Products Development grants orphan drug designation to support the development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the United States. Orphan drug designation may allow us to be eligible for a seven-year period of U.S. Marketing exclusivity upon approval of KB103, tax credits for certain clinical research costs, and a waiver of the Prescription Drug User Fee Act, or PDUFA, filing fees, subject to certain conditions.

On November 3, 2017, the Office of Science Policy or OSP at the National Institutes of Health or the NIH indicated that the Company’s Phase 1/2 protocol for KB103 has completed the RAC protocol registration process.

On January 16, 2018, the United States Patent and Trademark Office or USPTO granted U.S. Patent No. 9,877,990 to the Company which covers compositions comprising herpes simplex viral or HSV vectors and methods of using the same for providing prophylactic, palliative or therapeutic relief of a wound, disorder or disease of the skin in a subject.

On April 16, 2018, the European Commission granted the orphan medicinal product designation, or OMPD, for KB103. KB103 has the distinction of being the first investigational HSV-1 based gene therapy for DEB to receive this designation.

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. The Phase 1/2 trial at Stanford University is a single-center, open-label, placebo-controlled Phase 1/2 study conducting an intra-subject comparison of randomized treatment and control wounds. It is designed to evaluate the safety and tolerability of KB103 in subjects with the recessive form of dystrophic epidermolysis bullosa. Efficacy is also evaluated through analysis of collagen VII expression and anchoring fibril formation in the basement membrane zone and wound imaging.

In May 2018, the FDA granted Fast Track designation in the United States for KB103 for the treatment of DEB. Under the FDA Modernization Act of 1997, designation as a Fast Track product means the FDA will take action to expedite both the development and the review of the application for approval. The FDA may also evaluate for filing, and commence review of, portions of an application for approval of a Fast Track product under certain conditions.

On August 7, 2018, the FDA granted orphan drug designation to the Company’s second product candidate, KB105 which is currently in preclinical development for treatment of patients with transglutaminase 1, or TGM-1, deficient autosomal recessive congenital ichthyosis, or ARCI. 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 in the fourth quarter of 2018. TGM-1 is an essential epidermal enzyme that facilitates the formation of the epidermal barrier, which prevents dehydration, and protects the skin from unwanted toxins and surface microorganisms. The loss of TGM-1-activity results in

the severe genetic skin disease ARCI. Most patients with a TGM-1-deficiency exhibit life-long pronounced scaling with increased transepidermal water loss. The scales are plate-like, often of a dark color, and cover the whole-body surface area. TGM-1-deficient ARCI is associated with increased mortality in the neonatal period and has a dramatic impact on quality of life. KB105 is a replication-defective, non-integrating viral vector that has been engineered employing Krystal's STAR-D platform to deliver functional human TGM-1 gene directly to the patients' dividing and non-dividing skin cells. HSV-1 is Krystal's replication-deficient, non-integrating viral vector that can penetrate skin cells more efficiently than other viral vectors. Its high payload capacity allows it to accommodate large or multiple genes and its low immunogenicity makes it a suitable choice for direct and repeat delivery to the skin.

On October 15, 2018, we announced positive interim results from placebo-controlled Phase 1/2 study of KB103. In particular, results to date on 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. With respect to secondary endpoints, topically administered KB103 wounds closed in 2 weeks. KB103 shows presence functional COL7 expression and anchoring fibrils in both patients when administered intradermally to intact skin.

Since operations began, we have incurred operating losses. Our net losses were \$2.8 million and \$7.2 million for the three and nine months ended September 30, 2018, respectively. At September 30, 2018, we had an accumulated deficit of \$16.3 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.

Costs related to clinical trials can be unpredictable and therefore there can be no guarantee that we will have sufficient proceeds from our IPO and from other sources to fund our planned preclinical and clinical studies 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 (Expense), Net

Interest income consists primarily of income earned from our cash, cash equivalents and short-term investments. Interest expense incurred is primarily from convertible promissory notes.

Critical Accounting Policies, Significant Judgments and Estimates

There have been no significant changes during the three and nine months ended September 30, 2018 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, 2017.

Results of Operations

Three Months Ended September 30, 2018 and 2017

	Three Months Ended September 30,		Change
	2018	2017	
	(unaudited)		
(In thousands)			
Expenses			
Research and development	\$ 1,914	\$ 1,355	\$ 559
General and administrative	1,058	738	320
Total operating expenses	2,972	2,093	879
Loss from operations	(2,972)	(2,093)	(879)
Other Expense			
Interest and other income (expense), net	217	(3,180)	3,397
Total interest and other income (expense), net	217	(3,180)	3,397
Net loss applicable to stockholders	<u>\$ (2,755)</u>	<u>\$ (5,273)</u>	<u>\$ 2,518</u>

Research and Development Expenses

Research and development expenses increased \$559 thousand in the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. Higher research and development expenses were due largely to increases in payroll, employee benefits and stock-based compensation of \$419 thousand, lab supplies of \$322 thousand, and other research and development expenses of \$95 thousand partially offset by decreases in professional services related to outsourced manufacturing, in-vivo and clinical studies of \$277 thousand.

General and Administrative Expenses

General and administrative expenses increased \$320 thousand in the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. Higher general and administrative spending was due largely to increases in payroll, employee benefits and stock-based compensation costs of \$366 thousand, insurance expenses of \$80 thousand as a result of being a public company, and other administrative costs of \$143 thousand partially offset by decreases in legal and professional services of \$269 thousand.

Interest and Other Income (Expense), Net

Interest and other income for the three months ended September 30, 2018 was \$217 thousand and consisted of interest income earned from our cash, cash equivalents and short-term investments. Interest and other expense, net, for the three months ended September 30, 2017 was \$3.2 million and consisted primarily of interest expense incurred due to the beneficial conversion feature upon conversion of promissory notes to shares of preferred stock, and to a lesser degree due to interest expense on our convertible promissory notes before their conversion to shares of preferred stock, partially offset by interest earned on our cash.

Results of Operations

Nine Months Ended September 30, 2018 and 2017

(In thousands)	Nine Months Ended September 30,		Change
	2018	2017	
	(unaudited)		
Expenses			
Research and development	\$ 4,959	\$ 2,120	\$ 2,839
General and administrative	2,738	1,154	1,584
Total operating expenses	7,697	3,274	4,423
Loss from operations	(7,697)	(3,274)	(4,423)
Other Expense			
Interest and other income (expense), net	516	(3,253)	3,769
Total interest and other income (expense), net	516	(3,253)	3,769
Net loss applicable to stockholders and members	<u>\$ (7,181)</u>	<u>\$ (6,527)</u>	<u>\$ (654)</u>

Research and Development Expenses

Research and development expenses increased \$2.8 million in the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017. Higher research and development expenses were due largely to increases in professional services related to outsourced manufacturing, in-vivo and clinical studies of \$1.0 million, payroll, employee benefits and stock-based compensation of \$1.0 million, lab supplies of \$632 thousand, and other research and development expenses of \$196 thousand.

General and Administrative Expenses

General and administrative expenses increased \$1.6 million in the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017. Higher general and administrative spending was due largely to increases in legal and professional services of \$137 thousand, payroll, employee benefits and stock-based compensation costs of \$899 thousand, insurance expenses of \$253 thousand as a result of being a public company, and other administrative costs of \$296 thousand.

Interest and Other Income (Expense), Net

Interest and other income for the nine months ended September 30, 2018 was \$516 thousand and consisted of interest income earned from our cash, cash equivalents and short-term investments. Interest and other expense, net, for the nine months ended September 30, 2017 was \$3.3 million and consisted primarily of interest expense incurred due to the beneficial conversion feature upon conversion of promissory notes to shares of preferred stock, and to a lesser degree due to interest expense on our convertible promissory notes before their conversion to shares of preferred stock, partially offset by interest earned on our cash.

Liquidity and Capital Resources

Overview

As of September 30, 2018, we had an accumulated deficit of \$16.3million.

On October 25, 2018, we received net proceeds of approximately \$64.9 million from our secondary public offering before offering expenses payable by the Company.

On August 17, 2018, we closed the sale of common stock to Frazier Life Sciences for aggregate proceeds of \$10 million.

In November 2017, we closed the sale of common stock to EBMRF, a California not-for-profit corporation and EB Research Partnership, Inc., a New York not-for-profit corporation for aggregate proceeds of \$770,000.

On September 22, 2017, we received net proceeds of approximately \$40.7 million from our IPO.

In August 2017, we closed the sale of preferred stock to a single investor for aggregate proceeds of \$7.0 million, and the sale of 130,590 shares of our common stock with a party related to a member of our board of directors for aggregate proceeds of \$1.0 million.

Prior to August 2017, we had received \$1.4 million in gross proceeds from the issuance of equity securities and \$4.1 million in gross proceeds from debt financings.

We believe that our cash, cash equivalents and short-term investments of approximately \$52.3 million as of September 30, 2018 together with our secondary public offering in October 2018 which resulted in proceeds of \$64.9 million, net of underwriting discounts and commissions but before offering expenses payable by the Company, will be sufficient to allow us to fund our operations for at least 12 months from the filing date of this Quarterly Report on Form 10-Q. As we continue 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 our cost structure. We may never achieve profitability, and unless and until it does, we will continue to need to raise additional capital or obtain financing from other sources, such as partnerships. Management intends to fund future operations through equity and debt financings and may also seek additional capital through arrangements with strategic partners or other sources. There can be no assurances, however, that additional funding will be available on terms acceptable to us, 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):

	Nine Months Ended September 30,	
	2018	2017
	(unaudited)	
Net cash used in operating activities	\$ (5,927)	\$ (1,763)
Net cash used in investing activities	(6,556)	(51)
Net cash provided by financing activities	9,559	52,461
Net (decrease) increase in cash	<u>\$ (2,924)</u>	<u>\$ 50,647</u>

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2018 was \$5.9 million and consisted primarily of a net loss of \$7.2 million adjusted for non-cash items of depreciation and stock-based compensation expense of \$570 thousand, and cash provided by net decreases in operating assets and liabilities of \$684 thousand.

Net cash used by operating activities for the nine months ended September 30, 2017 was \$1.8 million and consisted primarily of a net loss of \$6.6 million adjusted for non-cash items of depreciation and stock-based compensation expense of \$197 thousand, non-cash interest expense from convertible promissory notes of \$3.3 million and cash provided by net decreases in operating assets and liabilities of \$1.3 million.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2018 was \$6.6 million and consisted primarily of purchases of \$5.6 million of short-term available-for-sale investment securities, expenditures of \$930 thousand on the build-out of our new GMP facilities and purchases of computer and laboratory equipment.

Net cash used in investing activities for the nine months ended September 30, 2017 was \$51 thousand and consisted primarily of computer and laboratory equipment purchases.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2018 was \$9.6 million and was primarily from proceeds from an August 2017 private placement of 625,000 shares of the Company's common stock at \$16.00 per share resulting in gross proceeds of \$10.0 million, partially offset by transactions costs of \$450,000.

Net cash provided by financing activities for the nine months ended September 30, 2017 was \$52.5 million and was from proceeds of \$1.3 million received from the issuance of convertible promissory notes, \$1.0 million received from the issuance of related party convertible promissory notes, \$43.2 million received from the issuance of common stock, and \$7.0 million received from issuance of preferred stock and preferred units.

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, 2017.

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 \$52.3 million at September 30, 2018, 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, 2017 and under the caption “Risk Factors” in our Prospectus Supplement, dated October 18, 2018 and filed with the SEC on October 19, 2018. 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, dated October 18, 2018 and filed with the SEC on October 19, 2018.

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	<u>Certification of Periodic Report by Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Periodic Report by Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1	<u>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.</u>
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: November 5, 2018

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)

**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: November 5, 2018

By: /s/ Krish S. Krishnan

Krish S. Krishnan
President and Chief Executive Officer
(Principal Executive Officer)

**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: November 5, 2018

By: /s/ Antony A. Riley

Antony A. Riley
Chief Financial Officer
(Principal Accounting and Financial Officer)

**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 September 30, 2018, (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: November 5, 2018

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 September 30, 2018, (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: November 5, 2018

By: /s/ Antony A. Riley

Antony A. Riley
Chief Financial Officer
(Principal Accounting and Financial Officer)