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 June 30, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to_____

Commission file number: 001-38210

Krystal Biotech, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	KRYS	NASDAQ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒

Emerging growth company ☒

If emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of July 30, 2021, there were 22,205,642 shares of the registrant's common stock issued and outstanding.

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

Krystal Biotech, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except shares and per share data)	(unaudited) June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 329,527	$ 268,269
Short-term investments	38,203	2,993
Prepaid expenses and other current assets	2,197	3,796
Total current assets	369,927	275,058
Property and equipment, net	44,972	30,876
Long-term investments	21,411	—
Right-of-use assets	7,136	3,298
Other non-current assets	110	1,612
Total assets	$ 443,556	$ 310,844
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,265	$ 2,105
Current portion of lease liability	934	638
Accrued expenses and other current liabilities	15,920	5,109
Build to suit lease liability	—	7,600
Total current liabilities	18,119	15,452
Lease liability	6,897	3,308
Total liabilities	25,016	18,760
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock; $0.00001 par value; 20,000,000 shares authorized at June 30, 2021 (unaudited) and December 31, 2020; 2,061,773 shares issued, and no shares outstanding at June 30, 2021 (unaudited) and December 31, 2020	—	—
Common stock; $0.00001 par value; 80,000,000 shares authorized at June 30, 2021 (unaudited) and December 31, 2020; 22,205,032 and 19,714,220 shares issued and outstanding at June 30, 2021 (unaudited) and December 31, 2020, respectively	—	—
Additional paid-in capital	521,950	363,292
Accumulated other comprehensive income (expense)	(21)	6
Accumulated deficit	(103,389)	(71,214)
Total stockholders' equity	418,540	292,084
Total liabilities and stockholders' equity	$ 443,556	$ 310,844

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except share and per share data)	**2021**	**2020**	**2021**	**2020**
Expenses				
Research and development	$ 6,594	$ 3,639	$ 12,795	$ 7,164
General and administrative	9,799	3,315	17,951	5,735
Total operating expenses	16,393	6,954	30,746	12,899
Loss from operations	(16,393)	(6,954)	(30,746)	(12,899)
Other Income (Expense)				
Interest and other income, net	30	121	64	725
Interest expense	—	—	(1,492)	—
Net loss	(16,363)	(6,833)	(32,174)	(12,174)
Unrealized gain (loss) on available-for-sale securities	(24)	16	(27)	30
Comprehensive loss	$ (16,387)	$ (6,817)	$ (32,201)	$ (12,144)
Net loss per common share: Basic and diluted	$ (0.74)	$ (0.37)	$ (1.48)	$ (0.68)
Weighted-average common shares outstanding: Basic and diluted	22,204,659	18,383,941	21,731,711	17,871,648

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

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

(In thousands, except shares)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2021	19,714,220	$ —	$ 363,292	$ 6	$ (71,214)	$ 292,084
Issuance of common stock, net	2,489,837	—	152,033	—	—	152,033
Stock-based compensation expense	—	—	2,350	—	—	2,350
Unrealized loss on investments	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(15,812)	(15,812)
Balances at March 31, 2021	22,204,057	$ —	$ 517,675	$ 3	$ (87,026)	$ 430,652
Issuance of common stock, net	975	—	14	—	—	14
Stock-based compensation expense	—	—	4,261	—	—	4,261
Unrealized loss on investments	—	—	—	(24)	—	(24)
Net loss	—	—	—	—	(16,363)	(16,363)
Balances at June 30, 2021	22,205,032	$ —	$ 521,950	$ (21)	$ (103,389)	$ 418,540

(In thousands, except shares)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balances at January 1, 2020	17,354,310	$ —	$ 241,951	$ 10	$ (39,047)	$ 202,914
Issuance of common stock, net	16,254	—	243	—	—	243
Stock-based compensation expense	—	—	539	—	—	539
Unrealized gain on investments	—	—	—	14	—	14
Net loss	—	—	—	—	(5,341)	(5,341)
Balances at March 31, 2020	17,370,564	$ —	$ 242,733	$ 24	$ (44,388)	$ 198,369
Issuance of common stock, net	2,293,495	—	117,337	—	—	117,337
Stock-based compensation expense	—	—	807	—	—	807
Unrealized gain on investments	—	—	—	16	—	16
Net loss	—	—	—	—	(6,833)	(6,833)
Balances at June 30, 2020	19,664,059	$ —	$ 360,877	$ 40	$ (51,221)	$ 309,696

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

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

(In thousands)	Six Months Ended June 30, 2021	2020
Operating Activities		
Net loss	$ (32,174)	$ (12,174)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,202	884
Stock-based compensation expense	6,508	1,346
Loss on disposals of fixed assets	—	3
Non-cash interest expense	1,492	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	1,366	378
Prepaid rent	—	(2,400)
Lease liability	(175)	(105)
Accounts payable	(680)	706
Accrued expenses and other current liabilities	2,678	81
Net cash used in operating activities	(19,783)	(11,281)
Investing Activities		
Purchases of property and equipment	(6,462)	(3,454)
Purchases of short-term investments	(38,103)	(3,205)
Proceeds from maturities of short-term investments	2,959	4,392
Purchases of long-term investments	(21,458)	—
Net cash used in investing activities	(63,064)	(2,267)
Financing Activities		
Issuance of common stock, net	152,065	117,712
Repayment of ASTRA build to suit liability	(7,960)	—
Net cash provided by financing activities	144,105	117,712
Net increase in cash and cash equivalents	61,258	104,164
Cash and cash equivalents at beginning of period	268,269	187,514
Cash and cash equivalents at end of period	$ 329,527	$ 291,678
Supplemental Disclosures of Non-Cash Investing and Financing Activities		
Unpaid purchases of property and equipment	$ 10,143	$ 2,675
Unpaid offering costs	$ 36	$ 132
Initial recognition of right-of-use assets and modification	$ 4,060	$ —

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

1. Organization

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

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

Liquidity

As of June 30, 2021, the Company had an accumulated deficit of $103.4 million. With the net proceeds raised from its public and private securities offerings, including the public offering of its common stock completed on February 1, 2021, the Company believes that its cash, cash equivalents and short-term investments of approximately $367.7 million as of June 30, 2021 will be sufficient to allow the Company to fund its planned operations for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. As the Company continues to incur losses, a transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and the achievement of a level of revenues adequate to support the Company’s cost structure. The Company may never achieve profitability and unless and until it does, the Company will continue to need to raise additional capital or obtain financing from other sources. Management intends to fund future operations through the sale of equity and debt financings and may also seek additional capital through arrangements with strategic partners or other sources. There can be no assurance that additional funding will be available on terms acceptable to the Company, if at all.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (“GAAP”), as found in the Accounting Standards Codification (“ASC”), the Accounting Standards Update (“ASU”), of the Financial Accounting Standards Board (“FASB”), and the rules and regulations of the US Securities and Exchange Commission (“SEC”). All intercompany balances and transactions have been eliminated in consolidation. Certain prior period amounts have been reclassified to conform to the current period presentation. The reclassified amounts have no impact on the Company’s previously reported financial position or results of operation.

These unaudited interim condensed financial statements should be read in conjunction with the Company’s audited consolidated financial statements and the notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the SEC on March 1, 2021.

Risks and Uncertainties

The novel coronavirus ("COVID-19") pandemic has resulted, and is likely to continue to result, in significant national and global economic uncertainty and may adversely affect our business. The Company is continuing to actively monitor the impact of the COVID-19 pandemic and the related effects on its financial condition, liquidity, operations, suppliers, industry, and workforce. However, the full extent, consequences, and duration of the COVID-19 pandemic and the resulting impact on the Company cannot currently be predicted. The Company will continue to evaluate the impact that these events could have on the operations, financial position, and the results of operations and cash flows during fiscal year 2021.

Use of Estimates

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

Segment and Geographical Information

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

Concentrations of Credit Risk and Off-Balance Sheet Risk

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

Cash, Cash Equivalents and Investments

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

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

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

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. There is a three-level hierarchy that prioritizes the inputs used in determining fair value by their reliability and preferred use, as follows:

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

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

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

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

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

Property and Equipment, net

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

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

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

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. The Company has not recognized any impairment losses for the three and six months ended June 30, 2021 and 2020.

Leases

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

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

Research and Development Expenses

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

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

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

Stock-Based Compensation Expense

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation-Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments, including grants of stock options and restricted stock, to be recognized in the statements of operations based on their grant-date fair values. Compensation expense is recognized on a straight-line basis based on the grant-date fair value over the associated service period of the award, which is generally the vesting term.

The Company estimates the fair value of its stock options using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including: (i) the expected stock price volatility; (ii) the expected term of the award; (iii) the risk-free interest rate; and (iv) expected dividends. Due to the lack of sufficient history and trading volume of our 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 risk-free interest rates are based on the US Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid and does not expect to pay dividends in the foreseeable future. The Company accounts for forfeitures as they occur. Stock-based compensation expense recognized in the financial statements is based on awards for which service conditions are expected to be satisfied.

Comprehensive Loss

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

Recent Accounting Pronouncements

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

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

3. Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of shares of common stock and common share equivalents outstanding for the period. Common share equivalents consist of common stock issuable upon exercise of stock options and vesting of restricted stock awards. There were 1,688,965 and 831,110 common share equivalents outstanding as of June 30, 2021 and 2020, respectively, in the form of stock options and unvested restricted stock awards, that have been excluded from the calculation of diluted net loss per common share as their effect would be anti-dilutive for all periods presented.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
(In thousands, except shares and per share data)	(Unaudited)		(Unaudited)	
Numerator:				
Net loss per common share	$ (16,363)	$ (6,833)	$ (32,174)	$ (12,174)
Denominator:				
Weighted-average basic and diluted common shares	22,204,659	18,383,941	21,731,711	17,871,648
Basic and diluted net loss per common share	$ (0.74)	$ (0.37)	$ (1.48)	$ (0.68)

4. Fair Value Instruments

The following tables show the Company's cash, cash equivalents and available-for-sale securities by significant investment category as of June 30, 2021 and December 31, 2020, respectively (in thousands):

	June 30, 2021 (unaudited)						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities [1]	Long-term Marketable Securities [2]
Level 1:							
Cash and cash equivalents	$ 329,527	$ —	$ —	$ 329,527	$ 329,527	$ —	$ —
Subtotal	329,527	—	—	329,527	329,527	—	—
Level 2:							
Commercial paper	17,483	3	—	17,486	—	17,486	—
Corporate bonds	30,588	1	(22)	30,567	—	18,209	12,358
U.S. government agency securities	11,567	—	(6)	11,561	—	2,508	9,053
Subtotal	59,638	4	(28)	59,614	—	38,203	21,411
Total	$ 389,165	$ 4	$ (28)	$ 389,141	$ 329,527	$ 38,203	$ 21,411

	December 31, 2020						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities [1]	Long-term Marketable Securities [2]
Level 1:							
Cash and cash equivalents	$ 268,269	$ —	$ —	$ 268,269	$ 268,269	$ —	$ —
Subtotal	268,269	—	—	268,269	268,269	—	—
Level 2:							
Certificates of deposit	2,986	7	—	2,993	—	2,993	—
Subtotal	2,986	7	—	2,993	—	2,993	—
Total	$ 271,255	$ 7	$ —	$ 271,262	$ 268,269	$ 2,993	$ —

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

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

5. Balance Sheet Components

Property and Equipment, Net

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

	June 30, 2021	December 31, 2020
	(Unaudited)	
Construction in progress	$ 36,180	$ 23,031
Leasehold improvements	5,725	4,631
Furniture and fixtures	891	870
Computer equipment and software	82	82
Laboratory equipment	5,376	4,630
Total property and equipment	48,254	33,244
Accumulated depreciation and amortization	(3,282)	(2,368)
Property and equipment, net	$ 44,972	$ 30,876

Depreciation expense was $475 thousand and $914 thousand for the three and six months ended June 30, 2021 and $394 thousand and $729 thousand three and six months ended June 30, 2020, respectively.

Accrued Expenses and Other Current Liabilities

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

	June 30, 2021	December 31, 2020
	(Unaudited)	
Accrued preclinical and clinical expenses	$ 2,970	$ 1,735
Accrued professional fees	2,119	642
Accrued payroll and benefits	1,273	1,486
Accrued taxes	22	40
Accrued construction in progress	9,170	1,049
Accrued financing costs	36	131
Other current liabilities	330	26
Total	$ 15,920	$ 5,109

6. Commitments and Contingencies

Significant Contracts and Agreements

Lease Agreements

On May 26, 2016, the Company signed an operating lease for laboratory and office space that commenced in June 2016 and expired on October 31, 2017 (the “2016 Lease”). The 2016 Lease has been amended several times to increase the area leased, which currently consists of approximately 41,000 square feet. As a result of the lease amendments, the lease expiration date was extended to October 31, 2031.

On December 26, 2019, we entered into a lease agreement for our second commercial gene therapy facility ("ASTRA") in the Pittsburgh, Pennsylvania area ("ASTRA lease") with Northfield I, LLC (the "Landlord" or "Northfield") with an initial lease term that expired on October 31, 2035. The ASTRA lease contained an option ("Purchase Option") to purchase the building, related improvements and take corresponding assignment of the Landlord's rights under its existing Ground Lease (the

"Ground Lease"). A cash contribution in the amount of $2.4 million was paid to escrow on January 21, 2020. The contribution was intended to reduce the amount of the building construction costs and had the effect of reducing the base rental rate of the lease and as such, was recorded as prepaid rent in the consolidated balance sheet at the time of payment.

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

On January 29, 2021, the Company entered into a Purchase and Sale Agreement ("PSA") for ASTRA with Northfield related to the purchase option exercised by the Company on October 15, 2020, for a purchase price of $9.4 million. The Company held approximately $1.5 million on deposit with Northfield under the existing lease agreement and applied this deposit as a credit against the purchase price at closing. On February 1, 2021, Northfield delivered the space as substantially complete and made the space available for access by the Company, thus triggering lease commencement. As a result, the Company concluded that this transaction did not qualify for sale-leaseback accounting because it did not meet the definition of a sale. As control did not transfer to the Lessor at lease commencement, the transaction continued to be accounted for as construction in progress and a financing obligation. On March 5, 2021, the purchase closed and the Company determined that reclassification of the construction in progress to buildings and leasehold improvements was not appropriate as the interior of the building was not yet ready for its intended use. The building continues to be held under construction in progress as of June 30, 2021. The interior of the building is currently under construction and is expected to be completed and validated in 2022. From construction completion to the closing of the purchase, the Company recognized interest expense to accrete the financial obligation to a balance that equaled the cash consideration that was paid upon the close of purchase. For more information about the expected construction costs associated with ASTRA, see "ASTRA Contractual Obligation" below.

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

As of June 30, 2021, future minimum commitments under the Company’s operating leases were as follows (in thousands):

	Operating Leases
2021 (remaining six months)	$ 457
2022	1,048
2023	1,067
2024	1,087
2025	1,113
Thereafter	12,480
Future minimum operating lease payments	$ 17,252
Less: Interest	9,421
Present value of lease liability	$ 7,831

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

	(unaudited) June 30, 2021		December 31, 2020	
Operating leases:				
Right-of-use assets	$ 7,136		$ 3,298	
Current portion of lease liability	934		638	
Lease liability	6,897		3,308	
Total lease liability	$ 7,831		$ 3,946	
Weighted average remaining lease term, in years		15.0		16.4
Weighted average discount rate	9.3	%	9.4	%

The Company recorded operating lease costs of $278 thousand and $497 thousand for the three and six months ended June 30, 2021 and $145 thousand and $310 thousand for the three and six months ended June 30, 2020, respectively, and variable lease costs of $81 thousand and $118 thousand for the three and six months ended June 30, 2021 and $15 thousand and $28 thousand for the three and six months ended June 30, 2020, respectively.

Agreements with Contract Manufacturing Organizations and Contract Research Organizations

The Company has entered into various agreements with Contract Manufacturing Organizations (“CMOs”) for the manufacture of sterile excipients that are formulated with in-house produced vectors as part of the final drug product applied in certain of our clinical trials. The Company has also entered into agreements with third-party Contract Research Organizations ("CROs") to provide research and development services to further the Company’s analysis of its product candidates. The agreements entered into with the CMOs and CROs provide the terms and conditions for their respective services, which may include research and development activities, storage, packaging, labelling, and/or testing of our preclinical and clinical-stage products. The Company is obligated to make milestone payments under certain of these agreements. The estimated remaining commitment as of June 30, 2021 under these agreements is approximately $3.8 million. The Company may also be responsible for the payment of a monthly service fee for project management services for the duration of any agreements. The Company has incurred expenses under these agreements of $718 thousand and $2.5 million for the three and six months ended June 30, 2021 and $330 thousand and $964 thousand for the three and six months ended June 30, 2020, respectively.

Other Contractual Obligations

The Company has contracted with various third parties to facilitate, coordinate and perform agreed upon market research activities relating to our lead product candidate, B-VEC. These contracts typically call for the payment of fees for services upon the achievement of certain milestones. Business activities being performed under these contracts primarily include market research and other related activities. The estimated remaining commitment as of June 30, 2021 is $4.0 million. The Company has incurred expenses under these activities of $974 thousand and $2.3 million for the three and six months ended June 30, 2021 and $489 thousand for the three and six months ended June 30, 2020, respectively.

ASTRA Contractual Obligations

The Company has contracted with various third parties to construct our second cGMP facility, ASTRA. Additionally, we have entered into various non-cancellable purchase agreements for long-lead materials to help avoid potential schedule disruptions or material shortages. These contracts typically call for the payment of fees for services or materials upon the achievement of certain milestones. The estimated remaining commitment as of June 30, 2021 is $38.0 million. The Company has included costs incurred to-date associated with ASTRA within construction in progress as of June 30, 2021.

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

Legal Proceedings

On May 1, 2020, a complaint was filed against us in the United States District Court for the Western District of Pennsylvania by PeriphaGen, Inc., which also named our Chief Executive Officer and Chief Operating Officer, Krish Krishnan and Suma Krishnan, respectively. The complaint alleges breach of contract and misappropriation of trade secrets, which secrets the plaintiff asserts were used to develop our product candidates, including the vector backbones, and our STAR-D platform. We answered the complaint on June 26, 2020 by denying the allegations and brought a counterclaim asking the court to declare that we did not misappropriate PeriphaGen's trade secrets or confidential information, and to further declare that we are the rightful and sole owner of our product candidates and STAR-D platform. In addition, we filed a third-party complaint against two principals of PeriphaGen, James Wechuck and David Krisky, alleging breach of contract and seeking contribution and indemnification from them in the event PeriphaGen is awarded damages. On July 29, 2020, PeriphaGen filed its response to our answer and counterclaim, denying the allegations in the counterclaim. On the same day, Messrs Wechuck and Krisky filed a motion to dismiss the third-party complaint on various grounds, and we opposed the motion. On December 1, 2020, the court ruled on Messrs. Wechuck and Krisky's motion to dismiss our third-party complaint. The court determined that our claims for contribution and indemnification based on PeriphaGen's state law claims for unfair competition and misappropriation of trade secrets can proceed. Our breach of contract claim will also go forward in full. Fact discovery is ongoing.

While we are unable to provide any assurances as to the ultimate outcome of the case, we believe the allegations in the complaint are without merit, and we intend to vigorously defend against them. We are currently unable to estimate the costs and timing of any litigation, including any potential damages if PeriphaGen were to prevail on its claims.

7. Capitalization

Sale of Common Stock

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

On December 31, 2020, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") with respect to an at-the-market equity offering program ("ATM Program"), under which Cowen will act as the Company's agent and/or principal and may issue and sell from time to time, during the term of the Sales Agreement, shares of our common stock, par value $0.0001 per share, having an aggregate offering price up to $150.0 million ("Placement Shares"). Related offering expenses payable by the Company were $172 thousand. The issuance and sale of the Placement Shares by the Company under the Sales Agreement will be made pursuant to the Company's effective "shelf" registration statement on Form S-3. During the six months ended June 30, 2021, 262,500 shares of common stock were issued pursuant to the ATM Program at a weighted average price of $66.50 per share for net proceeds of $17.5 million, resulting in a remaining $132.5 million available for issuance under the ATM Program.

On May 21, 2020, the Company completed a public offering of 2,275,000 shares of its common stock to the public at $55.00 per share. Net proceeds to the Company from the offering were $117.2 million after deducting underwriting discounts and commissions of approximately $7.5 million, and other offering expenses payable by the Company of approximately $463 thousand.

8. Stock-Based Compensation

Stock Options

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

The Company granted 297,500 and 799,950 stock options to employees and directors of the Company during the three and six months ended June 30, 2021, respectively, and 315,400 and 544,400 stock options to employees and directors of the Company during the three and six months ended June 30, 2020, respectively.

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

	Stock Options Outstanding	Weighted-average Exercise Price	Weighted-average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands) [1]
Outstanding at December 31, 2020	853,614	$ 40.31	9.0	$ 16,804
Granted	799,950	$ 73.42		
Exercised	(16,874)	$ 21.41		
Cancelled or forfeited	(46,525)	$ 53.79		
Outstanding at June 30, 2021	1,590,165	$ 56.77	9.0	$ 22,838
Exercisable at June 30, 2021	253,189	$ 29.73	6.9	$ 9,690

(1) Aggregate intrinsic value represents the difference between the closing stock price of our common stock on June 30, 2021 and the exercise price of outstanding in-the-money options.

The total intrinsic value (the amount by which the fair market value exceed the exercise price) of stock options exercised during the three and six months ended June 30, 2021 was $808 thousand and $872 thousand, respectively, and during the three and six months ended June 30, 2020 was $656 thousand and $1.2 million, respectively.

The weighted-average grant-date fair value per share of options granted to employees during the three and six months ended June 30, 2021 was $42.53 and $47.25, respectively, and during the three and six months ended June 30, 2020 was $29.78 and $31.71, respectively.

There was $49.0 million of unrecognized stock-based compensation expense related to employees' option awards that is expected to be recognized over a weighted-average period of 3.4 years as of June 30, 2021.

The Company has recorded aggregate stock-based compensation expense related to the issuance of stock option awards in the condensed consolidated statements of operations for the three and six months ended June 30, 2021 and 2020 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Research and development	$ 1,084	$ 181	$ 1,600	$ 370
General and administrative	2,625	626	4,240	976
Total stock-based compensation	$ 3,709	$ 807	$ 5,840	$ 1,346

We capitalize the portion of stock-based compensation that relates to work performed on the construction of new buildings. There was $66 thousand and $103 thousand of stock-based compensation that was capitalized in the three and six months ended June 30, 2021, respectively, and zero of stock-based compensation that was capitalized in the three and six months ended June 30, 2020, respectively.

The Company recorded stock-based compensation expense of $3.7 million and $5.8 million for the three and six months ended June 30, 2021, respectively, and $807 thousand and $1.3 million for the three and six months ended June 30, 2020, respectively. The fair value of options was estimated at the date of grant using the Black-Scholes valuation model with the following weighted-average assumptions for the three and six months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Expected stock price volatility	72 %	76 %	72 %	75 %
Expected term of the award (years)	6.10	6.18	6.18	6.20
Risk-free interest rate	1.05 %	0.41 %	1.02 %	0.78 %
Weighted average exercise price	$ 66.58	$ 45.07	$ 73.42	$ 48.09
Forfeiture rate	— %	6.42 %	— %	6.42 %

Restricted Stock Awards

Restricted stock awards ("RSAs") granted to employees vest ratably over a four-year period. Restricted stock awards have a life of ten years.

The Company granted zero and 98,800 RSAs to employees of the Company during the three and six months ended June 30, 2021, respectively, and zero RSAs to employees of the Company during the three and six months ended June 30, 2020, respectively.

The following table summarizes the Company's RSA activity:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested RSAs as of December 31, 2020	—	$ —
Granted	98,800	$ 78.89
Vested	—	$ —
Forfeited	—	$ —
Non-vested RSAs as of June 30, 2021	98,800	$ 78.89

As of June 30, 2021, 98,800 RSAs were outstanding. The fair value of each restricted stock was $78.89 reflecting the closing price of our common stock on the grant date. The Company recorded stock-based compensation expense related to RSAs of $486 thousand and $668 thousand for the three and six months ended June 30, 2021 and zero for the three and six months ended June 30, 2020, respectively, within general and administrative expenses in the accompanying condensed consolidated statements of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
General and administrative	$ 486	$ —	$ 668	$ —
Total stock-based compensation	$ 486	$ —	$ 668	$ —

Shares remaining available for grant under the Company's stock incentive plan were 1,626,006, with a sublimit for incentive stock options of 379,566, at June 30, 2021.

9. Related Party Transactions

In December 2019, the Company advanced $420 thousand to a member of our management team to cover the personal payroll and income taxes on their taxable income from NSO exercises. This employee repaid the Company in full in January 2020.

10. Subsequent Events

The Company evaluates events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements, to identify matters that require disclosure. The Company concluded that no subsequent events have occurred that would require recognition or disclosure in the condensed consolidated financial statements.

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

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed consolidated financial statements and related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the SEC, on March 1, 2021.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- changes in expectations with respect to the initiation, timing, progress and results of preclinical and clinical trials for B-VEC, KB105, KB104, KB407, KB408, KB301 and any other product candidates, including the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs and expenses;
- the continuing impact that the COVID-19 pandemic and measures implemented to prevent its spread may have on our business operations, access to capital, research and development activities, and preclinical and clinical trials for our product candidates;
- the timing, scope or results of regulatory filings and approvals, including timing of final US Food and Drug Administration ("FDA"), marketing and other regulatory approval of our product candidates;
- our ability to achieve certain accelerated or orphan drug designations from the FDA;
- changes in our estimates regarding the potential market opportunity for B-VEC, KB105, KB104, KB407, KB408, KB301 and any other product candidates;
- our ability to raise capital to fund our operations;
- increased costs associated with our research and development programs for our product candidates;
- our general and administrative expenses;
- risks related to our ability to successfully develop and commercialize our product candidates, including B-VEC, KB105, KB104, KB407, KB408, KB301 and our other product candidates;
- our ability to identify and develop new product candidates;
- our ability to identify, recruit and retain key personnel;
- risks related to our commercialization, marketing and manufacturing capabilities and strategy;
- our ability of our business model, strategic plans for our business, product candidates and technology;
- the scalability and commercial viability of our proprietary manufacturing methods and processes;
- the rate and degree of market acceptance and clinical utility of our product candidates and gene therapy, in general;
- our competitive position;
- our intellectual property position and our ability to protect and enforce our intellectual property;
- our financial performance;
- developments and projections relating to our competitors and our industry;
- our ability to establish and maintain collaborations or obtain additional funding;
- our estimates regarding expenses, future revenue, capital requirements and needs for or ability to obtain additional financing;

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

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

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

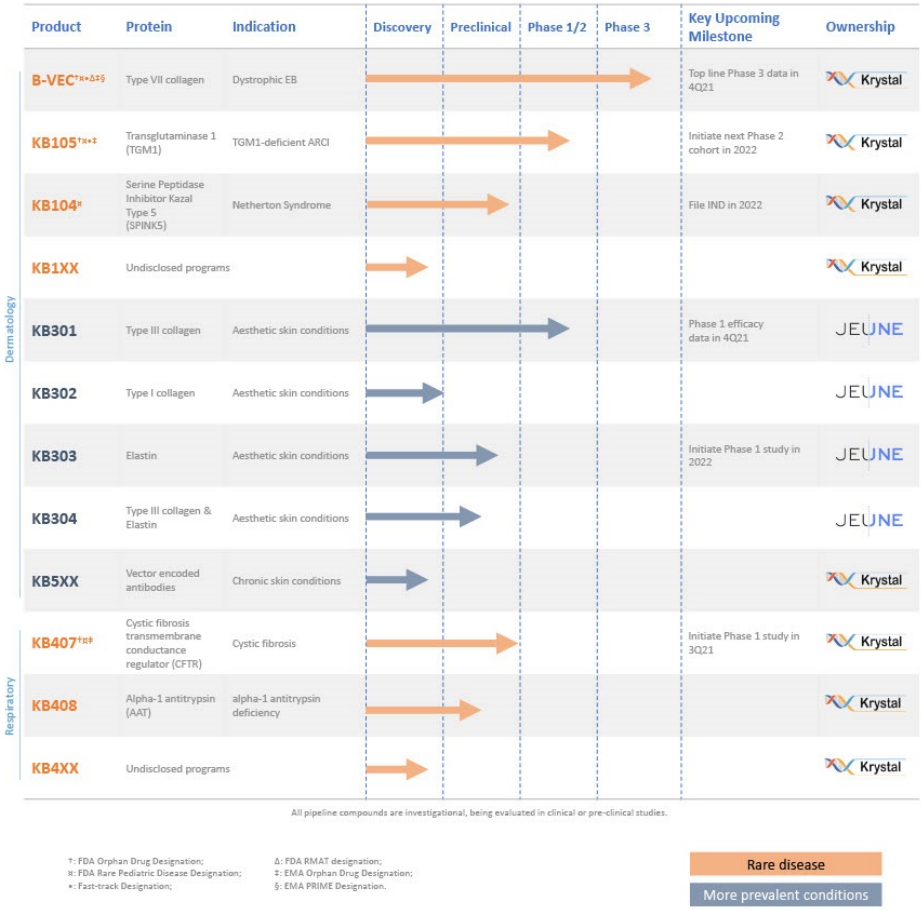
Throughout this Form 10-Q, unless the context requires otherwise, all references to “Krystal,” “the Company,” we,” “our,” “us” or similar terms refer to Krystal Biotech, Inc., together with its consolidated subsidiaries.

Overview

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

Our Product Candidates

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



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

Pipeline Highlights and Recent Developments

- B-VEC is a topical gel containing our novel vector designed to deliver two copies of the COL7A1 transgene for the treatment of dystrophic epidermolysis bullosa ("DEB"), a serious rare skin disease caused by missing or mutated type VII collagen protein ("COL7"). The randomized, double-blind, placebo-controlled GEM-3 pivotal study is ongoing. On March 30, 2021, we announced completion of patient enrollment, and we expect to announce top line data in 4Q21. Details of the pivotal study can be found at www.clinicaltrails.gov under NCT identifier NCT04491604. During 2Q21, we began enrolling patients into an open label extension ("OLE") study, including patients who participated in the Phase 3 study, as well as new participants who meet all enrollment criteria. Details of the OLE study can be found at www.clinicaltrails.gov under NCT identifier NCT04917874. Nothing included on this website shall be deemed incorporated by reference into this Quarterly Report on Form 10-Q.
- KB105 is a topical gel containing our novel vector designed to deliver two copies of the TGM1 transgene for the treatment of TGM1-deficient autosomal recessive congenital ichthyosis ("TGM1-ARCI"), a serious rare skin disorder caused by missing or mutated TGM1 protein. A randomized, placebo-controlled Phase 1/2 study is ongoing. On July 1, 2021, we announced data from the fourth patient dosed in the trial, showing repeat topical KB105 dosing continued to be well tolerated with no adverse events or evidence of immune response. Details of the Phase 1/2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732. Nothing included on this website shall be deemed incorporated by reference into this Quarterly Report on Form 10-Q.
- KB407 is an inhaled (nebulized) formulation of our novel vector designed to deliver two copies of the full-length CFTR transgene for the treatment of cystic fibrosis, a serious rare lung disease caused by missing or mutated cystic fibrosis transmembrane conductance regulator ("CFTR") protein. On April 19, 2021, we announced positive preclinical data from the Good Laboratory Practice toxicology and biodistribution study, in which the No-Observed-Adverse-Effect Level was determined to be the highest dose tested. More detailed data will be presented at the 2021 North American Cystic Fibrosis Conference that will take place September 30 through October 2, 2021. We expect to initiate clinical testing in 3Q21.
- KB408 is an inhaled (nebulized) formulation of our novel vector designed to deliver two copies of the SERPINA1 transgene, that encodes for normal human alpha-1 antitrypsin protein, for the treatment of alpha-1 antitrypsin deficiency. On April 19, 2021, we announced positive initial proof-of-concept preclinical in vitro and in vivo data. More detailed preclinical data will be presented at a future scientific conference.
- KB104 is a topical gel formulation of our novel vector designed to deliver two copies of the SPINK5 transgene for the treatment of Netherton Syndrome, a debilitating autosomal recessive skin disorder caused by missing or mutated SPINK5 protein. We expect to initiate a Phase 1 clinical study in 2022.

We are also leveraging the ability of our platform to deliver proteins of interest to cells in the skin in the context of aesthetic medicine via our wholly owned subsidiary Jeune. A summary description of Jeune's key product candidate and its status is as follows:

- KB301 is a solution formulation of our novel vector for intradermal injection designed to deliver two copies of the COL3A1 transgene to address signs of aging or damaged skin caused by declining levels of, or damaged proteins within the extracellular matrix, including type III collagen. A Phase 1 study is currently ongoing. On March 24, 2021, we announced initial data from Cohort 1 on the Phase 1 study that showed safety and tolerability of the two (2) repeat KB301 injections in human subjects. On August 2, 2021, Jeune announced the dosing of the first patient in the efficacy cohort of the PEARL-1 study. The efficacy cohort is a randomized, double-blind, saline controlled evaluation of safety and efficacy of KB301 for the improvement of skin quality in approximately 30 subjects. Bilateral treatment areas on the neck behind the ear, on the cheek, and above the knee will be chosen and randomized on Day 0. Patients will receive two repeat doses of low dose KB301, high dose KB301, or saline 14 days apart. Change in skin quality from baseline will be assessed via the Skin Roughness Score, Fine Lines Score, and the Subject Satisfaction Score. Treatment areas above the knee will be evaluated for change in thickness using a caliper. Jeune expects to announce initial data from Cohort 2 in 4Q21. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900. Nothing included on these websites shall be deemed incorporated by reference into this Quarterly Report on Form 10-Q

Jeune has several other aesthetic medicine product candidates in various stages of preclinical development.

Business Highlights and Recent Developments

- On May 3, 2021, the Company announced the appointment of Andy Orth to the position of Chief Commercial Officer of Krystal Biotech.

- In 2Q21, the Company began enrolling patients into an OLE study, including patients who participated in the Phase 3 study, as well as new participants who meet all enrollment criteria.
- On June 30, 2021, the Company entered into a Standard Form of Contract for Construction and the corresponding General Conditions of the Contract for Construction with Whiting-Turner, pursuant to which Whiting-Turner is constructing and managing the construction of ASTRA located in the Pittsburgh, Pennsylvania area. The 150,000 square foot ASTRA facility is under construction and expected to be completed and validated in 2022. The Agreement contains certain customary terms and conditions of the parties addressing the Project responsibilities. Subject to certain conditions in the Agreement, the Company will pay Whiting-Turner a contract price consisting of the cost of work plus a fee equal to 1.75% of the cost of work, subject to a guaranteed maximum price to be agreed upon in an amendment to the Agreement at a later date.

COVID-19 Update

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

Financial Overview

Revenue

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

Research and Development Expenses

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

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

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

We expect our research and development expenses will increase as we continue the manufacturing of preclinical and clinical materials and manage the clinical trials of, and seek regulatory approval for, our product candidates and expand our product portfolio. In the near term, we expect that our research and development expenses will increase as we continue with our

pivotal Phase 3 clinical trial for B-VEC, conduct our ongoing Phase 1/2 clinical trial for KB105, conduct our phase 1 safety study for KB301 and incur preclinical expenses for our other product candidates. Due to the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration, costs and timing of our clinical trials, and, as a result, the actual costs to complete our clinical trials may exceed the expected costs.

General and Administrative Expenses

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

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

ASTRA Capital Expenditures

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

Interest Income

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

Interest Expense

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

Critical Accounting Policies, Significant Judgments and Estimates

There have been no significant changes during the three and six months ended June 30, 2021 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, 2020.

Results of Operations

Three Months Ended June 30, 2021 and 2020

	Three Months Ended June 30,		
	2021	2020	Change
(In thousands)	(unaudited)		
Expenses			
Research and development	$ 6,594	$ 3,639	$ 2,955
General and administrative	9,799	3,315	6,484
Total operating expenses	16,393	6,954	9,439
Loss from operations	(16,393)	(6,954)	(9,439)
Other Income			
Interest and other income, net	30	121	(91)
Net loss	$ (16,363)	$ (6,833)	$ (9,530)

Research and Development Expenses

Research and development expenses increased $3.0 million in the three months ended June 30, 2021 compared to the three months ended June 30, 2020. Higher research and development expenses were due to an increase in outsourced research and development activities of approximately $951 thousand, lab supplies of $340 thousand, payroll related expenses of $1.2 million, which is primarily driven by an increase in headcount to support overall growth, and includes a $903 thousand increase in stock-based compensation, and other research and development expenses of $464 thousand, primarily due to depreciation, rent, and other overhead expenses.

General and Administrative Expenses

General and administrative expenses increased $6.5 million in the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. Higher general and administrative spending was due largely to increases in payroll related expenses of approximately $3.4 million, which is primarily driven by an increase in headcount to support overall growth, and includes a $2.5 million increase in stock-based compensation, market research related expenses of approximately $318 thousand, legal and professional fees of approximately $1.6 million and other administrative and professional expenses of $1.1 million.

Other Income

Interest and other income for the three months ended June 30, 2021 and 2020 was $30 thousand and $121 thousand, respectively, and consisted of interest and dividend income earned from our cash, cash equivalents and investments.

Six Months Ended June 30, 2021 and 2020

(In thousands)	Six Months Ended June 30, 2021	2020	Change
	(unaudited)		
Expenses			
Research and development	$ 12,795	$ 7,164	$ 5,631
General and administrative	17,951	5,735	12,216
Total operating expenses	30,746	12,899	17,847
Loss from operations	(30,746)	(12,899)	(17,847)
Other Income (Expense)			
Interest and other income, net	64	725	(661)
Interest expense	(1,492)	—	(1,492)
Net loss	$ (32,174)	$ (12,174)	$ (20,000)

Research and Development Expenses

Research and development expenses increased $5.6 million in the six months ended June 30, 2021 compared to the six months ended June 30, 2020. Higher research and development expenses were due to an increase in outsourced research and development activities of approximately $2.3 million, lab supplies of $918 thousand, payroll related expenses of $1.6 million, which is primarily driven by an increase in headcount to support overall growth, and includes a $1.2 million increase in stock-based compensation, and other research and development expenses of $817 thousand, primarily due to depreciation, rent, and other overhead expenses.

General and Administrative Expenses

General and administrative expenses increased $12.2 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020. Higher general and administrative spending was due largely to increases in payroll related expenses of approximately $5.8 million, which is primarily driven by an increase in headcount to support overall growth, and includes a $3.9 million increase in stock-based compensation, market research related expenses of approximately $1.3 million, legal and professional fees of approximately $3.5 million and other administrative expenses of $1.6 million.

Other Income (Expense)

Interest and other income for the six months ended June 30, 2021 and 2020 was $64 thousand and $725 thousand, respectively, and consisted of interest and dividend income earned from our cash, cash equivalents and investments.

Interest expense for the six months ended June 30, 2021 and 2020 was $1.5 million and zero, respectively, and related to accretion of the financial obligation for the build to suit lease liability during the six months ended June 30, 2021 to a balance that equaled the purchase consideration for ASTRA.

Liquidity and Capital Resources

Overview

At June 30, 2021, our cash, cash equivalents and short-term investments balance was approximately $367.7 million. Since operations began, we have incurred operating losses. Our net losses were $16.4 million and $6.8 million for the three months ended June 30, 2021 and 2020 and $32.2 million and $12.2 million for the six months ended June 30, 2021 and 2020, respectively. At June 30, 2021, we had an accumulated deficit of $103.4 million. With the net proceeds raised from its public and private securities offerings, including the public offering completed on February 1, 2021 and the ATM Program, the Company believes that its cash, cash equivalents and short-term investments as of June 30, 2021 will be sufficient to allow the Company to fund its operations for at least 12 months from the filing date of this Form 10-Q.

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

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

Operating Capital Requirements

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

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

- the timeline and cost of our pivotal Phase 3 clinical trials for B-VEC;
- the progress, timing, results and costs of our ongoing Phase 1/2 clinical trials for KB105;
- the progress, results and costs of our Phase 1 clinical trials for KB301;
- the progress, timing and costs of manufacturing of B-VEC for our pivotal Phase 3 clinical trials;
- the continued development and the filing on an IND application for future product candidates;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for any other product candidates that we may pursue in the future, if any;
- the costs of maintaining our own commercial-scale cGMP manufacturing facilities;
- the outcome, timing and costs of seeking regulatory approvals;

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

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

Sources and Uses of Cash

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

	Six Months Ended June 30,	
	2021	**2020**
	(unaudited)	
Net cash used in operating activities	$ (19,783)	$ (11,281)
Net cash used in investing activities	(63,064)	(2,267)
Net cash provided by financing activities	144,105	117,712
Net increase in cash	$ 61,258	$ 104,164

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2021 was $19.8 million and consisted primarily of a net loss of $32.2 million adjusted for non-cash items primarily of depreciation and amortization and stock-based compensation expense of $7.7 million and build to suit interest expense of $1.5 million, as well as cash used by increases in net operating assets of approximately $3.2 million.

Net cash used in operating activities for the six months ended June 30, 2020 was $11.3 million and consisted primarily of a net loss of $12.2 million adjusted for non-cash items of depreciation and amortization and stock-based compensation expense of approximately $2.2 million, and cash provided by decreases in net operating liabilities of approximately $1.3 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2021 was $63.1 million and consisted primarily of expenditures of $6.5 million on the build-out of our ASTRA facility, leasehold improvement of new office space, and purchases of computer and laboratory equipment, $59.6 million on the purchase of short-term and long-term investments, partially offset by proceeds of $3.0 million received from the maturities of short-term investments.

Net cash used in investing activities for the six months ended June 30, 2020 was $2.3 million and consisted primarily of purchases of $3.2 million of short-term available-for-sale investment securities, and expenditures of $3.5 million on the build-out of our ASTRA facility, leasehold improvement of new office space, and purchases of computer and laboratory equipment, partially offset by proceeds of $4.4 million received from the maturities of short-term investments.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2021 was $144.1 million and consisted primarily of proceeds of $152.1 million received from our public offering, ATM Program and exercises of stock options, partially offset by expenditures of $8.0 million used for the purchase of the ASTRA building.

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

During the six months ended June 30, 2021, pursuant to the ATM Program the Company issued 262,500 shares of common stock at a weighted average price of $66.50 per share for net proceeds of $16.9 million after deducting underwriting discounts and commissions of approximately $524 thousand. The Company also incurred $172 thousand of other offering expenses related to the ATM Program.

For the six months ended June 30, 2021, the Company received proceeds of $354 thousand from the exercise of stock options.

Net cash provided by financing activities for the six months ended June 30, 2020 was $117.7 million and was primarily from proceeds from our public offering in May 2020 of 2,275,000 shares of our common stock to the public at $55.00 per share. Net proceeds to the Company from the offering were $117.2 million after deducting underwriting discounts and commissions of approximately $7.5 million and other offering expenses of approximately $463 thousand, of which $132 thousand was unpaid as of June 30, 2020.

Off-Balance Sheet Arrangements

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

Contractual Obligations

There have been no material changes to our contractual obligations as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020 other than as described in Note 6 “Commitments and Contingencies” of our condensed consolidated financial statements on this Form 10-Q.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (“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. Beginning with our fiscal year ending December 31, 2022, we will cease to be an emerging growth company.

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 $367.7 million at June 30, 2021, which consist primarily of money market, bank deposits, commercial paper, corporate bonds, and government agency securities. The investments in these financial instruments are made in accordance with an investment policy which specifies the categories, allocations and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments in which we invest could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and short and long-term investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations or our financial position would be materially affected by an immediate change of 10% in interest rates.

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

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

Other than as discussed above, no change in our internal control over financial reporting occurred during the quarter ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information set forth under the heading “Legal Proceedings” in Note 6 of the Notes to Condensed Consolidated Financial Statements included in Item 1 of Part I of this Form 10-Q is incorporated by reference in response to this item.

Item 1A. Risk Factors.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred net losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred recurring losses and negative cash flows from operations and, at June 30, 2021, we had an accumulated deficit of $103.4 million. Our ability to achieve profitability depends on our ability to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our products candidates. We do not anticipate generating revenues from product sales for the next year, if ever. We have devoted substantially all our efforts to date to research and development of our gene therapy product candidates as well as to building out our infrastructure. We expect that it could be at least a year, if ever, before we have a commercialized product candidate. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we:

- continue our research and the clinical development of B-VEC, KB105, and KB301 including our current clinical trials and planned future trials;
- initiate clinical trials for KB104, KB407, KB408 and preclinical studies for any additional product candidates that we may pursue in the future;
- prepare our Biologics License Application ("BLA"), Marketing Authorisation Application and approvals in certain other countries for B-VEC;
- continue to operate our in-house commercial-scale cGMP manufacturing facility, ANCORIS, and complete the build out of our second cGMP manufacturing facility, ASTRA;
- manufacture material for clinical trials or potential commercial sales;
- further develop our gene therapy product candidate portfolio;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies; and
- seek marketing approval for B-VEC and additional product candidates in the European Union (“EU”) and in other key geographies.

To become and remain profitable, we must develop and eventually commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing the clinical trials for our product candidates, developing and validating commercial scale manufacturing processes, obtaining marketing approval for our product candidates, manufacturing, marketing and selling any product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. If we were required to discontinue development of any of our product candidates, if any of our product candidates do not receive regulatory approval, if we do not obtain our targeted indications for our product candidates or if any of our product candidates fails to achieve sufficient market acceptance for any indication, we could be delayed by many years in our ability to achieve profitability, if ever, and this would materially adversely affect our business prospects and financial condition. Moreover, if we decide to leverage any success with our B-VEC, KB105, KB301, KB104 or KB407 product candidates to develop other product opportunities, we may not be successful in such efforts, and our business could be materially adversely affected.

We currently have three product candidates, B-VEC, KB105, and KB301 in clinical trials and we may never develop, acquire or in-license additional product candidates. We may never succeed in any or all these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause investors to lose all or part of their investment.

Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, the European Medicines Agency ("EMA"), or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of B-VEC, KB105, and KB301 our expenses could increase and revenue could be further delayed.

We may need to raise additional funding in order to receive approval for our other product candidate. Such funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations.

To complete the process of obtaining regulatory approval for our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we may require substantial additional funding. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. We anticipate that we may need additional funding to complete the development of B-VEC, KB105, KB301 and any future product candidates and to commercialize any such approved products.

Our future capital requirements will depend on many factors, including:

- the progress, timing, results and costs of our Phase 3 clinical trials for B-VEC;
- the progress, timing, results and costs of our Phase 1/2 clinical trials for KB105;
- the progress, timing, results and costs of our Phase 1 clinical trials for KB301;
- the continued development and the filing of IND applications for KB104, KB407, KB408 and other product candidates;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for any other product candidates that we may pursue in the future, if any;
- the costs of building and maintaining our own commercial-scale cGMP manufacturing facilities;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs associated with the manufacturing process development and evaluation of third-party manufacturers, if necessary;
- the extent to which the costs of our product candidates, if approved, will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors;
- the costs of commercialization activities for our current and future product candidates if we receive marketing approval for B-VEC, KB105, KB301 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, if any, revenue received from commercial sale of our current and future product candidates;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements, if any;
- our current license agreements, if any, remaining in effect and our achievement of milestones under those agreements; and

- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. Our product candidates, if approved, may not achieve commercial success. Our product revenues, if any, will be derived from or based on sales of product candidates that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Furthermore, existing stockholders may not agree with our financing plans or the terms of such financings. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of additional financing may be impacted by, among other things, general market conditions, the market's perception of our product candidates and growth potential and the market price per share of our common stock

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a development-stage company that commenced operations in 2016. Our efforts to date, with respect to the development of our product candidates have been limited to organizing and staffing our company, business planning, raising capital, developing our vector platform and related technologies, identifying potential gene therapy product candidates and undertaking preclinical studies and clinical trials of B-VEC, KB105, KB301, KB104, KB407 and KB408. While we have conducted clinical trials of B-VEC, KB105, and KB301, we have not yet demonstrated the ability to complete clinical trials of any of our product candidates, obtain marketing approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success, performance or viability may not be as accurate as they could be if we had more experience developing gene therapy products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

Risks Related to Our Business

Business interruptions resulting from the coronavirus disease 2019 ("COVID-19") outbreak or similar public health crises could cause a disruption of the development efforts for our product candidates and adversely impact our business.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a new strain of coronavirus surfaced in Wuhan, China and has reached multiple other regions and countries, including Pittsburgh, Pennsylvania where our primary office, manufacturing and laboratory facilities are located. The COVID-19 pandemic is evolving, and to date has led to the implementation of various mitigation responses, including government-imposed quarantines, travel restrictions and other public health safety measures, as well as leading to reported adverse impacts on healthcare resources, facilities and providers across the United States and in other countries. The extent to which COVID-19 impacts our operations or those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions to contain COVID-19 or address its impact in the short and long term, among others.

Additionally, timely initiation and completion of planned clinical trials is dependent upon the availability of, for example, clinical trial sites, researchers and investigators, regulatory agency personnel, and materials, which may be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials in geographies that are currently being affected by COVID-19.

In the event that we or governmental authorities were to modify or implement restrictions, our employees conducting research and development or manufacturing activities may not be able to access our laboratory or manufacturing spaces, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

Some factors from the COVID-19 pandemic that could delay or otherwise adversely affect the completion of our preclinical activities and the planned initiation of our clinical trials for our investigational drug product candidates, as well as our business operations generally, include:

- the potential diversion of healthcare resources away from the conduct of preclinical activities and clinical trials to focus on pandemic concerns, including the availability of necessary materials and the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key preclinical and clinical trial activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our research, manufacturing and clinical trial sites or secure visas or entry permissions, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact our ability to conduct preclinical and clinical activities as well as product approval timelines;
- limitations on our business operations by local, state, or the federal government that could impact our ability to conduct our preclinical or clinical activities, including completing our IND-enabling studies or our ability to select future development candidates; and interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product candidates and conditioning drugs and other supplies used in our prospective clinical trials;
- interruption of, or delays in receiving, key materials from our suppliers and vendors due to staffing shortages, travel limitations, production slowdowns or stoppages and disruptions in delivery systems;
- interruption of, or delays in manufacturing our product candidates at our manufacturing facility in Pittsburgh or receiving supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, travel limitations, production slowdowns or stoppages and disruptions in delivery systems; and
- business disruptions caused by potential office, manufacturing and laboratory closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees, manufacturing sites, research sites and other important agencies and contractors.

These and other factors arising from COVID-19 could worsen in countries that are already afflicted with the coronavirus which could further adversely impact our ability to conduct clinical trials and our business generally and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. Further, conditions in the bank lending, capital and other financial markets may continue to deteriorate as a result of the pandemic such that our access to capital and other sources of funding may be constrained.

The COVID-19 pandemic continues to evolve. The extent to which the outbreak may impact our business, preclinical studies and planned clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and other actions to contain the outbreak or address its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and address the disease.

We are a development-stage company. If we are unable to advance our product candidates through clinical trials, obtain regulatory approval and ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We are a development stage company, and B-VEC entered its first clinical trial in May 2018, KB105 entered its first clinical trial in September 2019, and KB301 entered its first trial in August 2020. The development and commercialization of our product candidates are subject to many uncertainties, including the following:

- successful enrollment and completion of clinical trials;
- positive results from our current and planned future clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities;
- successful development of our internal manufacturing processes on an ongoing basis and maintenance of our existing arrangements with third-party manufacturers for clinical supply;
- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others; and
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;

If we fail in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Our lead candidate, B-VEC, is still in clinical development, and there is no guarantee that the results from preclinical studies will be indicative of our ability to complete or the results to be obtained in the current Phase 3 clinical trials.

We announced positive interim results from the Phase 1 portion of our Phase 1/2 clinical trial of B-VEC in October 2018 and positive interim results from the Phase 2 portion in June 2019, and complete Phase 1/2 results in May 2020. We commenced Phase 3 clinical trials for B-VEC in July 2020. There is no guarantee that results of this or any potential future clinical trials will be positive or that we will be able to complete this or any potential future clinical trials on the anticipated timelines, or at all. The positive results we have observed for B-VEC may not be predictive of the ultimate outcome of any future clinical trials, and the current and future clinical trial process may fail to demonstrate that B-VEC is safe for humans and effective for indicated uses, which may cause us to abandon B-VEC. Furthermore, research and discoveries by us or others may identify serious adverse events, undesirable side effects or other unexpected properties of our current and future product candidates, including B-VEC, that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize B-VEC and the approval may be for a narrower indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if B-VEC meets its safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority or policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a post-approval safety monitoring program. Regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of B-VEC. Any of the foregoing scenarios could materially harm the commercial prospects for B-VEC and materially and adversely affect our business, financial condition, results of operations and prospects.

B-VEC is based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

The clinical trial requirements of the FDA, EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in

either the United States or the EU or how long it will take to commercialize our product candidates. Approvals by the European Commission may not be indicative of what the FDA may require for approval, and approval by the FDA may not be indicative of what the European Commission would require for approval.

Regulatory requirements and policy governing gene and cell therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research ("CBER") to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review. If we were to engage a National Institutes of Health funded institution to conduct a clinical trial, that institution's Institutional Biosafety Committee as well as its Institutional Review Board ("IRB"), would need to review the proposed clinical trial to assess the safety of the trial. Similarly, the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of B-VEC or future product candidates or lead to significant post-approval limitations or restrictions. As we advance B-VEC, we may be required to consult with these regulatory and advisory groups and will need to comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of B-VEC. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be materially and adversely affected.

B-VEC may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

There have been several significant adverse side effects in gene therapy trials using other vectors in the past. Gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. The risk of cancer remains a concern for gene therapy, and we cannot assure that it will not occur in any of our planned or future clinical studies. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material.

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur with B-VEC, our clinical trials could be suspended or terminated. If we are unable to demonstrate that such adverse events were caused by the administration process or related procedures, the FDA, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, B-VEC for any or all targeted indications. Even if we can demonstrate that any serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of B-VEC, the commercial prospects may be harmed and our ability to generate product revenues may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

Additionally, if B-VEC receives marketing approval, the FDA could require us to adopt a post-approval safety monitoring program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by B-VEC, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of B-VEC;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way B-VEC is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of B-VEC and could significantly harm our business, financial condition, results of operations and prospects.

We may encounter substantial delays in our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidate for its intended indications. Clinical trials are expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or concerns with a class of drug candidates, or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the drug candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

In addition, if we make manufacturing or formulation changes to a product candidate, we may need to conduct additional studies to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could limit our potential revenue or impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects. Any delays, setbacks or failures in our clinical trials could materially and adversely affect our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our drug candidates, we may:

- be delayed in obtaining marketing approval, if at all, or be required to conduct additional confirmatory safety and/or efficacy studies;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or an IRB, may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our IND applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our drug candidates could be negatively impacted, and our ability to generate revenues from our drug candidates may be delayed.

We have a limited number of employees and limited corporate infrastructure and may experience difficulties in managing growth.

We are a small company with a limited number of employees and corporate infrastructure. We have experienced a period of significant expansion in headcount and expect to experience significant expansion of our facilities, infrastructure and overhead as we develop our own manufacturing facilities and increase our research and development efforts. Future growth will impose significant added capital requirements, as well as added responsibilities on members of management, including the need to identify, recruit, maintain and integrate new personnel. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively.

Even if we obtain regulatory approval for a product candidate, our product candidates will remain subject to regulatory oversight.

Even if we obtain any regulatory approval for B-VEC, our lead product candidate, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for B-VEC may also be subject to a post-approval safety monitoring program, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. Our current and each of our proposed clinical trials for B-VEC includes a five-year, long-term follow-up phase, limited to confirmed data collection from annual visits with standard care physicians. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or a regulatory authority disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of B-VEC or any future product candidate, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize B-VEC or any future product candidates and adversely affect our business, financial condition, results of operations and prospects.

The FDA’s policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of B-VEC or any future product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that

we may have obtained and we may not achieve or sustain profitability, which would materially and adversely affect our business, financial condition, results of operations and prospects.

While we have obtained orphan drug designation for B-VEC, KB105 and KB407, it may not effectively protect us from competition, and we may be unable to obtain orphan drug designation for our future product candidates. If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our product candidates before us, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

On November 2, 2017, the FDA granted orphan drug designation to our lead product candidate, B-VEC, for the treatment of DEB. On April 16, 2018, the European Commission granted the Orphan Medicinal Product Designation for B-VEC. On August 7, 2018, the FDA granted orphan drug designation to our second product candidate, KB105, currently in clinical development for treatment of patients with TGM1 deficient ARCI, and on October 10, 2019, the European Commission granted the Orphan Medicinal Product Designation for KB105. On August 17, 2020, the FDA granted orphan drug designation to our most recent product candidate, KB407, currently in preclinical development, for the treatment of cystic fibrosis. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the European Commission, upon a recommendation from the EMA's Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the EU. Additionally, orphan designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biologic product.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the applicable exclusivity period. The applicable period is seven years in the United States and 10 years in the EU. The exclusivity period in the EU can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even though we have obtained orphan drug exclusivity for B-VEC, KB105 and KB407, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EU, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although like the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply enough quantities of orphan medicinal product.

Breakthrough therapy designation, Regenerative Medicine Advanced Therapy ("RMAT") designation, Fast Track designation or Rare Pediatric Disease designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

The FDA granted Fast Track designation in the United States for B-VEC on May 23, 2018 and for KB105 on October 24, 2019. In addition, B-VEC was granted RMAT by the FDA on June 21, 2019 and Priority Medicine ("PRIME") by the EMA in March 2019. The receipt of any of these designations for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA and EMA procedures and does not assure ultimate approval by either the FDA or EMA.

A RMAT/PRIME therapy product candidate is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease. Drugs designated as RMAT therapies by the FDA are eligible for accelerated approval and increased interaction and communication with the FDA designed to expedite the development and review process. If a drug, or biologic in our case, is intended for the treatment of a serious or life-threatening condition and the biologic demonstrates the potential to address unmet medical needs for this condition, the biologic sponsor may apply for FDA Fast Track designation. Even after having received Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Many biologics that have received Fast Track designation have failed to obtain approval.

A sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. We received the designation of "rare pediatric disease" for B-VEC in December 2016, for KB105 in August 2018, for KB104 in April 2019, and for KB407 in September 2020, which could qualify us to receive a Rare Pediatric Priority Review Voucher.

There is no assurance we will receive RMAT, PRIME or breakthrough therapy or Fast Track designations for any of our product candidates and the receipt of any of these designations for a product candidate may not result in a faster development process, review or approval and does not assure ultimate approval by the FDA. Further, even though we have received rare pediatric disease designation for B-VEC, KB105, KB104 and KB407, we may not experience a faster review or approval for a subsequent marketing application.

We may expend our limited resources to pursue a product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our efforts focuses on the potential approval of B-VEC, KB105, KB301, KB104, KB407 and KB408 a key component our strategy is to discover, develop and potentially commercialize a portfolio of product candidates to treat orphan diseases and ultimately, non-orphan diseases. Identifying new product candidates requires substantial technical, financial and human resources, whether any product candidates are ultimately identified. Even if we identify product candidates that initially show promise, we may fail to successfully develop and commercialize such product candidates for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth will be impaired.

We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our lead product candidate, B-VEC or any future product candidate.

We are aware of several companies and institutions that are currently developing alternative autologous or palliative gene therapy approaches for DEB and cystic fibrosis. Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidate that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render B-VEC or any future product candidate uneconomical or obsolete, and we may not be successful in marketing B-VEC or any future product candidate against competitors.

In the future, even if we commercialize a product candidate faster than our competitors, we could also face competition from lower cost biosimilars in the United States or in Europe.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate that we may develop and commercialize.

Risks Related to Manufacturing

Delays in obtaining regulatory approvals of the process and facilities needed to manufacture our product candidates or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts.

Before we can begin to commercially manufacture our product candidates, whether in a third-party facility or in our own facilities, we must pass a pre-approval inspection of our manufacturing facilities by the FDA before our product candidates can obtain marketing approval. A manufacturing authorization must also be obtained from the appropriate EU regulatory authorities. The timeframe required for us to obtain such approvals is uncertain. To obtain approval, we will need to ensure that all our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any product candidate that we may develop.

In addition, the manufacturing process used to produce our product candidates is complex, novel and has not been validated for commercial use. In order to produce enough quantities of our product candidates for future clinical trials and initial U.S. commercial demand, we will need to increase the scale of our manufacturing process. The production of our product candidates requires processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the process works and that our product candidates are made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

Although we have established our own manufacturing facility for our product candidates, we may need to utilize third parties to conduct our product manufacturing for the near future. Therefore, we are subject to the risk that these third parties may not perform satisfactorily.

Even if we obtain the validation from the FDA of our cGMP manufacturing facility, we intend to maintain third-party manufacturing capabilities in order to provide multiple sources of supply. In the event that these third-party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements or if there are disagreements between us and these third-party manufacturers, we will not be able to complete, or may be delayed in completing, the preclinical studies required to support future IND submissions of product candidates or the clinical trials required for approval of our product candidates. In such instances, we may need to locate an appropriate replacement third-party manufacturer, which may not be readily available or on acceptable terms, which would cause additional delay or increased expense prior to the approval of our product candidates and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or our third-party manufacturer fails to comply with applicable cGMP regulations, the FDA and foreign regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate or suspension or revocation of a pre-existing approval. Such an occurrence may cause our business, financial condition, results of operations and prospects to be materially harmed.

Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce our product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage.

Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of Our Product Candidates

If we are unable to expand our market development capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any product revenue.

We currently have a small market development organization. To successfully commercialize our product candidates, if approved, we plan to expand our capabilities to promote market access and build awareness. To successfully commercialize any products that may result from our development programs, we will need to further expand our market development organization, either on our own or with a third party. The development of our own market development team will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may enter into collaboration agreements regarding any of our product candidates with third parties to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize our products, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded medical affairs, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our potential products. If any of our product candidates is approved but fails to achieve market acceptance among physicians, patients or third-party payors, we will not be able to generate significant revenues from such product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of our gene therapy product candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Gene therapy remains a novel technology. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of genetic diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. For example, earlier gene therapy trials led to several well- publicized adverse events, including cases of leukemia and death seen in trials using other vectors. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

If the market opportunities for our product candidates are smaller than we believe they are, our product revenues may be adversely impacted, and our business may suffer.

We have mainly focused our research and product development efforts to date on B-VEC for DEB. Our understanding of both the number of people who have this disease, as well as the subset of people with this disease who have the potential to benefit from treatment with B-VEC, are based on estimates in published literature. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the EU and elsewhere may turn out to be lower than expected or these patients may not be otherwise amenable to treatment with B-VEC or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

Further, there are several factors that could contribute to making the actual number of patients who receive B-VEC less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets. Further, the severity of the progression of a disease up to the time of treatment will likely diminish the therapeutic benefit conferred by a gene therapy due to irreversible cell damage. Lastly, certain patients' immune systems might prohibit the successful delivery of certain gene therapy products to the target tissue, thereby limiting the treatment outcomes.

The commercial success of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Ethical, social and legal concerns about gene therapy could result in additional regulations restricting or prohibiting our product candidates. Even with the requisite approvals from the FDA in the United States, the EMA in the EU and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance of physicians, patients and health care payors of gene therapy products in general, and our product candidates in particular, as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of gene therapy products and our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety of our product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of our product candidates over alternative treatments, if available;
- the cost of our product candidates relative to alternative treatments, if any are available;
- the clinical indications for which our product candidates are approved by the FDA or the EMA;
- the willingness of physicians to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;

- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of products and their ability to meet market demand;
- publicity concerning our product candidates or competing products and treatments;
- any restrictions on the use of our products together with other medications; and
- favorable third-party payor coverage and adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved, which would adversely affect our revenue and results of operations.

We expect that coverage and reimbursement of pharmaceuticals may be increasingly restricted both in the U.S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. Drug pricing by pharmaceutical companies recently has come under increased scrutiny and continues to be subject to intense political and public debate in the U.S. and abroad. Government and private third-party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the U.S. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. In some international markets, the government controls the pricing, which can affect the profitability of drugs. Current government regulations and possible future legislation regarding health care may affect coverage and reimbursement for medical treatment by third-party payors, which may render our product candidates, if approved, not commercially viable or may adversely affect our anticipated future revenues and gross margins.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs generally could restrict the amount that we are able to charge for our products, which would adversely affect our anticipated revenue and results of operations.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our products, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford our product candidates. Accordingly, sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates 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. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or

are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies. Currently, no gene therapy product has been approved for coverage and reimbursement by the Centers for Medicare & Medicaid Services ("CMS"), the agency responsible for administering the Medicare program. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these types of products. Moreover, reimbursement agencies in the European Union may be more conservative than CMS. For example, several cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European Union Member States. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Outside the United States, international operations generally are subject to extensive government price controls and other market regulations and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries may put pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It also can take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many counties outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Payors increasingly are considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price, and actual acquisition cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional potential legislative and administrative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours.

Ethical, legal and social issues related to genetic testing may reduce demand for our product candidates, if approved.

We anticipate that prior to receiving certain gene therapies, patients may be required to undergo genetic testing. Genetic testing has raised concerns regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic information. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate based on genetic information, resulting in barriers to the acceptance of genetic tests by consumers. Concerns have also been raised about the accuracy of genetic testing. This could lead to governmental authorities restricting genetic testing or calling for additional regulation of genetic testing, particularly for diseases for which there is no known cure. Any of these scenarios could decrease demand for our product candidates, if approved.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval for them outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of B-VEC or other future product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval.

Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product candidates, if approved, is also subject to approval. We intend to submit a marketing authorization application to the EMA for approval of B-VEC in the EU but obtaining such approval from the European Commission following the opinion of the EMA is a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the EU also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects will be adversely affected.

Risks Related to Our Business Operations

We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may be a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize product candidates based on our gene therapy platform. Research programs to identify new product candidates require substantial technical, financial and human resources. Although certain of our product candidates are currently in clinical or preclinical development, we may fail to identify other potential product candidates for clinical development for several reasons. For example, our potential product candidates may be shown to have harmful side effects, may be commercially impracticable to manufacture or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer.

If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of our product candidates that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is likely that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and product candidates requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain enough numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals.

Our future success depends on our ability to retain key employees, including scientific and technical personnel, and to attract, retain and motivate qualified personnel.

We are highly dependent on members of our management team, the loss of whose services may adversely impact the achievement of our objectives. Our employees are at-will employees, and the loss of one or more of them might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, also will be critical to our success. There currently is a shortage of skilled individuals with substantial gene therapy experience, which is likely to continue. As a result, competition for skilled personnel, including in gene therapy research and vector manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

Our employees, principal investigators and advisors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and advisors. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in criminal and civil penalties or sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines, criminal penalties, or other sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our current and future drug candidates.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the U.S., there have been and continue to be a number of legislative efforts to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (“PPACA”), was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care

organizations; (iii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the PPACA, and we expect there will be additional challenges in the future. As a result, there have been delays in the implementation of, and action taken to attempt to repeal or replace, certain aspects of the PPACA. Litigation and legislation over the ACA may continue in the future, with unpredictable and uncertain results.

We cannot predict the impact that such actions against the ACA or other health care reform efforts in the future will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States, or the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for the type of products we intend to commercialize in the United States (or our products more specifically, if approved) could adversely affect our business plan to introduce our products in the United States.

Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the time for Medicare contractors to recoup Medicare overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products and the cost of prescription drugs to consumers and government healthcare programs, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the United States government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint", or plan, to reduce the cost of drugs. The current administration's Blueprint contains certain measures that the US Department of Health and Human Services is already working to implement. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additional changes may affect our business, including those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse enforcement, and expansion of new programs, such as Medicare payment for performance initiatives.

These initiatives, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms could result in reduced demand for our product candidates or additional pricing pressures and may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for our product candidates and begin commercializing in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business as well as other jurisdictions. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The PPACA amended the intent requirement of the federal Anti-Kickback Statute to clarify that a person or entity does not have to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent. The PPACA provides that a claim for items or services resulting from an Anti-Kickback Statute violation is a false claim under the federal False Claims Act. Cases against pharmaceutical manufacturers support the view that certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach;
- Notification Rules under HITECH and the Genetic Information Nondiscrimination Act; Other modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;
- federal transparency laws, including the federal Physician Payment Sunshine Act, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals and (ii) ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Often, to avoid the threat of treble

damages and penalties under the False Claims Act, health care providers will resolve allegations in a settlement without admitting liability to avoid the potential of treble damages. Any such settlement could materially affect our business, financial operations, and reputation.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biologic materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

We also may incur substantial costs to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including conditions that are outside of our control, such as the U.S. presidential election and the impact of health and safety concerns, such as the current coronavirus outbreak. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Cyber-security incidents, including data security breaches or computer viruses, could harm our business by disrupting our delivery of services, damaging our reputation or exposing us to liability.

We receive, process, store, and transmit, often electronically, confidential data of others. Unauthorized access to our computer systems or stored data could result in the theft or improper disclosure of confidential information, the deletion or modification of records, or could cause interruptions in our operations. These cyber-security risks increase when we transmit information from one location to another, including transmissions over the Internet or other electronic networks. Despite implemented security measures, our facilities, systems, and procedures, and those of our third-party service providers, may be vulnerable to security breaches, acts of vandalism, software viruses, misplaced or lost data, programming and/or human errors, or other similar events which may disrupt our delivery of services or expose the confidential information of our customers and others. Any security breach involving the misappropriation, loss or other unauthorized disclosure or use of confidential information of others, whether by us or a third party, could: (i) subject us to civil and criminal penalties; (ii) have a negative impact on our reputation; or (iii) expose us to liability to our customers, third parties or government authorities.

Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations or the operations of manufacturing facilities and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans that we have in place currently are limited and may not prove adequate in the event of a serious disaster or similar event. Substantially all our current supply of our product candidates is located at our manufacturing facility in Pittsburgh, Pennsylvania. We are constructing an additional manufacturing facility and establishing a relationship with a third-party contract manufacturer as a back-up supplier for the commercial supply of our products, if necessary. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain adequate U.S. and foreign patent protection for our product candidates, including B-VEC, KB105, KB301, KB104, KB407, KB408 any future product candidates we may develop, and/or our vector platform, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technologies similar or identical to ours, and our ability to successfully commercialize our current product candidates, any future product candidates we may develop, and our platform technologies may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to B-VEC, KB105, KB301, KB104, KB407, KB408 and additional product candidates in our pipeline, current and future innovations related to our vector platform, and our institutional knowledge. The patent prosecution process is expensive, time-consuming and complex; we may not be able to file, prosecute, maintain, and/or enforce all necessary or desirable patent applications and issued patents at a reasonable cost or in a timely manner. We currently have six issued patents in the United States: (1) U.S. patent No. 9,877,990, covering, in part, pharmaceutical formulations comprising our lead clinical product B-VEC, as well as methods of its use for treating wounds, disorders, and diseases of the skin, which we refer to as the ’990 patent; (2) U.S. patent No. 10,155,016 covering pharmaceutical compositions containing B-VEC formulated for myriad routes of administration; (3) U.S. patent No. 10,441,614 covering aspects of our vector platform technology, and its uses in delivering any gene of interest to the skin; (4) U.S. patent No. 10,525,090, covering pharmaceutical compositions comprising our second clinical product candidate, KB105, and methods of its use for treating TGM1-deficient autosomal recessive

congenital ichthyosis; (5) U.S. Patent No. 10,786,438 covering pharmaceutical compositions comprising vectors encoding cosmetic proteins, including our third product candidate, KB301, and methods for their use for improving skin condition, quality, and/or appearance; and (6) U.S. Patent No. 10,829,529 covering the methods of using KB407 for the treatment of cystic fibrosis and other diseases causing progressive lung destruction. Furthermore, we have international patent applications filed in accordance with the Paris Cooperation treaty directed to multiple discovery, preclinical, and clinical programs, including B-VEC, KB105, KB301, KB104, KB407, and KB-408, as well as multiple patent applications filed in foreign jurisdictions stemming from these international applications. B-VEC is also the subject of multiple patents granted in foreign jurisdictions, including European Patent No. 3 377 637 B1, covering pharmaceutical compositions containing B-VEC as well as uses thereof.

Even if we are granted the patents that we are currently pursuing, they may not issue in a form that will provide us with the full scope of protection we desire, they may not prevent competitors or other third parties from competing with us, and/or they may not otherwise provide us with a competitive advantage. Our competitors, or other third parties, may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, there is no assurance that the ’990 patent, or any other patent we are granted, will prevent third parties from developing competing technologies. Moreover, our patent estate, including the ’990 patent, does not preclude third parties from having intellectual property rights that could interfere with our freedom to use our platform, including for dermatological indications. Even assuming patents issue from our pending and future patent applications, changes in either the patent laws or interpretation of the patent laws in the United States and foreign jurisdictions may diminish the value of our patents or narrow their scope of protection.

We also may not be aware of all third-party intellectual property rights potentially relating to technologies similar to our own. Publications of discoveries in the scientific literature often lag their actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, it is impossible to be certain that we were the first to develop the specific technologies as claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on each and every one of our product candidates, current and future innovations related to our vector platform, and our institutional knowledge in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the United States may differ in scope from those eventually granted in the United States. Thus, in some cases, we may not have the opportunity to obtain patent protection for certain technologies in some jurisdictions outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products. Such challenges in enforcing rights in these countries could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our current and future patent rights in foreign jurisdictions could result in substantial costs and may divert our efforts and attention from other aspects of our business; could put our patents at risk of being invalidated or interpreted narrowly; could put any future patent applications, including continuation and divisional applications, at risk of not issuing; and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce any intellectual property rights around the world stemming from intellectual property that we develop may be inadequate to obtain a significant commercial advantage in these foreign jurisdictions.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability (and the ability of any potential future collaborators) to develop, manufacture, market and sell our product candidates, and to freely use our proprietary technologies (*e.g.*, without infringing the

rights and intellectual property of others). Many companies and institutions have filed, and continue to file, patent applications related to various aspects of gene therapy. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing, and can be revised before issuance, there may be applications now pending which may later result in issued patents that a third-party asserts are infringed by the manufacture, use, sale, or importation of our products. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. On May 1, 2020, a complaint was filed against us in the United States District Court for the Western District of Pennsylvania by PeriphaGen Inc., which also named our Chief Executive Officer and Chief Operating Officer, Krish Krishnan and Suma Krishnan, respectively. The complaint alleges breach of contract and misappropriation of trade secrets, which secrets the plaintiff asserts were used to develop our product candidates, including the vector backbones, and our STAR-D platform. For more information, see "Legal Proceedings" in Note 6 of the Notes to Condensed Consolidated Financial Statements included in Item 1 of Part I of this Form 10-Q. We may in the future become party to, or be threatened with, other adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates or related technologies, including, for example, interference proceedings, post grant review challenges, and *inter partes* review before the United States Patent and Trademark Office ("USPTO"). For example, a third party may bring an *inter partes* review challenging our patents and any future patent that may be granted to us. Our competitors or other third parties may assert infringement claims against us, alleging that our therapeutics, manufacturing methods, formulations or administration methods are covered by their patents. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue, and against whom our patent portfolio may therefore have no deterrent effect.

There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patents or other intellectual property rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize our products, including B-VEC. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. In such a hypothetical situation, there is no assurance that a court of competent jurisdiction would find that our product candidates or technologies do not infringe a third-party patent.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcomes are uncertain. If we are found, or believe there is a risk that we may be found, to infringe a third party’s valid and enforceable intellectual property rights, we could be required (or may choose) to obtain a license from such a third party to continue developing, manufacturing and marketing our technologies. However, we may not be able to obtain any required license on commercially reasonable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and further, it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technologies, including B-VEC. We also could be found liable for monetary damages, including treble damages and attorneys’ fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our technologies, including B-VEC, or force us to cease some or all our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming. Competitors may infringe our current or future patents, should such patents issue, or we may be required to defend against claims of infringement or other unauthorized use of intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our scientific and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their

greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We are and may be subject to claims asserting that we, our employees or our advisors have wrongfully used or disclosed alleged trade secrets of other parties, including current or former employers, or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including potential competitors, and we have and may in the future entered into agreements providing us with rights to intellectual property of third parties for limited purposes. Although we try to observe the terms of agreements under which we obtain access to third party intellectual property and to ensure that our employees and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties or the current or former employers of employees or advisors. For instance, as described above under "Item 3—Legal Proceedings," on May 1, 2020, a complaint was filed against us by PeriphaGen Inc., which also named our Chief Executive Officer and our Chief Operating Officer, Krish Krishnan and Suma Krishnan, respectively. The complaint alleges breach of contract and misappropriation of trade secrets, which secrets the plaintiff asserts we used to develop vector platform and product candidates. If we fail in defending any such claims, in addition to paying monetary damages, we may be subject to an injunction and may lose valuable intellectual property rights or personnel. Moreover, any such litigation, or the threat thereof, may adversely affect our ability to hire new employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies, which would have an adverse effect on our business, results of operations, and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

While it is our policy to require our employees and contractors who may be involved in the conception of intellectual property to execute agreements assigning such intellectual property rights to us, unforeseen complications may arise when fully and adequately executing such an agreement with each party who, in fact, conceives of intellectual property that we regard as our own. Examples of such complications may include, for example, when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. Such complications may lead to us being forced to bring claims against third parties or current and former employees, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Moreover, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be insufficient in fully perfecting ownership of inventions developed by that individual. Disputes about the ownership of intellectual property that we may own may have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included several significant changes to U.S. patent law, including provisions that affected the way patent applications are prosecuted, and altered strategies regarding patent litigation. These provisions also switched the United States from a "first-to-invent" system to a "first-to-file" system, allowed third-party submissions of prior art to the USPTO during patent prosecution, and set forth additional procedures to attack the validity of a patent through various post grant proceedings administered by the USPTO. As patent reform legislation can inject serious uncertainty into the patent prosecution and litigation processes, it is not clear what impact future patent reform legislation will have on the operation of our business. However, such future legislation, and its implementation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, the patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain given the ever evolving and constantly shifting nature of precedential patent cases decided by both the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court. We cannot assure you that our efforts to seek patent protection for our technology and product candidates will not be negatively impacted by the future court decisions or changes in guidance or procedures issued by the USPTO. These decisions, and any guidance issued by the USPTO

(or changes thereto), could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property rights in the future.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We are in the process of registering certain of our trademarks and trade names. Once trademarks or trade names have been registered, they may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which are important for building name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. There also could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trade names that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to patents, trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats.

The degree of current and future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make gene therapy products that are similar to our product candidates but that are not covered by the claims of our current patents, or of patents that we may own or license in the future;
- we, or any future license partners or collaborators, might not have been the first to file patent applications covering certain aspects of the concerned technologies;
- others may independently develop similar or alternative technologies, or duplicate any of our technologies, potentially without falling within the scope of our current or future issued claims, thus not infringing our intellectual property rights;
- it is possible that our filed or future patent applications will not lead to issued patents;
- issued patents to which we currently hold rights or to which we may hold rights in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- others may have access to any future intellectual property rights licensed to us on a non-exclusive basis;
- our competitors might conduct research and development activities in countries where we do not have or pursue patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we may choose not to file a patent application covering certain of our trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

Our Chief Executive Officer and Chairman of the Board of Directors and our founder, Chief Operating Officer and director will have the ability to substantially influence all matters submitted to stockholders for approval.

As of June 30, 2021, Krish S. Krishnan and Suma M. Krishnan, our Chief Executive Officer and Chairman of the Board and our founder, Chief Operating Officer and director, respectively, in the aggregate, beneficially owned shares representing approximately 17% of our capital stock. As a result, they will be able to substantially influence all matters submitted to our

stockholders for approval, as well as our management and affairs. For example, these persons would substantially influence the election of directors and approval of any merger, consolidation or sale of all or substantially all our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in management of our company that our public stockholders disagree with.

If securities analysts publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If securities analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock.

Our stock price has been and is likely to continue to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies specifically has experienced extreme volatility that has often been unrelated to the operating performance of such companies. As a result of this volatility, you may not be able to sell your common stock at or above the price that you paid for it. The market price of our common stock may be influenced by many factors, including:

- our ability to successfully proceed to and conduct clinical trials;
- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

We are an “emerging growth company” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act ("JOBS Act"), and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not “emerging growth companies.” In particular, while we are an “emerging growth company: (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act; (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor’s report on financial statements; (iii) we will be subject to reduced disclosure

obligations regarding executive compensation in our periodic reports and proxy statements; and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. Investors may find our common stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will continue to incur costs as a result of becoming a public company, and such costs will increase when we cease to be an "emerging growth company."

As a public company, we expect to continue to incur significant legal, accounting, insurance and other expenses, including costs associated with public company reporting requirements. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect compliance with these public reporting requirements and associated rules and regulations to increase expenses, particularly after we are no longer an emerging growth company beginning in 2022, although we are currently unable to estimate these costs with any degree of certainty. We will be an emerging growth company until the end of 2021, after which, we will incur additional costs applicable to public companies that are not emerging growth companies.

If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.
Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Beginning with our fiscal year ending December 31, 2022, we will cease to be an "emerging growth company" as defined by the JOBs Act. After we are no longer an emerging growth company under the JOBS Act, Section 404 of the Sarbanes-Oxley Act requires our auditors to deliver an attestation report on the effectiveness of our internal control over financial reporting in conjunction with their opinion on our audited financial statements. Substantial work on our part is required to implement appropriate processes, document the system of internal control over key processes, assess their design, remediate any deficiencies identified and test their operation. This process is expected to be both costly and challenging. We cannot give any assurances that material weaknesses will not be identified in the future in connection with our compliance with the provisions of Section 404 of the Sarbanes-Oxley Act. The existence of any material weakness would preclude a conclusion by management and our independent auditors that we maintained effective internal control over financial reporting. Our management may be required to devote significant time and expense to remediate any material weaknesses that may be discovered and may not be able to remediate any material weakness in a timely manner. The existence of any material weakness in our internal control over financial reporting could also result in errors in our financial statements that could require us to restate our financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, all of which could lead to a decline in the per-share trading price of our common stock.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stakeholders might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 80% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

We have broad discretion in the use of our cash, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the application of our cash, cash equivalents and marketable securities and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Third-party expectations relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance factors. Some investors may use these factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased in number, resulting in varied and in some cases inconsistent standards. In addition, the criteria by which companies' corporate responsibility practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy such new criteria or do not meet the criteria of a specific third-party provider, some investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies. Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, in the event that we communicate certain initiatives and goals regarding environmental, social and governance matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors and other stakeholders or our initiatives are not executed as planned, our reputation and financial results could be adversely affected

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	
10.1	Standard Form of Contract for Construction and the corresponding General Conditions of the Contract for Construction with The Whiting-Turner Contracting Company
31.1	Certification of Periodic Report by Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Periodic Report by Chief Accounting Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Accounting Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Inline XBRL (Extensible Business Reporting Language). The following materials from this Quarterly Report on Form 10-Q for the periods ended June 30, 2021, formatted in Inline XBRL: (i) consolidated balance sheets of Krystal Biotech, Inc., (ii) consolidated statements of operations of Krystal Biotech, Inc., (iii) consolidated statements of comprehensive income/(loss) of Krystal Biotech, Inc., (iv) consolidated statements of changes in equity of Krystal Biotech, Inc., (v) consolidated statements of cash flows of Krystal Biotech, Inc. and (vi) notes to consolidated financial statements of Krystal Biotech, Inc. The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL

SIGNATURES

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

KRYSTAL BIOTECH, INC.
(Registrant)

Date: August 9, 2021	By:	/s/ Krish S. Krishnan
		Krish S. Krishnan President and Chief Executive Officer (Principal executive officer)
	By:	/s/ Kathryn A. Romano
		Kathryn A. Romano Chief Accounting Officer (Principal financial and accounting officer)

AIA® Document A133™ – 2019

Standard Form of Agreement Between Owner and Construction Manager as Constructor where the basis of payment is the Cost of the Work Plus a Fee with a Guaranteed Maximum Price

AGREEMENT made as of the day of in the year Two Thousand Twenty One
(In words, indicate day, month, and year.)

BETWEEN the Owner:
(Name, legal status, address, and other information)

Krystal Biotech, Inc.
2100 Wharton Street
Suite 701
Pittsburgh, PA 15203

and the Construction Manager:
(Name, legal status, address, and other information)

The Whiting-Turner Contracting Company
300 East Joppa Road
Baltimore, MD 21286

for the following Project:
(Name, location, and detailed description)

Krystal Biotech Facility
7001 International Drive
Coraopolis, PA 15108

The Architect:
(Name, legal status, address, and other information)

Clark, Richardson & Biskup Consulting Engineers, Inc.
220 W. Germantown Pike
Suite 170
Plymouth Meeting, PA 19462

The Owner and Construction Manager agree as follows.

ADDITIONS AND DELETIONS:
The author of this document has added information needed for its completion. The author may also have revised the text of the original AIA standard form. An *Additions and Deletions Report* that notes added information as well as revisions to the standard form text is available from the author and should be reviewed. A vertical line in the left margin of this document indicates where the author has added necessary information and where the author has added to or deleted from the original AIA text.

This document has important legal consequences. Consultation with an attorney is encouraged with respect to its completion or modification.

AIA Document A201™–2017, General Conditions of the Contract for Construction, is adopted in this document by reference. Do not use with other general conditions unless this document is modified.

TABLE OF ARTICLES

ARTICLE 1 INITIAL INFORMATION

§ 1.1 This Agreement is based on the Initial Information set forth in this Section 1.1.
(For each item in this section, insert the information or a statement such as "not applicable" or "unknown at time of execution.")

§ 1.1.1 The Owner's program for the Project, as described in Section 4.1.1:
(Insert the Owner's program, identify documentation that establishes the Owner's program, or state the manner in which the program will be developed.)

Preliminary Design Report dated 5/7/2020 and the Preliminary Design Report Addendum dated 6/5/2020 attached hereto as Exhibit C_

§ 1.1.2 The Project's physical characteristics:
(Identify or describe pertinent information about the Project's physical characteristics, such as size; location; dimensions; geotechnical reports; site boundaries; topographic surveys; traffic and utility studies; availability of public and private utilities and services; legal description of the site, etc.)

C-100 Site Plan and C-050 Existing Conditions dated 6/23/2020 attached hereto as Exhibit D_.

§ 1.1.3 The Owner's budget for the Guaranteed Maximum Price, as defined in Article 6:
(Provide total and, if known, a line item breakdown.)

N/A

§ 1.1.4 The Owner's anticipated design and construction milestone dates:

.1 Design phase milestone dates, if any:

Issued for Permit set – TBD
Issued for Bid set -- 11/24/2020
Issued for Construction set – 4/15/21

.2 Construction commencement date:

Construction Manager has been engaged pursuant to a written Letter of Intent dated December 30, 2020 ("LOI") to perform certain services and Work prior to the execution of this Agreement and the Exhibit A-Guaranteed Maximum Price ("GMP") Amendment the ("Pre-GMP Period"). All services and Work pursuant thereto shall be deemed to have been performed under this Agreement. A true and correct copy of the LOI is attached hereto and incorporated herein as Exhibit E. On site Work will commence prior to the issuance of a building permit in preparation for construction. Such Work shall be billed as the Pre-GMP and is to be paid under the LOI.
The Owner and Construction Manager agree that since the execution of the LOI (which incorporates the BAFO), the parties are adjusting the Project Schedule and BAFO General Conditions. Such changes are reflected in the Exhibits hereto or will be further modified in writing. The Exhibits shall supersede any conflicting information in the LOI or BAFO.

.3 Substantial Completion date or dates:

Phased in accordance with 1.1.4.4

.4 Other milestone dates:

See Whiting-Turner schedule dated February 2021

§ 1.1.5 The Owner's requirements for accelerated or fast-track scheduling, or phased construction, are set forth below:
(Identify any requirements for fast-track scheduling or phased construction.)

1. Prepurchase of Long Lead Equipment
2. Phased construction in accordance with 1.1.4.4

§ 1.1.6 The Owner's anticipated Sustainable Objective for the Project:
(Identify and describe the Owner's Sustainable Objective for the Project, if any.)

There are no anticipated Sustainable Objectives.

(Paragraph deleted)
§ 1.1.7 Other Project information:
(Identify special characteristics or needs of the Project not provided elsewhere.)

Construction Manager is advised that the Work is to be performed on land owned by the Allegheny Airport Authority and adjacent to Pittsburgh International Airport ("Airport"). Construction Manager's Work may not interfere with or be detrimental to any operations or the Airport.

§ 1.1.8 The Owner identifies the following representative in accordance with Section 4.2 and in accordance with Section 1.1.9 below:
(List name, address, and other contact information.)
Stantec Consulting Services, Inc
475 Fifth Avenue, Fl 12
New York, NY 10017

Michael Kempin, AIA

§ 1.1.9 The persons or entities, in addition to the Owner's representative, who are required to review the Construction Manager's submittals to the Owner are as follows:
(List name, address and other contact information.)

The Owner has engaged Stantec to assist the Owner with the administration of the Project. As used for administrative purposes herein and in the A201-2017 General Conditions, as amended, the Owner shall mean Stantec. Stantec shall receive all project documentation that is to be provided to the Owner, shall coordinate the activities of the Owner, and shall review Construction Manager's Work. The services and role of Stantec shall not relieve the Construction Manager of any obligations under the Contract Documents or implied by law. It is expressly acknowledged and agreed that Stantec shall have no authority, express or implied, to bind the Owner.

Only Kate Romano shall have authority to bind the Owner.

§ 1.1.10 The Owner shall retain the following consultants and contractors:
(List name, legal status, address, and other contact information.)

.1 Geotechnical Engineer:

n/a

.2 Civil Engineer:

n/a

.3 Other, if any:
(List any other consultants retained by the Owner, such as a Project or Program Manager.)

Security Consultant (Ross and Baruzzini), Equipment Consultant (SMW), IT Consultant (TBD), Furniture Vendor (TBD), Commissioning Agent(TBD)
Process Controls System Integrator (PCS)
Special Inspections (Intertek-PSI)

§ 1.1.11 The Architect's representative:
(List name, address, and other contact information.)

Michael Asher
Clark, Richardson & Biskup Consulting Engineers, Inc.
220 West Germanton Pike, Suite 170
Plymouth Meeting, PA 19462

§ 1.1.12 The Construction Manager identifies the following representative in accordance with Article 3:
(List name, address, and other contact information.)

Stacy Percoski
The Whiting-Turner Contracting Company
300 East Joppa Road
Baltimore, MD 21286

§ 1.1.13 The Owner's requirements for the Construction Manager's staffing plan for Preconstruction Services, as required under Section 3.1.9:
(List any Owner-specific requirements to be included in the staffing plan.)

See Whiting-Turner Organization Chart attached hereto and incorporated herein as Exhibit F.

§ 1.1.14 The Owner's requirements for subcontractor procurement for the performance of the Work:
(List any Owner-specific requirements for subcontractor procurement.)

The Owner anticipates that Construction Manager will engage certain subcontractor for design-assistance during the preconstruction phase. All such subcontracts and/or purchase orders shall provide for transfer of any and all design documents to the Owner upon payment. Nothing shall require that said subcontractors be engaged for construction phase services.

§ 1.1.15 Other Initial Information on which this Agreement is based:

§ 1.2 The Owner and Construction Manager may rely on the Initial Information as modified hereby. Both parties agree that since the issuance of the Initial Information and execution of the LOI, the parties are adjusting the Project Schedule and Owner's budget. Such changes are reflected in the Exhibits hereto which shall supersede any conflicting information in the LOI.

§ 1.3 The Construction Manager's representative shall not be changed without ten days' prior notice to the Owner.

ARTICLE 2 GENERAL PROVISIONS

§ 2.1 The Contract Documents

The Contract Documents consist of this Agreement, Conditions of the Contract (General, Supplementary and other Conditions), as amended, Drawings, Specifications, Addenda issued prior to execution of this Agreement, other documents listed in this Agreement, and Modifications issued after execution of this Agreement, all of which form the Contract and are as fully a part of the Contract as if attached to this Agreement or repeated herein. Upon the Owner's acceptance of the Construction Manager's Guaranteed Maximum Price proposal, the Contract Documents will also include the documents described in Section 3.2.3 and identified in the Guaranteed Maximum Price Amendment and revisions prepared by the Architect and furnished by the Owner as described in Section 3.2.8. The Contract represents the entire and integrated agreement between the parties hereto and supersedes prior negotiations, representations or agreements, either written or oral. If anything in the other Contract Documents, other than a Modification, is inconsistent with this Agreement, this Agreement shall govern. An enumeration of the Contract Documents, other than a Modification, appears in Article 15.

§ 2.2 Relationship of the Parties

The Construction Manager accepts the relationship of trust and confidence established by this Agreement and covenants with the Owner to cooperate with the Architect and exercise the Construction Manager's skill and judgment in furthering the interests of the Owner to furnish efficient construction administration, management services, and supervision; to furnish at all times an adequate supply of workers and materials; and to perform the Work in an expeditious and economical manner consistent with the Owner's interests. The Owner agrees to furnish or approve, in a timely manner, information required by the Construction Manager and to make payments to the Construction Manager in accordance with the requirements of the Contract Documents. Nothing in this Agreement is intended to create a fiduciary duty or fiduciary relationship between the Construction Manager and the Owner in connection with any of the obligations of the Parties to this Agreement, except to the extent expressly provided.

§ 2.3 General Conditions

§ 2.3.1 For the Preconstruction Phase, AIA Document A201™–2017, General Conditions of the Contract for Construction, as amended, shall apply as follows: Section 1.5, Ownership and Use of Documents; Section 1.7, Digital Data Use and Transmission; Section 1.8, Building Information Model Use and Reliance; Section 2.2.4, Confidential

Information; Section 3.12.10, Professional Services; Section 10.3, Hazardous Materials; Section 13.1, Governing Law. The term "Contractor" as used in A201–2017 shall mean the Construction Manager. Any reference herein as to Sections of the A201-2017 General Conditions shall mean the Sections as amended. It is agreed that the Construction Manager shall not be responsible for the errors or omissions of the Architect and that Construction Manager is only responsible for the professional services that it provides pursuant to the terms of this Agreement.

§ 2.3.2 For the Construction Phase, the general conditions of the contract shall be as set forth in A201–2017, which document is incorporated herein by reference. The term "Contractor" as used in A201–2017 shall mean the Construction Manager.

ARTICLE 3 CONSTRUCTION MANAGER'S RESPONSIBILITIES

The Construction Manager's Preconstruction Phase responsibilities are set forth in Sections 3.1 and 3.2, and in the applicable provisions of A201-2017 referenced in Section 2.3.1. The Construction Manager's Construction Phase responsibilities are set forth in Section 3.3. The Owner and Construction Manager may agree, in consultation with the Architect, for the Construction Phase to commence prior to completion of the Preconstruction Phase, in which case, both phases will proceed concurrently. The Construction Manager shall identify a representative authorized to act on behalf of the Construction Manager with respect to the Project.

§ 3.1 Preconstruction Phase

§ 3.1.1 Extent of Responsibility

The Construction Manager shall exercise reasonable care in performing its Preconstruction Services. The Owner and Architect shall be entitled to rely on, and shall not be responsible for, the accuracy, completeness, and timeliness of services and information furnished by the Construction Manager. The Construction Manager, however, does not warrant or guarantee estimates and schedules except as may be included as part of the Guaranteed Maximum Price. The Construction Manager is not required to ascertain that the Drawings and Specifications are in accordance with applicable laws, statutes, ordinances, codes, rules and regulations, or lawful orders of public authorities, but the Construction Manager shall promptly report to the Architect and Owner any nonconformity discovered by or made known to the Construction Manager as a request for information in such form as the Architect may require. The Construction Manager shall perform a constructability review to identify conflicts and omitted items, among other things.

§ 3.1.2 The Construction Manager shall provide a preliminary evaluation of the Owner's program, schedule and construction budget requirements, each in terms of the other, and such services as set forth in the LOI as adjusted by the Exhibits hereto.

§ 3.1.3 Consultation

§ 3.1.3.1 The Construction Manager shall schedule and conduct meetings with the Architect and Owner to discuss such matters as procedures, progress, coordination, and scheduling of the Work.

§ 3.1.3.2 The Construction Manager shall advise the Owner and Architect on proposed site use and improvements, selection of materials, building systems, and equipment. The Construction Manager shall also provide recommendations to the Owner and Architect, consistent with the Project requirements, on constructability; availability of materials and labor; time requirements for procurement, installation and construction; prefabrication; and factors related to construction cost including, but not limited to, costs of alternative designs or materials, preliminary budgets, life-cycle data, and possible cost reductions. The Construction Manager shall consult with the Architect regarding professional services to be provided by the Construction Manager during the Construction Phase.

§ 3.1.3.3 The Construction Manager shall assist the Owner and Architect in establishing building information modeling and digital data protocols for the Project, using AIA Document E203™–2013, Building Information Modeling and Digital Data Exhibit, to establish the protocols for the development, use, transmission, and exchange of digital data.

§ 3.1.4 Project Schedule

When Project requirements in Section 4.1.1 have been sufficiently identified, the Construction Manager shall prepare and monthly update a Project schedule for the Architect's review and the Owner's acceptance. The Construction Manager shall obtain the Architect's approval for the portion of the Project schedule relating to the performance of the Architect's services. The Project schedule shall coordinate and integrate the Construction Manager's services, the Architect's services, other Owner consultants' services, and the Owner's responsibilities; and identify items that affect the Project's timely completion. The updated Project schedule shall include the following: submission of the Guaranteed Maximum

Price proposal; components of the Work; times of commencement and completion required of each Subcontractor; review and approval of submittals, ordering and delivery of products, including those that must be ordered in advance of construction; and the occupancy requirements of the Owner.

§ 3.1.5 Phased Construction

The Construction Manager, in consultation with the Architect, shall provide recommendations with regard to accelerated or fast-track scheduling, procurement, and sequencing for phased construction. The Construction Manager shall take into consideration cost reductions, cost information, constructability, provisions for temporary facilities, and procurement and construction scheduling issues.

§ 3.1.6 Cost Estimates

§ 3.1.6.1 Based on the preliminary design and other design criteria issued for bidding prepared by the Architect, the Construction Manager shall prepare, for the Architect's review and the Owner's approval, preliminary estimates of the Cost of the Work or the cost of program requirements using area, volume, or similar conceptual estimating techniques. If the Architect or Construction Manager suggests alternative materials and systems, the Construction Manager shall provide cost evaluations of those alternative materials and systems.

§ 3.1.6.2 The Construction Manager shall include in the estimate those costs to allow for the further development of the design, price escalation, and market conditions, until such time as the Owner and Construction Manager agree on a Guaranteed Maximum Price for the Work. The estimate shall be provided for the Architect's review and the Owner's approval. The Construction Manager shall inform the Owner and Architect in the event that the estimate of the Cost of the Work exceeds the latest approved Project budget, and make recommendations for corrective action.

§ 3.1.6.3 If the Architect is providing cost estimating services as a Supplemental Service, and a discrepancy exists between the Construction Manager's cost estimates and the Architect's cost estimates, the Construction Manager and the Architect shall work together to reconcile the cost estimates.

§ 3.1.7 As the Architect progresses with the preparation of the Construction Documents, the Construction Manager shall consult with the Owner and Architect and make recommendations regarding constructability and schedules, for the Architect's review and the Owner's approval.

§ 3.1.8 The Construction Manager shall provide recommendations and information to the Owner and Architect regarding equipment, materials, services, and temporary Project facilities.

§ 3.1.9 The Construction Manager shall provide a staffing plan for Preconstruction Phase services for the Owner's review and approval.

§ 3.1.10 If the Owner identified a Sustainable Objective in Article 1, the Construction Manager shall fulfill its Preconstruction Phase responsibilities as required in AIA Document E234™–2019, Sustainable Projects Exhibit, Construction Manager as Constructor Edition, attached to this Agreement.

§ 3.1.11 Subcontractors and Suppliers

§ 3.1.11.1 If the Owner has provided requirements for subcontractor procurement in section 1.1.14, the Construction Manager shall provide a subcontracting plan, addressing the Owner's requirements, for the Owner's review and approval.

§ 3.1.11.2 The Construction Manager shall develop bidders' interest in the Project and shall furnish to the Architect, Owner's Representative and Owner for their review a list of possible, pre-qualified, bondable subcontractors and suppliers.

§ 3.1.11.3 The processes described in Article 9 shall apply if bid packages will be issued during the Preconstruction Phase.

§ 3.1.12 Procurement

The Construction Manager shall prepare, for the Architect's review and the Owner's acceptance, a procurement schedule for items that must be ordered in advance of construction. The Construction Manager shall expedite and coordinate the ordering and delivery of materials that must be ordered in advance of construction. If the Owner agrees to procure any items prior to the establishment of the Guaranteed Maximum Price, the Owner shall procure the items on terms and conditions acceptable to the Construction Manager. Upon the establishment of the Guaranteed Maximum Price, the

Owner shall assign all contracts for these items to the Construction Manager and the Construction Manager shall thereafter accept responsibility for them.

§ 3.1.13 Compliance with Laws

In accordance with the terms of the Contract Documents, the Construction Manager shall comply with applicable laws, statutes, ordinances, codes, rules and regulations, and lawful orders of public authorities applicable to its performance of the Work under this Contract, and with equal employment opportunity programs, and other programs as may be required by governmental and quasi-governmental authorities.

§ 3.1.14 Other Preconstruction Services

Insert a description of any other Preconstruction Phase services to be provided by the Construction Manager, or reference an exhibit attached to this document

(Describe any other Preconstruction Phase services, such as providing cash flow projections, development of a project information management system, early selection or procurement of subcontractors, etc.)

Such services as set forth in the LOI as amended by the Exhibits attached hereto.

§ 3.2 Guaranteed Maximum Price Proposal

§ 3.2.1 At a time to be mutually agreed upon by the Owner and the Construction Manager, the Construction Manager shall prepare a Guaranteed Maximum Price ("GMP") proposal for the Owner's and Architect's review, and the Owner's acceptance. The Guaranteed Maximum Price in the proposal shall be the sum of the Construction Manager's estimate of the Cost of the Work, the Construction Manager's contingency described in Section 3.2.4, and the Construction Manager's Fee described in Section 6.1.2. The Construction Manager's contingency will be established and agreed upon in the Guaranteed Maximum Price Amendment.

§ 3.2.2 To the extent that the Contract Documents are anticipated to require further development, the Guaranteed Maximum Price includes the costs attributable to such further development consistent with the Contract Documents and reasonably inferable therefrom. Such further development does not include changes in scope, systems, kinds and quality of materials, finishes, or equipment, all of which, if required, shall be incorporated by Change Order. Construction Manager, in preparing the proposed GMP, shall have the responsibility of performing a constructability review to assure the GMP drawings, specifications, construction holds, construction allowances, alternatives, assumption, and clarifications are an accurate and complete statement of the Construction Manager's intent.

§ 3.2.3 The Construction Manager shall include with the Guaranteed Maximum Price proposal a written statement of its basis, which shall include the following:

.1 A list of the Drawings and Specifications, including all Addenda thereto, and the Conditions of the Contract;

.2 A list of the clarifications and assumptions made by the Construction Manager in the preparation of the Guaranteed Maximum Price proposal, including assumptions under Section 3.2.2;

.3 A statement of the proposed Guaranteed Maximum Price, including a statement of the estimated Cost of the Work organized by trade categories or systems, including allowances; the Construction Manager's contingency set forth in Section 3.2.4; construction logistics plan; construction schedule and utility rough-in schedule (Exhibit G hereto) and separate list of all Holds (identified item properly chargeable as a Cost of the Work but is not specifically indicated in the Contract Document ("Holds")), allowances, and Alternatives, and the Construction Manager's Fee, General Conditions, insurances as provided herein;

.4 The anticipated date of Substantial Completion upon which the proposed Guaranteed Maximum Price is based; and

.5 A date by which the Owner must accept the Guaranteed Maximum Price.

§ 3.2.4 In preparing the Construction Manager's Guaranteed Maximum Price proposal, the Construction Manager shall disclose to the Owner and Owner shall agree on the contingency for the Construction Manager's use to cover those costs that are included in the Guaranteed Maximum Price and properly chargeable as a Cost of the Work, but not otherwise allocated to another line item or included in a Change Order as provided herein. The use of the Construction Contingency by the Construction Manager is subject to the approval of the Owner as hereafter set forth. The GMP shall include Holds which may or may not be exceeded. To the extent that funds associated with a particular Hold are not used, they will be

credited to the contingency. To the extent that funds associated with a particular Hold exceeds the value of the Hold in the GMP, the contingency shall be used.

The Guaranteed Maximum Price includes a Contingency. The Contingency is not intended to be used for any changes in scope, systems, kinds, qualities, quantities of materials, finishes or equipment from that shown on the Contract Documents, any of which, if required, may be the basis for Change Order in accordance with this Agreement unless such is incorporated into the Guaranteed Maximum Price Amendment. The Contingency may be used for, but shall not be limited to, adjustments in estimated costs, and other items which arise during the course of the Project which in the reasonable judgment of the Construction Manager and Owner shall be included in the Cost of the Work. The Contingency may not be used if there is a line item within the Cost of the Work schedule of values that has not been exhausted to which the cost may be charged. Further, the Construction Manager shall not use the Contingency to cover an error in installation by Construction Manager or any of its subcontractors, correction of non-conforming Work, repairs, damage to the extent caused by Contractor or subcontractors, or overtime costs and/or additional supervision where caused by Construction Manager's failure to manage the Project or from delay caused by a Subcontractor or one for whom the Construction Manager is responsible. It is acknowledged and agreed that notwithstanding the foregoing, the Construction Manager may request to use Contingency for increased material costs or material delays due to circumstances beyond Construction Manager's control pursuant to Article 8.3.1.1 of the General Conditions relating to COVID-19. The Construction Manager may also request to the use of contingency for the betterment of the Project and shall provide the Owner with justification for the same. The Construction Manager shall obtain the Owner's prior written approval for the use of the Contingency for any items in the aggregate amount of $7,500 for any given month, which approval shall not be unreasonably withheld.

The Construction Manager shall submit to the Owner a written request to use an amount from the Contingency which would result in the $7,500 threshold being exceeded. The Contingency request shall include detailed information in terms of labor and material costs and schedule impact. The Owner shall approve or object within five business days of receipt of said Request and supporting documentation from the Construction Manager. In the event of exigent circumstances where a review period of five business days will unnecessarily impact the Contract Time or Contract Sum, Construction Manager shall immediately advise the Owner and request expedited written approval.

§ 3.2.5 The Construction Manager shall meet with the Owner and Architect to review the Guaranteed Maximum Price proposal. In the event that the Owner or Architect discover any inconsistencies or inaccuracies in the information presented, they shall promptly notify the Construction Manager, who shall make appropriate adjustments to the Guaranteed Maximum Price proposal, its basis, or both.

§ 3.2.6 If the Owner notifies the Construction Manager that the Owner has accepted the Guaranteed Maximum Price proposal in writing before the date specified in the Guaranteed Maximum Price proposal, the Guaranteed Maximum Price proposal shall be deemed effective without further acceptance from the Construction Manager. Following acceptance of a Guaranteed Maximum Price, the Owner and Construction Manager shall execute the Guaranteed Maximum Price Amendment amending this Agreement, a copy of which the Owner shall provide to the Architect. The Guaranteed Maximum Price Amendment shall set forth the agreed upon Guaranteed Maximum Price with the information and assumptions upon which it is based.

§ 3.2.7 The Construction Manager shall not incur any cost to be reimbursed as part of the Cost of the Work prior to the execution of the Guaranteed Maximum Price Amendment, unless the Owner provides prior written authorization for such costs.

§ 3.2.8 The Owner shall authorize preparation of revisions to the Contract Documents that incorporate the agreed-upon assumptions and clarifications contained in the Guaranteed Maximum Price Amendment. The Owner shall promptly furnish such revised Contract Documents to the Construction Manager. The Construction Manager shall notify the Owner and Architect of any inconsistencies between the agreed-upon assumptions and clarifications contained in the Guaranteed Maximum Price Amendment and the revised Contract Documents.

§ 3.2.9 The Construction Manager shall include in the Guaranteed Maximum Price all sales, consumer, use and similar taxes for the Work provided by the Construction Manager that are legally enacted, whether or not yet effective, at the time the Guaranteed Maximum Price Amendment is executed.

§ 3.3 Construction Phase

§ 3.3.1 General

§ 3.3.1.1 For purposes of Section 8.1.2 of A201–2017, the date of commencement of the Work shall mean the date of commencement of the Construction Phase.

§ 3.3.1.2 The Construction Phase shall commence as set forth in Section 1.1.4. The written agreement shall set forth a description of the Work to be performed by the Construction Manager, and any insurance and bond requirements for Work performed prior to execution of the Guaranteed Maximum Price Amendment.

§ 3.3.2 Administration

§ 3.3.2.1 The Construction Manager shall schedule and conduct meetings to discuss such matters as procedures, progress, coordination, scheduling, and status of the Work. The Construction Manager shall prepare and promptly distribute minutes of the meetings to the Owner and Architect.

§ 3.3.2.2 The Construction Manager shall prepare a construction schedule and submittal schedule covering the Pre-GMP Period. Upon the execution of the Guaranteed Maximum Price Amendment, the Construction Manager shall prepare and submit to the Owner and Architect a comprehensive construction schedule for the Work and a submittal schedule in accordance with Section 3.10 of A201–2017. Such Work shall be completed by the date of Substantial Completion identified in the agreed upon Construction Schedule per Phase. Upon request, the Construction Manager shall provide the Owner will all native data used to prepare the Construction Schedule and shall provide the Owner with electronic copies of the Construction Schedule.

§ 3.3.2.3 Monthly Report

The Construction Manager shall record the progress of the Project. On a monthly basis, or otherwise as agreed to by the Owner, the Construction Manager shall submit written progress reports to the Owner and Architect, showing percentages of completion and other information required by the Owner.

§ 3.3.2.4 Daily Logs

The Construction Manager shall keep, and make available to the Owner and Architect, a daily log containing a record for each day of weather, portions of the Work in progress, number of workers on site, identification of equipment on site, problems that might affect progress of the work, accidents, injuries, and other information required by the Owner.

§ 3.3.2.5 Cost Control

The Construction Manager shall develop a system of cost control for the Work, including regular monitoring of actual costs for activities in progress and estimates for uncompleted tasks and proposed changes. The Construction Manager shall identify variances between actual and estimated costs and report the variances to the Owner and Architect and shall provide this information in its monthly reports to the Owner and Architect, in accordance with Section 3.3.2.3 above.

ARTICLE 4 OWNER'S RESPONSIBILITIES

§ 4.1 Information and Services Required of the Owner

§ 4.1.1 The Owner shall provide information with reasonable promptness, regarding requirements for and limitations on the Project, including a written program which shall set forth the Owner's objectives, constraints, and criteria, including schedule, space requirements and relationships, flexibility and expandability, special equipment, systems, sustainability and site requirements.

(Paragraph deleted)

§ 4.1.2 The Owner, a publicly traded company, has provided public information evidencing that financial arrangements have been made to fulfill the Owner's obligations under this Agreement. The Owner will continue to post its federally required financial information which shall be available to the Construction Manager.

§ 4.1.3 The Owner shall establish and periodically update the Owner's budget for the Project, including (1) the budget for the Cost of the Work as defined in Article 7, (2) the Owner's other costs, and (3) reasonable contingencies related to all of these costs. If the Owner significantly increases or decreases the Owner's budget for the Cost of the Work, the Owner shall notify the Construction Manager and Architect. The Owner and the Architect, in consultation with the Construction Manager, shall thereafter agree to a corresponding change in the Project's scope and quality.

§ 4.1.4 Structural and Environmental Tests, Surveys and Reports. During the Preconstruction Phase, the Owner shall furnish the following information or services with reasonable promptness upon written request of the Construction Manager. The Owner shall also furnish any other information or services under the Owner's control and relevant to the Construction Manager's performance of the Work with reasonable promptness after receiving the Construction Manager's written request for such information or services. The Construction Manager shall be entitled to rely on the accuracy of information and services furnished by the Owner unless it has knowledge that such information is incorrect, but shall exercise proper precautions relating to the safe performance of the Work.

§ 4.1.4.1 The Owner shall furnish tests, inspections, and reports, required by law and as otherwise agreed to by the parties, such as structural, mechanical, and chemical tests, tests for air and water pollution, and tests for hazardous materials.

§ 4.1.4.2 The Owner shall furnish surveys describing physical characteristics, legal limitations and utility locations for the site of the Project upon written request, and a written legal description of the site. The surveys and legal information shall include, as applicable, grades and lines of streets, alleys, pavements and adjoining property and structures; designated wetlands; adjacent drainage; rights-of-way, restrictions, easements, encroachments, zoning, deed restrictions, boundaries and contours of the site; locations, dimensions and other necessary data with respect to existing buildings, other improvements and trees; and information concerning available utility services and lines, both public and private, above and below grade, including inverts and depths. All the information on the survey shall be referenced to a Project benchmark.

§ 4.1.4.3 The Owner, when such services are requested in writing, shall furnish services of geotechnical engineers, which may include test borings, test pits, determinations of soil bearing values, percolation tests, evaluations of hazardous materials, seismic evaluation, ground corrosion tests and resistivity tests, including necessary operations for anticipating subsoil conditions, with written reports and appropriate recommendations.

§ 4.1.5 During the Construction Phase, the Owner shall furnish information or services required of the Owner by the Contract Documents with reasonable promptness. The Owner shall also furnish any other information or services under the Owner's control and relevant to the Construction Manager's performance of the Work with reasonable promptness after receiving the Construction Manager's written request for such information or services.

§ 4.1.6 If the Owner identified a Sustainable Objective in Article 1, the Owner shall fulfill its responsibilities as required in AIA Document E234™–2019, Sustainable Projects Exhibit, Construction Manager as Constructor Edition, attached to this Agreement.

§ 4.2 Owner's Designated Representative

The Owner shall identify a representative authorized to act on behalf of the Owner with respect to the Project as provided herein. The Owner's representative shall render decisions promptly and furnish information expeditiously, so as to avoid unreasonable delay in the services or Work of the Construction Manager. Except as otherwise provided in Section 4.2.1 of A201–2017, the Architect does not have such authority. The term "Owner" means the Owner or the Owner's authorized representative.

§ 4.2.1 Legal Requirements. The Owner shall furnish all legal, insurance and accounting services, including auditing services, that may be reasonably necessary at any time for the Project to meet the Owner's needs and interests.

§ 4.3 Architect

The Owner shall retain an Architect to provide construction administration services, duties and responsibilities, including any additional services requested by the Construction Manager that are necessary for the Preconstruction and Construction Phase services under this Agreement.

ARTICLE 5 COMPENSATION AND PAYMENTS FOR PRECONSTRUCTION PHASE SERVICES

§ 5.1 Compensation

§ 5.1.1 For the Construction Manager's Preconstruction Phase services described in Sections 3.1 and 3.2, the Owner shall compensate the Construction Manager as follows:

(Insert amount of, or basis for, compensation and include a list of reimbursable cost items, as applicable.)

§ 5.1.2 The hourly billing rates for Preconstruction Phase services of the Construction Manager and the Construction Manager's Consultants and Subcontractors, if any, are set forth below.
(If applicable, attach an exhibit of hourly billing rates or insert them below.)

See Whiting-Turner Rate Schedule attached hereto and incorporated herein as Exhibit H. Such rates shall be all inclusive of the items set forth in Section 5.1.2.1 below.

Individual or Position	Rate

§ 5.1.2.1 Hourly billing rates for Preconstruction Phase services include all costs to be paid or incurred by the Construction Manager, as required by law or collective bargaining agreements, for taxes, insurance, contributions, assessments and benefits and, for personnel not covered by collective bargaining agreements, customary benefits such as sick leave, medical and health benefits, holidays, vacations and pensions, and shall remain unchanged unless the parties execute a Modification.

§ 5.1.3 If the Preconstruction Phase services covered by this Agreement have not been completed by March 31, 2021, through no fault of the Construction Manager, the Construction Manager's compensation for Preconstruction Phase services shall be equitably adjusted.

§ 5.2 Payments
§ 5.2.1 Unless otherwise agreed, payments for services shall be made monthly in proportion to services performed.

§ 5.2.2 Payments are due and payable upon presentation of the Construction Manager's invoice. Amounts unpaid sixty (60) days after the invoice date shall bear interest at the rate entered below, or in the absence thereof at the legal rate prevailing from time to time at the principal place of business of the Construction Manager.
(Insert rate of monthly or annual interest agreed upon.)

per annum interest shall be prime rate as set forth in the Money Section of the *Wall Street Journal* as of the date of execution of this Agreement %

ARTICLE 6 COMPENSATION FOR CONSTRUCTION PHASE SERVICES
§ 6.1 Contract Sum
§ 6.1.1 The Owner shall pay the Construction Manager the Contract Sum in current funds for the Construction Manager's performance of the Contract after execution of the Guaranteed Maximum Price ("GMP") Amendment. The Contract Sum is the Cost of the Work as defined in Article 7 plus the Construction Manager's Fee.

§ 6.1.2 The Construction Manager's Fee:
(State a lump sum, percentage of Cost of the Work or other provision for determining the Construction Manager's Fee.)

Construction Manager's Fee will be One and three quarter's percent (1.75%) % of the Cost of Work. The Construction Manager shall provide a credit of One Hundred Fifty Thousand Dollars ($150,000) to its first Application for Payment after execution of the GMP Amendment.

§ 6.1.3 The method of adjustment of the Construction Manager's Fee for changes in the Work:

One and three quarter's percent (1.75%) on Contract Changes result in an increase or decrease to the GMP

§ 6.1.4 Limitations, if any, on a Subcontractor's overhead and profit for increases in the cost of its portion of the Work:

See General Conditions, as amended, for limitations

§ 6.1.5 Rental rates for Construction Manager-owned equipment shall not exceed the reasonable standard rental rate paid at the place of the Project.

§ 6.1.6 Liquidated damages, if any:

(Insert terms and conditions for liquidated damages, if any.)

N/A

§ 6.1.7 Other:
(Insert provisions for bonus, cost savings or other incentives, if any, that might result in a change to the Contract Sum.)

If at the completion of the Project the actual Cost of the Work is less than the GMP as adjusted by Change Order, the difference shall be deemed to be "Savings". All Savings shall inure to the benefit of the Owner.

§ 6.2 Guaranteed Maximum Price

The Construction Manager guarantees that the Contract Sum shall not exceed the Guaranteed Maximum Price set forth in the Guaranteed Maximum Price Amendment, subject to additions and deductions by Change Order as provided in the Contract Documents. Costs which would cause the Guaranteed Maximum Price to be exceeded shall be paid by the Construction Manager without reimbursement by the Owner.

§ 6.3 Changes in the Work

§ 6.3.1 The Owner may, without invalidating the Contract, order changes in the Work within the general scope of the Contract consisting of additions, deletions or other revisions. The Owner shall issue such changes in writing. The Construction Manager may be entitled to an equitable adjustment in the Contract Time as a result of changes in the Work.

§ 6.3.1.1 The Architect may order minor changes in the Work as provided in Article 7 of AIA Document A201–2017, General Conditions of the Contract for Construction.

§ 6.3.2 Adjustments to the Guaranteed Maximum Price on account of changes in the Work subsequent to the execution of the Guaranteed Maximum Price Amendment may be determined by any of the methods listed in Article 7 of AIA Document A201–2017, General Conditions of the Contract for Construction.

§ 6.3.3 Adjustments to subcontracts awarded on the basis of a stipulated sum shall be determined in accordance with Article 7 of A201–2017, as they refer to "cost" and "fee," and not by Articles 6 and 7 of this Agreement. Adjustments to subcontracts awarded with the Owner's prior written consent on the basis of cost plus a fee shall be calculated in accordance with the terms of those subcontracts.

§ 6.3.4 In calculating adjustments to the Guaranteed Maximum Price, the terms "cost" and "costs" as used in Article 7 of AIA Document A201–2017 shall mean the Cost of the Work as defined in Article 7 of this Agreement and the term "fee" shall mean the Construction Manager's Fee as defined in Section 6.1.2 of this Agreement.

§ 6.3.5 If no specific provision is made in Section 6.1.3 for adjustment of the Construction Manager's Fee in the case of changes in the Work, or if the extent of such changes is such, in the aggregate, that application of the adjustment provisions of Section 6.1.3 will cause substantial inequity to the Owner or Construction Manager, the Construction Manager's Fee shall be equitably adjusted on the same basis that was used to establish the Fee for the original Work, and the Guaranteed Maximum Price shall be adjusted accordingly.

ARTICLE 7 COST OF THE WORK FOR CONSTRUCTION PHASE

§ 7.1 Costs of the Work to Be Reimbursed

§ 7.1.1 The term Cost of the Work shall mean costs necessarily incurred by the Construction Manager in the proper performance of the Work. The Cost of the Work shall include only the items set forth in Sections 7.1 through 7.7.

§ 7.1.2 Where, pursuant to the Contract Documents, any cost is subject to the Owner's prior approval, the Construction Manager shall obtain such approval in writing prior to incurring the cost.

§ 7.1.3 Costs shall be at rates not higher than the standard rates paid at the place of the Project, except with prior written approval of the Owner.

§ 7.2 Labor Costs

§ 7.2.1 Wages or salaries of construction workers directly employed by the Construction Manager to perform the construction of the Work at the site or, with the Owner's prior approval, at off-site workshops, at the rates set forth on the "Rate Schedule," attached as Exhibit H. Construction Manager shall provide Owner with details in support of all wage rates. Said rates shall be all inclusive of taxes, benefits of whatever kind or nature, vacation, leave, training, safety and insurance. The Construction Manager shall disclose what, if any, portion of any rate is attributable to a vehicle allowance. The Construction Manager shall only be entitled to its Fee on Work performed by individuals/positions set forth on Exhibit H. The Construction Manager may substitute people, as provided herein, at the positions identified on Exhibit H. The Construction Manager may not add positions or individuals to positions without the prior written consent of the Owner. The rates agreed upon Rate Schedule may not be audited.

§ 7.2.2 Wages or salaries of the Construction Manager's supervisory and administrative personnel when stationed at the site and performing Work, with the Owner's prior approval at the rates set forth on the "Rate Schedule" attached as Exhibit H and subject to the above. All of the Construction Manager's own supervisory and administrative personnel which is authorized in this Article 7.2 shall be considered Labor Costs and not General Conditions and the positions and hours billed subject to audit, but not the rates themselves.

§ 7.2.2.1 Wages or salaries of the Construction Manager's supervisory and administrative personnel when performing Work and stationed at a location other than the site, but only for that portion of time required for the Work and limited to the personnel and activities identified on the "Rate Schedule" attached as Exhibit H, and subject to the above.:
(Identify the personnel, type of activity and, if applicable, any agreed upon percentage of time to be devoted to the Work.)

§ 7.2.3 Wages and salaries of the Construction Manager's supervisory or administrative personnel engaged at factories, workshops or while traveling, in expediting the production or transportation of materials or equipment required for the Work, but only for that portion of their time required for the Work and with the Owner's prior written approval, and at the rate set forth on the "Rate Schedule" attached as Exhibit H.

§ 7.2.4 Costs paid or incurred by the Construction Manager, as required by law or collective bargaining agreements, for taxes, insurance, contributions, assessments and benefits and, for personnel not covered by collective bargaining agreements, customary benefits such as sick leave, medical and health benefits, holidays, vacations and pensions, provided such costs are based on wages and salaries included in the Labor Rates set forth in the Rate Schedule .

§ 7.2.5 If agreed rates for labor costs, in lieu of actual costs, are provided in this Agreement, the rates shall remain unchanged throughout the duration of this Agreement, but subject to the yearly increase as set forth in the particular Rate Schedule.

§ 7.3 Subcontract Costs

Payments made by the Construction Manager to Subcontractors in accordance with the requirements of the subcontracts and this Agreement. Should Construction Manager require Subcontractors to provide performance and payment bonds, the Owner shall be names as a dual obligee/benefiary on the performance bonds.

§ 7.4 Costs of Materials and Equipment Incorporated in the Completed Construction

§ 7.4.1 Costs, including transportation and storage at the site, of materials and equipment incorporated, or to be incorporated, in the completed construction.

§ 7.4.2 Costs of materials described in the preceding Section 7.4.1 in excess of those actually installed to allow for reasonable waste and spoilage. Unused excess materials, if any, shall become the Owner's property at the completion of the Work or, at the Owner's option, shall be sold by the Construction Manager. Any amounts realized from such sales shall be credited to the Owner as a deduction from the Cost of the Work.

§ 7.5 Costs of Other Materials and Equipment, Temporary Facilities and Related Items

§ 7.5.1 Costs of transportation, storage, installation, dismantling, maintenance, and removal of materials, supplies, temporary facilities, machinery, equipment and hand tools not customarily owned by construction workers that are provided by the Construction Manager at the site and fully consumed in the performance of the Work. Costs of materials, supplies, temporary facilities, machinery, equipment, and tools, that are not fully consumed, shall be based on the

reasonable cost or value of the item at the time it is first used on the Project site less the value of the item when it is no longer used at the Project site. Costs for items not fully consumed by the Construction Manager shall mean fair market value.

§ 7.5.2 Reasonable rental charges for temporary facilities, machinery, equipment, and hand tools not customarily owned by construction workers that are provided by the Construction Manager at the site, and the costs of transportation, installation, dismantling, minor repairs, and removal of such temporary facilities, machinery, equipment, and hand tools. Rates and quantities of equipment owned by the Construction Manager, or a related party as defined in Section 7.8, shall be subject to the Owner's prior approval. The total rental cost of any such equipment may not exceed the purchase price of any comparable item.

§ 7.5.3 Costs of removal of debris from the site of the Work and its proper and legal disposal.

§ 7.5.4 Costs of the Construction Manager's site office, including general office equipment and supplies.

§ 7.5.5 Costs of materials and equipment suitably stored off the site at a mutually acceptable location, subject to the Owner's prior written approval. When materials are stored off site, the Construction Manager shall:

.1 Prepare and file a UCC-1 Financing Statement in the Commonwealth of Pennsylvania
.2 Ensure materials stored off site are specifically identified and marked as owned by the Owner
.3 Provide a release of liens to the Owner
.4 Provide photographs of the marked stored materials
.5 Ensure that the materials are properly secured
.6 Provide evidence that such materials have been insured to the Owner's reasonable satisfaction.

§ 7.6 Miscellaneous Costs

§ 7.6.1 Premiums for that portion of insurance and bonds required by the Contract Documents that can be directly attributed to this Contract and with the Owner's prior written approval. The parties agree on .97% (GLI) and .23% (Builders Risk).

§ 7.6.1.1 Costs for self-insurance, for either full or partial amounts of the coverages required by the Contract Documents, with the Owner's prior written approval.

§ 7.6.1.2 Costs for insurance through a captive insurer owned or controlled by the Construction Manager, with the Owner's prior written approval.

§ 7.6.2 Sales, use, or similar taxes, imposed by a governmental authority, that are related to the Work and for which the Construction Manager is liable.

§ 7.6.3 Fees and assessments for the building permit, and for other permits, licenses, and inspections, for which the Construction Manager is required by the Contract Documents to pay. If the Owner is paying for the building permit, such shall not be included in the Cost of the Work. Any other costs or fees imposed by an issuing authority shall be reimbursed at actual cost and shall not be subject to a Fee.

§ 7.6.4 Fees of laboratories for tests required by the Contract Documents; except those related to defective or nonconforming Work for which reimbursement is excluded under Article 13 of AIA Document A201–2017 or by other provisions of the Contract Documents, and which do not fall within the scope of Section 7.7.3.

§ 7.6.5 Royalties and license fees paid for the use of a particular design, process, or product, required by the Contract Documents.

§ 7.6.5.1 The cost of defending suits or claims for infringement of patent rights, copyrights or trademarks arising from requirements of the Contract Documents, payments made in accordance with legal judgments against the Construction Manager resulting from such suits or claims, and payments of settlements made with the Owner's consent, unless the Construction Manager for designated design or design assist Work had reason to believe that the required design, process, or product was an infringement of a copyright or a patent, and the Construction Manager failed to promptly furnish such information to the Architect as required by Article 3 of AIA Document A201–2017. The costs of legal defenses,

judgments, and settlements shall not be included in the Cost of the Work used to calculate the Construction Manager's Fee or subject to the Guaranteed Maximum Price.

§ 7.6.6 Costs for communications services, electronic equipment, and software, directly related to the Work and located at the site, with the Owner's prior written approval. The Cost of the Work shall not include technology equipment that is customarily provided by the Construction Manager to employees such as cell phones and I-Pads, etc.

§ 7.6.7 Costs of document reproductions and delivery charges.

§ 7.6.8 Subject to the Owner's prior written approval, deposits lost for causes other than the Construction Manager's negligence or failure to fulfill a specific responsibility in the Contract Documents.

§ 7.6.9 Legal, mediation and arbitration costs, including reasonable attorneys' fees, other than those arising from disputes between the Owner and Construction Manager or between Construction Manager and any subcontractor or supplier, reasonably incurred by the Construction Manager after the execution of this Agreement in the performance of the Work and with the Owner's prior written approval. All legal issues which may involve the Owner shall be immediately brought to the attention of the Owner. In no event and notwithstanding anything to the contrary shall the Cost of the Work include damages, losses, expenses, or legal fees and costs associated with a dispute between the Construction Manager and any subcontractor or supplier.

§ 7.6.10 Expenses incurred in accordance with the Construction Manager's standard written personnel policy for relocation and temporary living allowances of the Construction Manager's personnel required for the Work, with the Owner's prior written approval.

§ 7.6.11 That portion of the reasonable expenses of the Construction Manager's supervisory or administrative personnel incurred while traveling in discharge of duties connected with the Work.

§ 7.7 Other Costs and Emergencies

§ 7.7.1 Other costs incurred in the performance of the Work, with the Owner's prior approval.

§ 7.7.2 Costs incurred in taking action to prevent threatened damage, injury, or loss, in case of an emergency affecting the safety of persons and property, as provided in Article 10 of AIA Document A201–2017.

§ 7.7.3 Costs of repairing or correcting damaged or nonconforming Work executed by the Construction Manager, Subcontractors, or suppliers, provided that such damaged or nonconforming Work was not caused by the negligence of, or failure to fulfill a specific responsibility by, the Construction Manager, and only to the extent that the cost of repair or correction is not recovered by the Construction Manager from insurance, sureties, Subcontractors, suppliers, or others. In no event and notwithstanding anything to the contrary herein shall the Cost of the Work include the cost of repair or correction of any defective or deficient Work or warranty items.

§ 7.7.4 The costs described in Sections 7.1 through 7.7 shall be included in the Cost of the Work, notwithstanding any provision of AIA Document A201–2017 or other Conditions of the Contract which may require the Construction Manager to pay such costs, unless such costs are excluded by the provisions of Section 7.9.

§ 7.8 Related Party Transactions

§ 7.8.1 For purposes of this Section 7.8, the term "related party" shall mean (1) a parent, subsidiary, affiliate, or other entity having common ownership of, or sharing common management with, the Construction Manager; (2) any entity in which any stockholder in, or management employee of, the Construction Manager holds an equity interest in excess of ten percent in the aggregate; (3) any entity which has the right to control the business or affairs of the Construction Manager; or (4) any person, or any member of the immediate family of any person, who has the right to control the business or affairs of the Construction Manager.

§ 7.8.2 If any of the costs to be reimbursed arise from a transaction between the Construction Manager and a related party, the Construction Manager shall notify the Owner in writing of the specific nature of the contemplated transaction, including the identity of the related party and the anticipated cost to be incurred, before any such transaction is consummated or cost incurred. If the Owner, after such notification, authorizes the proposed transaction in writing, then the cost incurred shall be included as a cost to be reimbursed, and the Construction Manager shall procure the Work,

equipment, goods, or service, from the related party, as a Subcontractor, according to the terms of Article 9. If the Owner fails to authorize the transaction in writing, the Construction Manager shall procure the Work, equipment, goods, or service from some person or entity other than a related party according to the terms of Article 9.

§ 7.9 Costs Not To Be Reimbursed or Paid

§ 7.9.1 The Cost of the Work shall not include the items listed below:

.1 Salaries and other compensation of the Construction Manager's personnel stationed at the Construction Manager's principal office or offices other than the site office, except as specifically provided in Section 7.2, or as may be provided in Article 14;

.2 Bonuses, profit sharing, incentive compensation, and any other discretionary payments, paid to anyone hired by the Construction Manager or paid to any Subcontractor or vendor, unless the Owner has provided prior approval;

.3 Expenses of the Construction Manager's principal office and offices other than the site office;

.4 Overhead and general expenses, except as may be expressly included in Sections 7.1 to 7.7;

.5 The Construction Manager's capital expenses, including interest on the Construction Manager's capital employed for the Work;

.6 Except as provided in Section 7.7.3 of this Agreement, costs due to the negligence of, or failure to fulfill a specific responsibility of the Contract by, the Construction Manager, Subcontractors, and suppliers, or anyone directly or indirectly employed by any of them or for whose acts any of them may be liable;

.7 Any cost not specifically and expressly described in Sections 7.1 to 7.7 or the GMP Amendment;

.8 Costs, other than costs included in Change Orders approved by the Owner, that would cause the Guaranteed Maximum Price, as adjusted pursuant to this Agreement to be exceeded; and

.9 Costs for services incurred during the Preconstruction Phase unless agreed to in writing by the Owner and only to the extent of such written authorization.

ARTICLE 8 DISCOUNTS, REBATES, AND REFUNDS

§ 8.1 Cash discounts obtained on payments made by the Construction Manager shall accrue to the Owner if (1) before making the payment, the Construction Manager included the amount to be paid, less such discount, in an Application for Payment and received payment from the Owner, or (2) the Owner has deposited funds with the Construction Manager with which to make payments; otherwise, cash discounts shall accrue to the Construction Manager. Trade discounts, rebates, refunds, and amounts received from sales of surplus materials and equipment shall accrue to the Owner, and the Construction Manager shall make provisions so that they can be obtained.

§ 8.2 Amounts that accrue to the Owner in accordance with the provisions of Section 8.1 shall be credited to the Owner as a deduction from the Cost of the Work.

ARTICLE 9 SUBCONTRACTS AND OTHER AGREEMENTS

§ 9.1 Those portions of the Work that the Construction Manager does not customarily perform with the Construction Manager's own personnel shall be performed under subcontracts or other appropriate agreements with the Construction Manager. The Owner may designate specific persons from whom, or entities from which, the Construction Manager shall obtain bids. The Construction Manager shall obtain bids from prequalified Subcontractors, and from suppliers of materials or equipment fabricated especially for the Work, who are qualified to perform that portion of the Work in accordance with the requirements of the Contract Documents. The Construction Manager shall be responsible for analyzing and then reviewing the complete scope of all bids with the Architect and the Owner, after which time a recommendation will be made to the Owner as to which bids the Construction Manager intends to accept. The Owner then has the right to review the Construction Manager's list of proposed subcontractors and suppliers in consultation with the Architect and, subject to Section 9.1.1, to object to any subcontractor or supplier. Any advice of the Architect, or approval or objection by the Owner, shall not relieve the Construction Manager of its responsibility to perform the Work in accordance with the Contract Documents. The Construction Manager shall not be required to contract with anyone to whom the Construction Manager has reasonable objection. The Construction Manager shall sign and hold written contracts with the various Subcontractors and Suppliers and shall be fully responsible to the Owner for their Work.

§ 9.1.1 When a specific subcontractor or supplier (1) is recommended to the Owner by the Construction Manager; (2) is qualified to perform that portion of the Work; and (3) has submitted a bid that conforms to the requirements of the Contract Documents without reservations or exceptions, but the Owner requires that another bid be accepted, then the Construction Manager may require that a Change Order be issued to adjust the Guaranteed Maximum Price by the

difference between the bid of the person or entity recommended to the Owner by the Construction Manager and the amount of the subcontract or other agreement actually signed with the person or entity designated by the Owner.

§ 9.2 Subcontracts or other agreements shall conform to the applicable payment provisions of this Agreement and shall not be awarded on the basis of cost plus a fee without the Owner's prior written approval. If a subcontract is awarded on the basis of cost plus a fee, the Construction Manager shall provide in the subcontract for the Owner to receive the same audit rights with regard to the Subcontractor as the Owner receives with regard to the Construction Manager in Article 10.

ARTICLE 10 ACCOUNTING RECORDS

The Construction Manager shall keep full and detailed records and accounts related to the Cost of the Work, and exercise such controls, as may be necessary for proper financial management under this Contract and to substantiate all costs incurred. The accounting and control systems shall be satisfactory to the Owner. The Owner and the Owner's auditors shall, during regular business hours and upon reasonable notice, be afforded access to, and shall be permitted to audit and copy, the Construction Manager's records and accounts, including complete documentation supporting accounting entries, books, job cost reports, correspondence, instructions, drawings, receipts, subcontracts, Subcontractor's proposals, Subcontractor's invoices, purchase orders, vouchers, memoranda, and other data relating to this Contract. The Construction Manager shall preserve these records for a period of four years after final payment, or for such longer period as may be required by law.

ARTICLE 11 PAYMENTS FOR CONSTRUCTION PHASE SERVICES

§ 11.1 Progress Payments

§ 11.1.1 The Construction Manager shall prepare and submit a preliminary Schedule of Values ("SOV") to the Architect and Owner for review and acceptance as an exhibit to the GMP Amendment. The SOV shall not be front-loaded. Based upon Applications for Payment submitted to the Architect by the Construction Manager, and Certificates for Payment issued by the Architect, the Owner shall make progress payments on account of the Contract Sum, to the Construction Manager, as provided below and elsewhere in the Contract Documents. With every Application for Payment, Construction Manager shall provide Owner with a live excel file of the G702 and G703. The Applications for Payment shall not include Change Orders which have not been approved by the Owner in writing. The Owner's Representative shall receive a pencil-draft of the Application for Payment and supporting documents as required herein (except for lien releases) from the Construction Manger by the 15th of the month. The Owner's Representative and Construction Manager shall visit the site to confirm Work in place. The Owner's representative shall provide written comment within five (5) business days.

§ 11.1.2 The period covered by each Application for Payment shall be one calendar month ending on the last day of the month.

§ 11.1.3 Provided that an Application for Payment including all supporting documentation is received by the Architect and Owner's Representative not later than the first day of a month, the Owner shall make payment of the amount certified to the Construction Manager not later than the last day of the same month. If an Application for Payment is received by the Architect and Owner's Representative after the application date fixed above, payment of the amount certified shall be made by the Owner not later than thirty (30) days after the Architect and Owner's Representative receives the Application for Payment.
(Federal, state or local laws may require payment within a certain period of time.)

§ 11.1.4 With each Application for Payment, the Construction Manager shall submit payrolls, petty cash accounts, receipted invoices or invoices with check vouchers attached, and any other evidence required by the Owner or Architect to demonstrate that payments already made by the Construction Manager on account of the Cost of the Work equal or exceed progress payments already received by the Construction Manager, plus payrolls for the period covered by the present Application for Payment, less that portion of the progress payments attributable to the Construction Manager's Fee.

§ 11.1.4.1 Prior to its first Application for Payment, Construction Manager shall further submit a list of the name and address of any individuals or entities who or which have been engaged or will be engaged as a subcontractor or supplier to the Construction Manager on the Project, as well as the type of materials, service, equipment or labor to be supplied by them to the extent individuals or entities are known by the Construction Manager at the time of submission. Construction Manager shall provide the Owner with the names and addresses of any additional subcontractors and/or suppliers

involved in the Work, and the requested information within five (5) days of engaging same. Failure to submit such information to the Owner shall serve as a basis for withholding payment to the Construction Manager.

§ 11.1.4.2 With each Application for Payment, the Construction Manager shall include a notarized Acknowledgment of Progress Payment and Release of Liens and Claims, the form and content of which shall be provided by the Owner to the Construction Manager for itself and ones from all with lien rights on the Project. In addition, starting with the Second Application for Payment, the Construction Manager shall provide an Unconditional Acknowledgement of Progress Payment and Release of Liens and Claims in a form and content provided by the Owner and similar ones from all subcontractor and suppliers with lien rights confirming their receipt of payment out of the funds paid by the Owner.

§ 11.1.5 Each Application for Payment shall be based on the most recent schedule of values submitted by the Construction Manager in accordance with the Contract Documents and approved by the Owner which identifies each subcontractor and all components of the GMP. The schedule of values shall allocate the entire Guaranteed Maximum Price among: (1) the various portions of the Work; (2) any contingency for costs that are included in the Guaranteed Maximum Price but not otherwise allocated to another line item or included in a Change Order; and (3) the Construction Manager's Fee.

§ 11.1.5.1 The schedule of values shall be prepared in such form and supported by such data to substantiate its accuracy as the Owner may require. The schedule of values shall be used as a basis for reviewing the Construction Manager's Applications for Payment.

§ 11.1.5.2 The allocation of the Guaranteed Maximum Price under this Section 11.1.5 shall not constitute a separate guaranteed maximum price for the Cost of the Work of each individual line item in the schedule of values.

§ 11.1.5.3 When the Construction Manager allocates costs from a contingency to another line item in the schedule of values, the Construction Manager shall submit supporting documentation to the Architect and Owner in accordance with the provisions herein for use of Contingency.

§ 11.1.6 Applications for Payment shall show the percentage of completion of each portion of the Work as of the end of the period covered by the Application for Payment. The percentage of completion shall be the lesser of (1) the percentage of that portion of the Work which has actually been completed, or (2) the percentage obtained by dividing (a) the expense that has actually been incurred by the Construction Manager on account of that portion of the Work and for which the Construction Manager has made payment or intends to make payment prior to the next Application for Payment, by (b) the share of the Guaranteed Maximum Price allocated to that portion of the Work in the schedule of values.

§ 11.1.7 In accordance with AIA Document A201–2017 and subject to other provisions of the Contract Documents, the amount of each progress payment shall be computed as follows:

§ 11.1.7.1 The amount of each progress payment shall first include:

.1 That portion of the Guaranteed Maximum Price properly allocable to completed Work as determined by multiplying the percentage of completion of each portion of the Work by the share of the Guaranteed Maximum Price allocated to that portion of the Work in the most recent schedule of values;

.2 That portion of the Guaranteed Maximum Price properly allocable to materials and equipment delivered and suitably stored at the site for subsequent incorporation in the completed construction or, if approved in writing in advance by the Owner, suitably stored off the site at a location agreed upon in writing;

.3 That portion of Construction Change Directives that the Architect determines, in the Architect's professional judgment, to be reasonably justified; and

.4 The Construction Manager's Fee, computed upon the Cost of the Work described in the preceding Sections 11.1.7.1.1 and 11.1.7.1.2 at the rate stated in Section 6.1.2 or, if the Construction Manager's Fee is stated as a fixed sum in that Section, an amount that bears the same ratio to that fixed-sum fee as the Cost of the Work included in Sections 11.1.7.1.1 and 11.1.7.1.2 bears to a reasonable estimate of the probable Cost of the Work upon its completion.

§ 11.1.7.2 The amount of each progress payment shall then be reduced by:

.1 The aggregate of any amounts previously paid by the Owner;

.2 The amount, if any, for Work that remains uncorrected and for which the Architect has previously withheld a Certificate for Payment as provided in Article 9 of AIA Document A201–2017;

.3 Any amount for which the Construction Manager does not intend to pay a Subcontractor or material supplier, unless the Work has been performed by others the Construction Manager intends to pay;

.4 For Work performed or defects discovered since the last payment application, any amount for which the Architect may withhold payment, or nullify a Certificate of Payment in whole or in part, as provided in Article 9 of AIA Document A201–2017 or for which the Owner may withhold payment;

.5 The shortfall, if any, indicated by the Construction Manager in the documentation required by Section 11.1.4 to substantiate prior Applications for Payment, or resulting from errors subsequently discovered by the Owner's auditors in such documentation; and

.6 Retainage withheld pursuant to Section 11.1.8.

§ 11.1.8 Retainage

§ 11.1.8.1 For each progress payment made prior to Substantial Completion of the Work, the Owner may withhold the following amount, as retainage, from the payment otherwise due:
(Insert a percentage or amount to be withheld as retainage from each Application for Payment. The amount of retainage may be limited by governing law.)

Retainage shall be 10% of the Cost of the Work and Construction Manager's Fee that the Construction Manager invoices in the Application for Payment.

§ 11.1.8.1.1 The following items are not subject to retainage:
(Insert any items not subject to the withholding of retainage, such as general conditions, insurance, etc.)

All items which the Construction Manager is including in an Application for Payment shall be subject to retainage, but for deposits for long-lead items, Preconstruction Costs, Construction Manager's own staff and General Conditions costs.

§ 11.1.8.2 Reduction or limitation of retainage, if any, shall be as follows:
(If the retainage established in Section 11.1.8.1 is to be modified prior to Substantial Completion of the entire Work,

At the time the Work is fifty percent (50%) complete, and thereafter, if the manner of the completion and its progress are and remain satisfactory to the Owner and in the absence of other good and sufficient reasons, the Owner will no longer withhold retainage from subsequent payments so that over time, retainage is reduced to five percent (5%). Owner in its sole discretion reserves the right to restore retainage to ten percent (10%) of the Contract Sum as is necessary to protect Owner against claims or if the Work or its progress is unsatisfactory to the Owner.

§ 11.1.8.3 Except as set forth in this Section 11.1.8.3, upon Substantial Completion of the Work, the Construction Manager may submit an Application for Payment that includes the retainage withheld from prior Applications for Payment pursuant to this Section 11.1.8. The Application for Payment submitted at Substantial Completion shall not include retainage as follows:
(Insert any other conditions for release of retainage, such as upon completion of the Owner's audit and reconciliation, upon Substantial Completion.)

Upon Substantial Completion of the Work, the Construction Manager will be paid all retainage, less one hundred fifty percent (150%) of the value of incomplete and/or defective work, i.e. "punch list". If retainage is insufficient to cover the value of the punch list as provided herein, the Owner may withhold sums due under an Application for Payment. As items on the punch list are completed, the Construction Manager shall invoice the Owner monthly for the same and Construction Manager will be paid one hundred fifty percent (150%) of their value at the next progress payment, subject to the provisions hereof. In the event that Construction Manager is not making sufficient progress on completion of punch list items, the Owner may continue to withhold the full amount of the punch list until such time as all punch list items are satisfied.

§ 11.1.9 If final completion of the Work is materially delayed through no fault of the Construction Manager, the Owner may pay the Construction Manager any additional amounts in accordance with Article 9 of AIA Document A201–2017.

§ 11.1.10 Except with the Owner's prior written approval, the Construction Manager shall not make advance payments to suppliers for materials or equipment which have not been delivered and suitably stored at the site.

§ 11.1.11 The Owner and the Construction Manager shall agree upon a mutually acceptable procedure for review and approval of payments to Subcontractors, and the percentage of retainage held on Subcontracts, and the Construction Manager shall execute subcontracts in accordance with those agreements.

§ 11.1.12 In taking action on the Construction Manager's Applications for Payment the Architect and Owner shall be entitled to rely on the accuracy and completeness of the information furnished by the Construction Manager, and such action shall not be deemed to be a representation that (1) the Architect or Owner has made a detailed examination, audit, or arithmetic verification, of the documentation submitted in accordance with Section 11.1.4 or other supporting data; (2) that the Architect or Owner has made exhaustive or continuous on-site inspections; or (3) that the Architect or Owner has made examinations to ascertain how or for what purposes the Construction Manager has used amounts previously paid on account of the Contract. Such examinations, audits, and verifications, if required by the Owner, will be performed by the Owner's auditors acting in the sole interest of the Owner.

§ 11.2 Final Payment

§ 11.2.1 Final payment, constituting the entire unpaid balance of the Contract Sum shall be determined by taking the Cost of the Work substantiated by the Construction Manager's final accounting and the Construction Manager's Fee to the extent less the aggregate of previous payments made by the Owner, shall be made by the Owner to the Construction Manager when

.1 the Construction Manager has fully performed the Contract and has provide an unconditional Certificate of Occupancy and all approvals of governmental bodies with jurisdiction over the Project, except for the Construction Manager's responsibility to correct Work as provided in Article 12 of AIA Document A201–2017, and to satisfy other requirements, if any, which extend beyond final payment;

.2 the Construction Manager has submitted a final accounting for the Cost of the Work which includes a breakdown of all Change Orders, the use of Contingency, construction holds, construction allowances, alternatives, savings and costs and a final Application for Payment; and

.3 a final Certificate for Payment has been issued by the Architect in accordance with Section 11.2.2.2 and approved by the Owner; and

.4 the Construction Manager has provided the Owner with written assignment by all Subcontractors and suppliers of materials and equipment of all warranties and guarantees as specified in the Project Specifications and Contract Documents; and

.5 the Construction Manager has provided the Owner with three (3) copies of any Maintenance Manual issued by any manufacturer and/or supplier or such training as required by the Contract Documents; and

.6 the Construction Manager has provided the Owner with the project Record reproducible drawings showing changes made during construction in the format and content acceptable to the Owner; and

.7 the Owner's receipt of conditional Acknowledgment of Receipt of Payment and Release of Liens and Claims. Should any subcontractor or supplier with lien rights refuse to provide the same, the Construction Manager shall furnish a bond satisfactory to the Owner to indemnify it against and liens and claims; and

.8 the Owner's receipt of all deliverables as specified in the Project Specifications and Contract Documents; and

.9 the Owner's receipt of all keys issued to Construction Manager and subcontractors, if applicable.

The Construction Manager shall provide Unconditional and Final Acknowledgments of Payment and Release of Liens and Claims for itself and all subcontractors and suppliers with lien rights within ten (10) days after the Construction Manager receives final payment.

§ 11.2.2 Within 45 days of the Owner's receipt of the Construction Manager's final accounting for the Cost of the Work, the Owner shall commence an audit of the Cost of the Work or notify the Architect that it will not conduct an audit.

§ 11.2.2.1 If the Owner conducts an audit of the Cost of the Work, the Owner shall, within 20 days after completion of the audit, submit a written report based upon the auditors' findings to the Architect. The parties shall work cooperatively to exchange information during the course of the audit in order to complete it in a timely manner.

§ 11.2.2.2 Within seven days after receipt of the written report described in Section 11.2.2.1, or receipt of notice that the Owner will not conduct an audit, and provided that the other conditions of Section 11.2.1 have been met, the Architect will either issue to the Owner a final Certificate for Payment with a copy to the Construction Manager, or notify the Construction Manager and Owner in writing of the Architect's reasons for withholding a certificate as provided in Article 9 of AIA Document A201–2017. The time periods stated in this Section 11.2.2 supersede those stated in Article 9 of AIA

Document A201–2017. The Architect is not responsible for verifying the accuracy of the Construction Manager's final accounting.

§ 11.2.2.3 If the Owner's auditors' report concludes that the Cost of the Work, as substantiated by the Construction Manager's final accounting, is less than claimed by the Construction Manager, the Construction Manager shall be entitled to request mediation of the disputed amount without seeking an initial decision pursuant to Article 15 of AIA Document A201–2017. A request for mediation shall be made by the Construction Manager within 30 days after the Construction Manager's receipt of a copy of the Architect's final Certificate for Payment. Failure to request mediation within this 30-day period shall result in the substantiated amount reported by the Owner's auditors becoming binding on the Construction Manager. Pending a final resolution of the disputed amount, the Owner shall pay the Construction Manager the amount certified in the Architect's final Certificate for Payment.

§ 11.2.3 The Owner's final payment to the Construction Manager shall be made no later than 30 days after the issuance of the Architect's final Certificate for Payment, or as follows:

§ 11.2.4 If, subsequent to final payment, and at the Owner's written request, the Construction Manager incurs costs, described in Sections 7.1 through 7.7, and not excluded by Section 7.9 or elsewhere in the Contract Documents, to correct defective or nonconforming Work, the Owner shall reimburse the Construction Manager for such costs, and the Construction Manager's Fee applicable thereto, on the same basis as if such costs had been incurred prior to final payment, but not in excess of the Guaranteed Maximum Price. If adjustments to the Contract Sum are provided for in Section 6.1.7, the amount of those adjustments shall be recalculated, taking into account any reimbursements made pursuant to this Section 11.2.4 in determining the net amount to be paid by the Owner to the Construction Manager. In no event shall Construction Manager be entitled to any compensation for correction of warranty items or related damages or costs.

§ 11.3 Interest

Payments due and unpaid under the Contract shall bear interest from the date payment is due at the rate stated below, or in the absence thereof, at the legal rate prevailing from time to time at the place where the Project is located.
(Insert rate of interest agreed upon, if any.)

per annum interest shall be Prime Rate as set forth in the Money section of the *Wall Street Journal* as of the date of execution of this Agreement %

ARTICLE 12 DISPUTE RESOLUTION

§ 12.1 Initial Decision Maker

§ 12.1.1 Any Claim between the Owner and Construction Manager shall be resolved in accordance with the provisions set forth in this Article 12 and Article 15 of A201–2017. However, for Claims arising from or relating to the Construction Manager's Preconstruction Phase services, no decision by the Initial Decision Maker shall be required as a condition precedent to mediation or binding dispute resolution, and Section 12.1.2 of this Agreement shall not apply.

§ 12.1.2 The Owner will serve as the Initial Decision Maker pursuant to Article 15 of AIA Document A201–2017 for Claims arising from or relating to the Construction Manager's Construction Phase services, unless the parties appoint below another individual, not a party to the Agreement, to serve as the Initial Decision Maker.
(If the parties mutually agree, insert the name, address and other contact information of the Initial Decision Maker, if other than the Architect.)

All initial decisions shall be made by Kate Romano on behalf of the Owner.

§ 12.2 Binding Dispute Resolution

For any Claim subject to, but not resolved by mediation pursuant to Article 15 of AIA Document A201–2017, the method of binding dispute resolution shall be as follows:
(Check the appropriate box.)

[ ] Arbitration pursuant to Article 15 of AIA Document A201–2017

[X] Arbitration or litigation at the option of the Owner. If litigation, litigation shall be in the Court of Common Pleas of Allegheny County, Pennsylvania which shall have exclusive jurisdiction and venue

[ ] Other: *(Specify)*

If the Owner and Construction Manager do not select a method of binding dispute resolution, or do not subsequently agree in writing to a binding dispute resolution method other than litigation, Claims will be resolved by litigation in a court of competent jurisdiction.

ARTICLE 13 TERMINATION OR SUSPENSION

§ 13.1 Termination Prior to Execution of the Guaranteed Maximum Price Amendment

§ 13.1.1 If the Owner and the Construction Manager do not reach an agreement on the Guaranteed Maximum Price, the Owner may terminate this Agreement upon not less than seven days' written notice to the Construction Manager, and the Construction Manager may terminate this Agreement, upon not less than seven days' written notice to the Owner.

§ 13.1.2 In the event of termination of this Agreement pursuant to Section 13.1.1, the Construction Manager shall be compensated for Preconstruction Phase services and Work performed prior to receipt of a notice of termination, in accordance with the terms of this Agreement. In no event shall the Construction Manager's compensation under this Section exceed the compensation set forth in Section 5.1.

§ 13.1.3 Prior to the execution of the Guaranteed Maximum Price Amendment, the Owner may terminate this Agreement upon not less than seven days' written notice to the Construction Manager for the Owner's convenience and without cause, and the Construction Manager may terminate this Agreement, upon not less than seven days' written notice to the Owner, for the reasons set forth in Article 14 of A201–2017.

§ 13.1.4 In the event of termination of this Agreement pursuant to Section 13.1.3, the Construction Manager shall be equitably compensated for Preconstruction Phase services as provided herein and Work performed prior to receipt of a notice of termination. In no event shall the Construction Manager's compensation under this Section exceed the compensation set forth in Section 5.1.

§ 13.1.5 If the Owner terminates the Contract pursuant to Section 13.1.3 after the commencement of the Construction Phase but prior to the execution of the Guaranteed Maximum Price Amendment, the Owner shall pay to the Construction Manager an amount calculated as follows, which amount shall be in addition to any compensation paid to the Construction Manager under Section 13.1.4:

.1 Take the Cost of the Work incurred by the Construction Manager to the date of termination;

.2 Add the Construction Manager's Fee computed upon the Cost of the Work to the date of termination at the rate stated in Section 6.1; and

.3 Subtract the aggregate of previous payments made by the Owner for Construction Phase services.

In no event shall Construction Manager be entitled to lost profits, home office overhead, or similar renumeration.

§ 13.1.6 The Owner shall also pay the Construction Manager fair and reasonable compensation, either by purchase or rental at the election of the Owner, for any equipment owned by the Construction Manager that the Owner elects to retain and that is not otherwise included in the Cost of the Work under Section 13.1.5.1. To the extent that the Owner elects to take legal assignment of subcontracts and purchase orders (including rental agreements), the Construction Manager shall, as a condition of receiving the payments referred to in this Article 13, execute and deliver all such papers and take all such steps, including the legal assignment of such subcontracts and other contractual rights of the Construction Manager, as the Owner may require for the purpose of fully vesting in the Owner the rights and benefits of the Construction Manager under such subcontracts or purchase orders. All Subcontracts, purchase orders and rental agreements entered into by the Construction Manager will contain provisions allowing for assignment to the Owner as described above.

§ 13.1.6.1 If the Owner accepts assignment of subcontracts, purchase orders or rental agreements as described above, the Owner will reimburse or indemnify the Construction Manager for all costs arising under the subcontract, purchase order

or rental agreement, if those costs would have been reimbursable as Cost of the Work if the contract had not been terminated. If the Owner chooses not to accept assignment of any subcontract, purchase order or rental agreement that would have constituted a Cost of the Work had this agreement not been terminated, the Construction Manager will terminate the subcontract, purchase order or rental agreement and the Owner will pay the Construction Manager the reasonable out-of-pocket costs necessarily incurred by the Construction Manager and its subcontractors and suppliers because of such termination.

§ 13.2 Termination or Suspension Following Execution of the Guaranteed Maximum Price Amendment
§ 13.2.1 Termination
The Contract may be terminated by the Owner or the Construction Manager as provided in Article 14 of AIA Document A201–2017.

§ 13.2.2 Termination by the Owner for Cause
§ 13.2.2.1 If the Owner terminates the Contract for cause as provided in Article 14 of AIA Document A201–2017, the amount, if any, to be paid to the Construction Manager under Article 14 of AIA Document A201–2017 shall not cause the Guaranteed Maximum Price to be exceeded, nor shall it exceed an amount calculated as follows:

.1 Take the Cost of the Work incurred by the Construction Manager to the date of termination;
.2 Add the Construction Manager's Fee, computed upon the Cost of the Work to the date of termination at the rate stated in Section 6.1;
.3 Subtract the aggregate of previous payments made by the Owner; and
.4 Subtract the costs and damages incurred, or to be incurred, by the Owner under Article 14 of AIA Document A201–2017.

§ 13.2.2.2 The Owner shall also pay the Construction Manager fair compensation, either by purchase or rental at the election of the Owner, for any equipment owned by the Construction Manager that the Owner elects to retain and that is not otherwise included in the Cost of the Work under Section 13.2.2.1.1. To the extent that the Owner elects to take legal assignment of subcontracts and purchase orders (including rental agreements), the Construction Manager shall, as a condition of receiving the payments referred to in this Article 13, execute and deliver all such papers and take all such steps, including the legal assignment of such subcontracts and other contractual rights of the Construction Manager, as the Owner may require for the purpose of fully vesting in the Owner the rights and benefits of the Construction Manager under such subcontracts or purchase orders.

§ 13.2.3 Termination by the Owner for Convenience
If the Owner terminates the Contract for convenience in accordance with Article 14 of AIA Document A201–2017, then the Owner shall pay the Construction Manager a termination fee as follows:
(Insert the amount of or method for determining the fee, if any, payable to the Construction Manager following a termination for the Owner's convenience.)

If termination for Owner's convenience, Construction Manager shall be paid in accordance with Article 14.4 of AIA Document A201-2017, as amended.

§ 13.3 Suspension
The Work may be suspended by the Owner as provided in Article 14 of AIA Document A201–2017; in such case, the Guaranteed Maximum Price and Contract Time shall be increased as provided in Article 14 of AIA Document A201–2017, except that the term "profit" shall be understood to mean the Construction Manager's Fee as described in Sections 6.1 and 6.3.5 of this Agreement.

ARTICLE 14 MISCELLANEOUS PROVISIONS
§ 14.1 Terms in this Agreement shall have the same meaning as those in A201–2017. Where reference is made in this Agreement to a provision of AIA Document A201–2017 or another Contract Document, the reference refers to that provision as amended or supplemented by other provisions of the Contract Documents.

§ 14.2 Successors and Assigns
§ 14.2.1 The Owner and Construction Manager, respectively, bind themselves, their partners, successors, assigns and legal representatives to covenants, agreements, and obligations contained in the Contract Documents. Except as provided in Section 14.2.2 of this Agreement, and in Section 13.2.2 of A201–2017, neither party to the Contract shall assign the

Contract as a whole without written consent of the other. If either party attempts to make an assignment without such consent, that party shall nevertheless remain legally responsible for all obligations under the Contract.

§ 14.2.2 The Owner may, without consent of the Construction Manager, assign the Contract to a lender providing construction financing for the Project, if the lender assumes the Owner's rights and obligations under the Contract Documents. The Construction Manager shall execute all consents reasonably required to facilitate the assignment.

§ 14.3 Insurance and Bonds

§ 14.3.1 Preconstruction Phase

The Construction Manager shall maintain the insurance for the duration of the Preconstruction Services performed under this Agreement as set forth in Exhibit B - Insurance and Bonds.

(Paragraphs deleted)
(Table deleted)
(Paragraphs deleted)

§ 14.3.2 Construction Phase

After execution of the Guaranteed Maximum Price Amendment, the Owner and the Construction Manager shall purchase and maintain insurance as set forth in Exhibit B, Insurance and Bonds, as amended and elsewhere in the Contract Documents.

§ 14.3.2.1 The Construction Manager shall upon request provide bonds as set forth in AIA Document A133™–2019 Exhibit B, and elsewhere in the Contract Documents. Should bonds be required, such shall be from a surety licensed in the Commonwealth of Pennsylvania and appearing on the most recent Treasury Circular 570.

§ 14.4 Notice in electronic format, pursuant to Article 1 of AIA Document A201–2017, may be given in accordance with AIA Document E203™–2013, Building Information Modeling and Digital Data Exhibit, if completed, or as otherwise set forth below:
(If other than in accordance with AIA Document E203–2013, insert requirements for delivering notice in electronic format such as name, title, and email address of the recipient and whether and how the system will be required to generate a read receipt for the transmission.)

§ 14.5 Other provisions:

The Contractor acknowledges and agrees that all personnel shall comply with the COVID-19 Safety & Health Guidelines as issued by governmental and regulatory agencies. All contractors/vendors/suppliers are required to educate their personnel on the current guidelines and provide the required PPE (face mask, gloves, etc.) to aid in the prevention of spreading the COVID-19 virus. It is the responsibility of the Contractor and each company working for it to ensure their personnel are following the guidelines and utilizing the required PPE. Contractor and its subcontractors, vendors and suppliers shall be solely responsible for and have control over the means, methods, techniques, sequences and procedures, including site safety and safety precautions and programs, including its COVID-19 safety program. Therefore, Owner assumes no liability for financial or health consequences from the actions or lack of actions taken by Contractor and ones for whom it is responsible, their employees and representatives, delays or suspensions, with regard to the COVID-19 guidelines, governmental actions or pandemic.

ARTICLE 15 SCOPE OF THE AGREEMENT

§ 15.1 This Agreement represents the entire and integrated agreement between the Owner and the Construction Manager and supersedes all prior negotiations, representations or agreements, either written or oral. This Agreement may be amended only by written instrument signed by both Owner and Construction Manager.

§ 15.2 The following documents comprise the Agreement:

.1 AIA Document A133™–2019, Standard Form of Agreement Between Owner and Construction Manager as Constructor where the basis of payment is the Cost of the Work Plus a Fee with a Guaranteed Maximum Price, as amended

.2 AIA Document A133™-2019, Exhibit A, Guaranteed Maximum Price Amendment, if executed

.3 AIA Document A133™–2019, Exhibit B, Insurance and Bonds, as amended
.4 AIA Document A201™–2017, General Conditions of the Contract for Construction, as amended
.5 Whiting-Turner VDC Execution Plan

Exhibit C – Preliminary Design Report & Addendum
Exhibit D C-100 Site Plan &C-050 Existing Conditions
Exhibit E- Letter of Intent
Exhibit F- Whiting-Turner Organization Chart
Exhibit G – Utility Rough-In Schedule
Exhibit H- Rate Schedule
Exhibit I – Preliminary Construction Schedule
Exhibit J – General Conditions

.6 Other Exhibits:
(Check all boxes that apply.)

[ ] AIA Document E234™–2019, Sustainable Projects Exhibit, Construction Manager as Constructor Edition, dated as indicated below:
(Insert the date of the E234-2019 incorporated into this Agreement.)

[ ] Supplementary and other Conditions of the Contract:

Document	Title	Date	Pages

.7 Other documents, if any, listed below:
(List here any additional documents that are intended to form part of the Contract Documents. AIA Document A201–2017 provides that the advertisement or invitation to bid, Instructions to Bidders, sample forms, the Construction Manager's bid or proposal, portions of Addenda relating to bidding or proposal requirements, and other information furnished by the Owner in anticipation of receiving bids or proposals, are not part of the Contract Documents unless enumerated in this Agreement. Any such documents should be listed here only if intended to be part of the Contract Documents.)

This Agreement is entered into as of the day and year first written above.

KRYSTAL BIOTECH, INC.

DocuSigned by:
krishi krishnan
26B27F8883E84C0...

OWNER *(Signature)*

(Printed name and title)

THE WHITING-TURNER CONTRACTING COMPANY

DocuSigned by:
Samuel R. Wells
E81A4E756BE45B...

CONSTRUCTION MANAGER *(Signature)*

Samuel R. Wells SR Vice President

(Printed name and title)

DS AP DS KK

DS DS

AIA® Document A201® – 2017

General Conditions of the Contract for Construction

for the following PROJECT:
(Name and location or address)

Krystal Biotech – Project Astra
Krystal Biotech Facility
7001 International Drive
Coraopolis, PA 15108

THE OWNER:
(Name, legal status and address)

Krystal Biotech, Inc.
2100 Wharton Street
Suite 701
Pittsburgh, PA 15203

THE ARCHITECT:
(Name, legal status and address)

Clark, Richardson & Biskup Consulting Engineers, Inc.
220 W. Germantown Pike
Suite 170
Plymouth Meeting, PA 19462

ADDITIONS AND DELETIONS:
The author of this document has added information needed for its completion. The author may also have revised the text of the original AIA standard form. An *Additions and Deletions Report* that notes added information as well as revisions to the standard form text is available from the author and should be reviewed. A vertical line in the left margin of this document indicates where the author has added necessary information and where the author has added to or deleted from the original AIA text.

This document has important legal consequences. Consultation with an attorney is encouraged with respect to its completion or modification.

For guidance in modifying this document to include supplementary conditions, see AIA Document A503™, Guide for Supplementary Conditions.

TABLE OF ARTICLES

INDEX– NOTE THAT INDEX REFERENCES HAVE NOT BEEN MODIFIED
(Topics and numbers in bold are Section headings.)

ARTICLE 1 GENERAL PROVISIONS

§ 1.1 Basic Definitions

§ 1.1.1 The Contract Documents

The Contract Documents are enumerated in the Agreement between the Owner and Contractor (hereinafter the Agreement) and consist of the Agreement, Conditions of the Contract (General, Supplementary and other Conditions), Guaranteed Maximum Price ("GMP") Exhibit, such other Exhibits identified in the Agreement or GMP Exhibit, Drawings, Specifications, Addenda issued prior to execution of the Contract, other documents listed in the Agreement, and Modifications issued after execution of the Contract. A Modification is (1) a written amendment to the Contract signed by both parties, (2) a Change Order, (3) a Construction Change Directive, or (4) a written order for a minor change in the Work issued by the Architect. Unless specifically enumerated in the Agreement, the Contract Documents do not include the advertisement or invitation to bid, Instructions to Bidders, sample forms, other information furnished by the Owner in anticipation of receiving bids or proposals, the Contractor's bid or Contractor's proposal, or portions of Addenda relating to bidding or proposal requirements. As used herein, Contract Sum shall mean GMP. The parties acknowledge and agree that during the course of the Project, Contractor and Owner may agree to GMP's per phase. The Contractor shall be bound to each.

§ 1.1.2 The Contract

The Contract Documents form the Contract for Construction. The Contract represents the entire and integrated agreement between the parties hereto and supersedes prior negotiations, representations, or agreements, either written or oral. The Contract may be amended or modified only by a Modification. The Contract Documents shall not be construed to create a contractual relationship of any kind (1) between the Contractor and the Architect or the Architect's consultants, (2) between the Owner and a Subcontractor or a Sub-subcontractor, except as set forth in paragraphs 5.3 and 5.4, (3) between the Owner and the Architect or the Architect's consultants, or (4) between any persons or entities other than the Owner and the Contractor. The Architect shall, however, be entitled to performance and enforcement of obligations under the Contract intended to facilitate performance of the Architect's duties.

§ 1.1.3 The Work

The term "Work" means the construction and services required by the Contract Documents, whether completed or partially completed, and includes all other labor, materials, equipment, and services provided or to be provided by the Contractor to fulfill the Contractor's obligations. The Work may constitute the whole or a part of the Project. The Contractor shall perform all Work in accordance with the skill, care and diligence of a contractor experienced in biotechnology construction projects ("Performance Expectations"). Contractor is advised that the Work is to be performed on land owned by the Allegheny Airport Authority and adjacent to Pittsburgh International Airport ("Airport"). Contractor's Work may not interfere with or be detrimental to any operations or the Airport.

§ 1.1.4 The Project

The Project is the total construction of which the Work performed under the Contract Documents may be the whole or a part and which may include construction by the Owner and by Separate Contractors.

§ 1.1.5 The Drawings

The Drawings are the graphic and pictorial portions of the Contract Documents showing the design, location and dimensions of the Work, generally including plans, elevations, sections, details, schedules, and diagrams.

§ 1.1.6 The Specifications

The Specifications are that portion of the Contract Documents consisting of the written requirements for materials, equipment, systems, standards and workmanship for the Work, and performance of related services.

§ 1.1.7 Instruments of Service

Instruments of Service are representations, in any medium of expression now known or later developed, of the tangible and intangible creative work performed by the Architect and the Architect's consultants under their respective professional services agreements. Instruments of Service may include, without limitation, studies, surveys, models, sketches, drawings, specifications, and other similar materials

§ 1.1.8 Initial Decision Maker

The Initial Decision Maker is the Owner as identified in the Agreement to render initial decisions on Claims in accordance with Section 15.2.

§ 1.1.9 Architect's Supplemental Instructions

An Architect's Supplemental Instruction ("ASI") is a document issued after the execution of the Agreement, instructing the Contractor to proceed with certain specific minor changes to the Work, with no change to either the Contract Time or Contract Sum as defined in Paragraph 7.4. To the extent Contractor believes that a change is not minor and should warrant an adjustment to either the Contract Time or Contract Sum, Contractor shall request a Change Order.

§ 1.1.10 Architect's Addendum

An Addendum is a modification, issued by the Architect, to the documents provided to the Contractor for bidding. The GMP shall take into consideration all Addendum.

§ 1.1.11 Architect's Bulletin

A Bulletin is a document, issued by the Architect, after execution of the GMP Exhibit and shall constitute a modification to the scope of Work to be agreed upon in a Change Order or subject to a Construction Change Directive and may or may not result in an adjustment to the Contract Time.

§ 1.2 Correlation and Intent of the Contract Documents

§ 1.2.1 The intent of the Contract Documents is to include all items necessary for the proper execution and completion of the Work by the Contractor. The Contract Documents are complementary, and what is required by one shall be as binding as if required by all; performance by the Contractor shall be required only to the extent consistent with the Contract Documents and reasonably inferable from them as being necessary to produce the intended results In the event of inconsistencies within or between parts of the Contract Documents, the Contractor shall (i) provide the better quality or greater quantity of Work or (ii) comply with the more stringent requirements; either or both in accordance with the Architect's reasonable interpretation unless Contractor has specified difficulty in writing and specifically advised the Owner in writing of such and obtained Owner's knowing consent. The Contractor shall be required to comply with applicable standards, codes and ordinances related to Contractor's performance of the Work

.1 On the Drawings, given dimensions shall take precedence over scaled measurements, and large scale drawings over small scale drawings.

.2 Before requesting the ordering of any material or doing any Work, the Contractor and each Subcontractor shall verify measurements at the Project site and shall be responsible for the correctness of such measurements. No extra charges or compensation will be allowed on account of differences between actual dimensions indicated on the Drawings. In the event a disparity arises, the Contractor and Owner shall meet to discuss the possible use of contingency or Change Order to address the disparity.

.3 If a minor change in the Work is found to be necessary due to actual field conditions, the Contractor shall submit detailed sketch of such departure to the Architect for approval before making the change. Approval of such change shall not be unreasonably withheld. Such change shall be subject to the Change Order procedures included herein.

.4 Contractor shall thoroughly acquaint itself with and comply with the terms, statutes, rules and regulations governing excavation in the area of underground utilities to the extent applicable to Contactor's express scope of Work.

(Paragraph deleted)

§ 1.2.1.5 The invalidity of any provision of the Contract Documents shall not invalidate the Contract or its remaining provisions. If it is determined that any provision of the Contract Documents violates any law, or is otherwise invalid or unenforceable, then that provision shall be revised to the extent necessary to make that provision legal and enforceable. In such case the Contract Documents shall be construed, to the fullest extent permitted by law, to give effect to the parties' intentions and purposes in executing the Contract.

§ 1.2.2 Organization of the Specifications into divisions, sections and articles, and arrangement of Drawings shall not control the Contractor in dividing the Work among Subcontractors or in establishing the extent of Work to be performed by any trade.

§ 1.2.3 Unless otherwise stated in the Contract Documents, words that have well-known technical or construction industry meanings are used in the Contract Documents in accordance with such recognized meanings.

§ 1.2.4 It is the intent of the Contract Documents to accomplish a complete and high- quality installation and Contractor's workmanship shall be that of an experienced contractor, executed by competent and experienced workers.

§ 1.2.5 Anything shown on the Drawings and not mentioned in the Specifications or mentioned in the Specifications and not shown on the Drawings shall have the same effect as if shown or mentioned respectively in both. Any Work shown on one Drawing shall be construed to be shown in all Drawings, and the Contractor shall coordinate the Work and Drawings to conform to the requirements of the Contract Documents.

§ 1.3 Capitalization

Terms capitalized in these General Conditions include those that are (1) specifically defined, (2) the titles of numbered articles, or (3) the titles of other documents published by the American Institute of Architects.

§ 1.4 Interpretation

In the interest of brevity the Contract Documents frequently omit modifying words such as "all" and "any" and articles such as "the" and "an," but the fact that a modifier or an article is absent from one statement and appears in another is not intended to affect the interpretation of either statement.

§ 1.5 Ownership and Use of Drawings, Specifications, and Other Instruments of Service

§ 1.5.1 The Owner shall be deemed the author and owner of the respective Instruments of Service, including the Drawings and Specifications, and retain all common law, statutory, and other reserved rights in their Instruments of Service, including copyrights. The Contractor, Subcontractors, Sub-subcontractors, and suppliers shall not own or claim a copyright in the Instruments of Service. Submittal or distribution to meet official regulatory requirements or for other purposes in connection with the Project is not to be construed as publication in derogation of the Owner's reserved rights.

§ 1.5.2 The Contractor, Subcontractors, Sub-subcontractors, and suppliers are authorized to use and reproduce the Instruments of Service provided to them, subject to any protocols established pursuant to Sections 1.7 and 1.8, solely and exclusively for execution of the Work. All copies made under this authorization shall bear the copyright notice, if any, shown on the Instruments of Service. The Contractor, Subcontractors, Sub-subcontractors, and suppliers may not use the Instruments of Service on other projects or for additions to the Project outside the scope of the Work without the specific written consent of the Owner.

§ 1.6 Notice

§ 1.6.1 Except as otherwise provided in Section 1.6.2, where the Contract Documents require one party to notify or give notice to the other party, such notice shall be provided in writing to the designated representative of the party to whom the notice is addressed and shall be deemed to have been duly served if delivered in person, by mail, by courier, or by electronic transmission if a method for electronic transmission is set forth in the Agreement.

§ 1.6.2 Notice of Claims as provided in Section 15.1.3 shall be provided in writing and shall be deemed to have been duly served only if delivered to the designated representative of the party to whom the notice is addressed by certified or registered mail, or by courier providing proof of delivery.

§ 1.7 Digital Data Use and Transmission

The parties shall agree upon protocols governing the transmission and use of Instruments of Service or any other information or documentation in digital form. The parties will use AIA Document E203™–2013, Building Information Modeling and Digital Data Exhibit, to establish the protocols for the development, use, transmission, and exchange of digital data.

§ 1.8 Building Information Models Use and Reliance

Any use of, or reliance on, all or a portion of a building information model without agreement to protocols governing the use of, and reliance on, the information contained in the model and without having those protocols set forth in AIA Document E203™–2013, Building Information Modeling and Digital Data Exhibit, and the requisite AIA Document G202™–2013, Project Building Information Modeling Protocol Form, shall be at the using or relying party's sole risk and without liability to the other party and its contractors or consultants, the authors of, or contributors to, the building information model, and each of their agents and employees.

ARTICLE 2 OWNER

§ 2.1 General

§ 2.1.1 The Owner is the person or entity identified as such in the Agreement and is referred to throughout the Contract Documents as if singular in number. The Owner shall designate in writing a representative who shall have express authority to represent the Owner with respect to all matters requiring the Owner's approval or authorization. Except as otherwise provided in Section 4.2.1, the Architect does not have such authority. The term "Owner" means the Owner or the Owner's authorized representative.

§ 2.1.2 The Owner shall furnish to the Contractor, within fifteen days after receipt of a written request, information necessary and relevant for the Contractor to evaluate, give notice of, or enforce mechanic's lien rights. Such information shall include a correct statement of the record legal title to the property on which the Project is located, usually referred to as the site, and the Owner's interest therein.

§ 2.2 Evidence of the Owner's Financial Arrangements

§ 2.2.1 Prior to commencement of the Work and upon written request by the Contractor, the Owner shall furnish to the Contractor reasonable evidence that the Owner has made financial arrangements to fulfill the Owner's obligations under the Contract.

§ 2.2.2 Following commencement of the Work and upon written request by the Contractor, the Owner shall furnish to the Contractor reasonable evidence that the Owner has made financial arrangements to fulfill the Owner's obligations under the Contract only if (1) the Owner fails to make payments to the Contractor as the Contract Documents require; (2) the Contractor identifies in writing a reasonable concern regarding the Owner's ability to make payment when due; or (3) a change in the Work materially changes the Contract Sum.

§ 2.2.3 After the Owner furnishes evidence of financial arrangements under this Section 2.2, the Owner shall not materially vary such financial arrangements without prior notice to the Contractor.

§ 2.2.4 The Owner has furnished information regarding its finances under this Section 2.2, and such other information regarding its business, all of which it deems to be "confidential". The Contractor shall keep the information confidential and shall not disclose it to any other person. However, the Contractor may disclose "confidential" information, after seven (7) days' notice to the Owner, where disclosure is required by law, including a subpoena or other form of compulsory legal process issued by a court or governmental entity, or by court or arbitrator(s) order, or where the "confidential" information is part of the public record, is already known to the Contractor, or is independently developed by Contractor without reference to such "confidential" information. The Contractor may also disclose "confidential" information to its employees, consultants, sureties, Subcontractors and their employees, Sub-subcontractors, and others who need to know the content of such information solely and exclusively for the Project and who agree to maintain the confidentiality of such information.

§ 2.3 Information and Services Required of the Owner

§ 2.3.1 Except for permits and fees that are the responsibility of the Contractor under the Contract Documents, including those required under Section 3.7.1, the Owner shall secure and pay for necessary approvals, easements, assessments and charges required for construction, use or occupancy of permanent structures or for permanent changes in existing facilities.

§ 2.3.2 The Owner shall retain an architect lawfully licensed to practice architecture, or an entity lawfully practicing architecture, in the jurisdiction where the Project is located. That person or entity is identified as the Architect in the Agreement and is referred to throughout the Contract Documents as if singular in number.

§ 2.3.3 If the employment of the Architect terminates, the Owner shall employ a successor to whom the Contractor has no reasonable objection and whose status under the Contract Documents shall be that of the Architect.

§ 2.3.4 The Owner shall furnish surveys describing physical characteristics, legal limitations and utility locations for the site of the Project, and a legal description of the site. The Contractor shall be entitled to rely on the accuracy of information furnished by the Owner but shall exercise proper precautions relating to the safe performance of the Work. The Contractor shall advise the Owner and Architect in writing of any inaccuracies or discrepancies discovered that may affect the Work.

§ 2.3.5 The Owner shall furnish information or services required of the Owner by the Contract Documents with reasonable promptness. The Owner shall also furnish any other information or services under the Owner's control and necessary to the Contractor's performance of the Work with reasonable promptness after receiving the Contractor's written request for such information or services. The Contractor will provide its Subcontractors with the Contract Documents. Upon written request, the Contractor will be provided with electronic versions of the Contract Documents, subject to the use and limitations set forth herein.

§ 2.3.6 Unless otherwise provided in the Contract Documents, the Owner shall furnish to the Contractor one copy of the Contract Documents for purposes of making reproductions pursuant to Section 1.5.2.

§ 2.4 Owner's Right to Stop the Work

If the Contractor fails to correct Work that is not in accordance with the requirements of the Contract Documents as required by Section 12.2 or fails to carry out Work in accordance with the Contract Documents, the Owner may issue a written order to the Contractor to stop the Work, or any portion thereof, until the cause for such order has been eliminated; however, the right of the Owner to stop the Work shall not give rise to a duty on the part of the Owner to exercise this right for the benefit of the Contractor or any other person or entity, except to the extent required by Section 6.1.3. The Owner's right to stop the Work shall be in addition to any other rights afforded the Owner under this Agreement or by law. The Owners right to stop the Work due to the Contractor's failure to perform shall not relieve the Contractor of its responsibilities and obligations under or pursuant to the Contract Documents. If there is an emergency and an immediate need to correct such deficiencies that may affect the safety of persons or property, then the Owner may proceed to correct them without prior notice to the Contractor.

§ 2.5 Owner's Right to Carry Out the Work

If the Contractor defaults or neglects to carry out the Work in accordance with the Contract Documents and fails within a five (5) business day period after receipt of notice from the Owner to commence and continue correction of such default or neglect with diligence and promptness, the Owner may, without prejudice to other remedies the Owner may have, correct such default or neglect. Such action by the Owner shall allow the Owner to withhold Payment in whole or in part, to the extent reasonably necessary to reimburse the Owner for the reasonable cost of correcting such deficiencies, including the Owner's reasonable expenses including the Architect's fees and expenses for additional services or any other professional services made necessary by such default, neglect, or failure. If current and future payments are not sufficient to cover such amounts, the Contractor shall pay the difference to the Owner upon demand. If the Contractor disagrees with the actions of the Owner, or the amounts claimed as costs to the Owner, the Contractor may file a Claim pursuant to Article 15.

§ 2.6 In no event shall the Owner have control over, charge of, or any responsibility for construction means, methods, techniques, sequences or procedures or for safety precautions and programs in connection with the Work, notwithstanding any of the rights and authority granted the Owner in the Contract Documents.

§ 2.7 These rights shall be in addition to and not in restriction of or derogation of the Owner's rights under Article 14 hereof. The rights stated in this Article and elsewhere in the Contract Documents are cumulative and not in limitation of any rights of the Owner (1) granted in the Contract Documents, (2) at law, or (3) in equity.

ARTICLE 3 CONTRACTOR

§ 3.1 General

§ 3.1.1 The Contractor is the person or entity identified as such in the Agreement and is referred to throughout the Contract Documents as if singular in number. The Contractor shall be lawfully licensed, if required in the jurisdiction where the Project is located. The Contractor shall designate in writing a representative who shall have express authority to bind the Contractor with respect to all matters under this Contract. The term "Contractor" means the Contractor or the Contractor's authorized representative.

§ 3.1.2 The Contractor shall perform the Work in accordance with the Contract Documents

§ 3.1.3 The Contractor shall not be relieved of its obligations to perform the Work in accordance with the Contract Documents either by activities or duties of the Owner or the Architect in the Architect's administration of the Contract, or by tests, inspections or approvals required or performed by persons or entities other than the Contractor. Contractor is responsible for ensuring that the Contractor, Contractor's representatives, employees and agents abide by Owner's rules, policies and procedures while on Owner's property, including, but not limited to prohibitions and limitations on the use or possession of drugs, alcohol or tobacco.

§ 3.2 Review of Contract Documents and Field Conditions by Contractor

§ 3.2.1 Execution of the Contract by the Contractor is a representation that the Contractor has visited the site, become generally familiar with local conditions under which the Work is to be performed, and correlated personal observations with requirements of the Contract Documents. Execution of the Contract by the Contractor is also a representation that the Contractor, as the Construction Manager providing pre-construction services, has carefully reviewed and thoroughly evaluated the Contract Documents to determine whether the Contractor needs clarification of the Contract Documents or additional interpretation of the intent of the Contract Documents to determine its GMP and that it has identified any contingencies in its GMP. Contractor represents that it has the knowledge, skill and expertise to perform the Work, and that it is capable of determining the means, methods, sequences or procedures for performing the Work.

§ 3.2.2 Because the Contract Documents are complementary, the Contractor shall, before starting each portion of the Work, carefully study and compare the various Contract Documents relative to that portion of the Work, as well as the information furnished by the Owner pursuant to Section 2.3.4, shall take field measurements of any existing conditions related to that portion of the Work, and shall observe any conditions at the site affecting it. These obligations are for the purpose of facilitating coordination and construction by the Contractor and are not for the purpose of discovering errors, omissions, or inconsistencies in the Contract Documents; however, the Contractor shall promptly report to the Architect and Owner any errors, inconsistencies or omissions discovered by or made known to the Contractor as a request for information in such form as the Architect may require. It is recognized that the Contractor's review is made in the Contractor's capacity as a contractor and not as a licensed design professional, unless otherwise specifically provided in the Contract Documents. Nothing herein shall relieve Contractor of its obligations for pre-construction services as a Construction Manager.

§ 3.2.3 The Contractor is not required to ascertain that the Contract Documents are in accordance with applicable laws, statutes, ordinances, codes, rules and regulations, or lawful orders of public authorities, but the Contractor shall promptly report to the Architect and Owner any nonconformity discovered by or made known to the Contractor as a request for information in such form as the Architect may require.

§ 3.2.4 If the Contractor believes that additional cost or time is involved because of clarifications or instructions the Architect issues in response to the Contractor's notices or requests for information pursuant to Sections 3.2.2 or 3.2.3, the Contractor shall submit Claims as provided in Article 15. If the Contractor fails to perform the obligations of Sections 3.2.2 or 3.2.3, or as the Construction Manager, the Contractor shall pay such costs and damages to the Owner, subject to Section 15.1.7, as would have been avoided if the Contractor had performed such obligations. If the Contractor performs those obligations, the Contractor shall not be liable to the Owner or Architect for damages resulting from errors, inconsistencies or omissions in the Contract Documents, for differences between field

measurements or conditions and the Contract Documents, or for nonconformities of the Contract Documents to applicable laws, statutes, ordinances, codes, rules and regulations, and lawful orders of public authorities unless the Contractor recognized such error, inconsistency, omission or difference and failed to report it to the Architect and Owner or subject to the applicable standard of care, such should have been identified by Contractor's constructability review of the Contract Documents.

§ 3.3 Supervision and Construction Procedures

§ 3.3.1 The Contractor shall supervise and direct the Work, using the Contractor's best skill and attention. The Contractor shall be solely responsible for, and have control over, construction means, methods, techniques, sequences, and procedures, and for coordinating all portions of the Work under the Contract. If the Contract Documents give specific instructions concerning construction means, methods, techniques, sequences, or procedures, the Contractor shall evaluate the jobsite safety thereof and shall be solely responsible for the jobsite safety of such means, methods, techniques, sequences, or procedures. If the Contractor determines that such means, methods, techniques, sequences or procedures may not be safe, the Contractor shall give timely notice to the Owner and Architect, and shall propose alternative means, methods, techniques, sequences, or procedures. The Architect shall evaluate the proposed alternative solely for conformance with the design intent for the completed construction. Unless the Architect objects to the Contractor's proposed alternative, the Contractor shall perform the Work using its alternative means, methods, techniques, sequences, or procedures.

§ 3.3.2 The Contractor shall be responsible to the Owner for acts and omissions of the Contractor's employees, Subcontractors and their agents and employees, and other persons or entities performing portions of the Work for, or on behalf of, the Contractor or any of its Subcontractors. The Contractor shall direct and control its Subcontractors at any tier and shall be responsible for correlation of their Work with that of others on the Project.

§ 3.3.3 The Contractor shall be responsible for inspection of portions of Work already performed to determine that such portions are in proper condition to receive subsequent Work.

§ 3.3.4 The Contractor shall not be relieved of obligation to perform the Work in accordance with the Contract Documents either by activities or duties of the Owner in the Owner's administration of the Contract, or by tests, inspections or approvals required or performed by persons other than the Contractor. In the event any of the Work is required to be inspected or approved by any governmental authority having jurisdiction, the Contractor shall cause such inspection or approval to be scheduled and performed. No inspection performed or failed to be performed shall release the Contractor from its obligations to have such Work inspected nor shall it be construed as an approval or acceptance of the Work or any part thereof nor shall such be deemed evidence of performance in accordance with the Contract Documents.

§ 3.3.5 The Contractor acknowledges that it is the Contractor's responsibility to hire all personnel for the proper and diligent prosecution of the Work. Contractor shall be responsible for implementing policies and procedures, as needed, with respect to its Work and its portion of the Project so as to minimize disruption to its Work from strikes, picket lines or other labor disputes and shall take reasonable steps to maintain labor harmony.

§ 3.4 Labor and Materials

§ 3.4.1 Unless otherwise provided in the Contract Documents, the Contractor shall provide and pay for labor, materials, equipment, tools, construction equipment and machinery, water, heat, utilities, transportation, and other facilities and services necessary for proper execution and completion of the Work, whether temporary or permanent and whether or not incorporated or to be incorporated in the Work.

§ 3.4.2 Except in the case of minor changes in the Work approved by the Architect in accordance with Section 3.12.8 or ordered by the Architect in accordance with Section 7.4, the Contractor may make substitutions only with the consent of the Owner, after evaluation by the Architect and in accordance with a Change Order or Construction Change Directive.

§ 3.4.3 The Contractor shall enforce strict discipline and good order among the Contractor's employees and other persons carrying out the Work. The Contractor shall not permit employment of unfit persons or persons not properly skilled in tasks assigned to them. The Owner reserves the right to require the Contractor to remove from the Project any of its personnel or any Subcontractor's personnel for violating Owner's rules or regulations, breach of any confidentiality provisions.

§ 3.5 Warranty

§ 3.5.1 The Contractor warrants to the Owner and Architect that materials and equipment furnished under the Contract will be of good quality and new unless the Contract Documents require or permit otherwise. The Contractor further warrants that the Work will conform to the requirements of the Contract Documents and will be free from defects, except for those inherent in the quality of the Work the Contract Documents require or permit. Work, materials, or equipment not conforming to these requirements will be considered defective. The Contractor's warranty excludes remedy for damage or defect to the extent caused by abuse, alterations or modifications to the Work not executed by the Contractor, improper or insufficient maintenance, improper operation, or normal wear and tear and normal usage. If required by the Architect, or Owner, the Contractor shall furnish satisfactory evidence as to the kind and quality of materials and equipment. The Contractor shall provide prompt emergency call back service for all vital systems included within its Work and keep the Owner advised of the status of repairs.

§ 3.5.2 All manufacturers and vendors' warranties for products and other Work incorporated into the Project will be assigned and transferred without loss or limitations to the Owner. Except as otherwise provided in the Contract Documents, all workmanships and product and other Work shall be warranted for one year following the date of Substantial Completion or for the period of time stated in the applicable manufacturer or vendor's warranty, whichever is longer, to be new upon installation (and not of such age as to affect durability), free from faults and defects in material and workmanship that is not inherent in the quality required or permitted in the Contract Documents, expect to the extent any deficiencies arises from Owner's failure to maintain product or use of a product outside of its intended use as required hereunder. The warranty shall be extended insofar as a vendor or manufacturer's standard guarantees exceed those specified.

§ 3.5.3 The Contractor (and vendor or manufacturer for extended guarantees or warranties) shall warrant throughout the warranty period described in Subsection 3.5.2 that the Work shall continue to function in conformance with the Contract Documents (including the performance standards set forth in the Specifications), provided, however, that Contractor shall assume no responsibility for design services, and the provisions of any applicable user/maintenance manuals. Contractor shall, at its expense (including, without limitation, payment of all costs to remove defective Work and reinstall conforming Work) remedy all deficiencies appearing within the warranty period and, at its option, repair or replace all defective Work as required to accomplish this. If a manufacturer's or vendor's warranty, which has been assigned to the Owner by Contractor, is available, the Contractor shall assist the Owner in pursuing its remedies under such warranties. During any effort to pursue manufacturer's or vendor's warranties, the period with respect to breach of warranty shall be tolled. If the Contractor fails to remedy such deficiencies within a reasonable time after written notice from the Owner, the Owner may cause such remediates to be performed and charge the expense thereof to the Contractor.

§ 3.5.4 Contractor warrants that the installation of all products shall be in strict accordance with the manufacturer's requirements unless the Architect has specified otherwise. If the Architect has specified a different method of installation, Contractor shall notify the Owner in writing. In the event Owner seeks to enforce a claim based upon a manufacturer's warranty and should such manufacturer then fail to honor its warranty based, in whole or in part, on a claim of defective installation, the Owner shall be entitled to enforce said warranty against Contractor in accordance with the terms of said warranty, except that a claim of defective installation shall not be a defense to any such warranty claim by Owner against Contractor.

§ 3.5.5 All required maintenance of the Work shall be the Contractor's responsibility until Substantial Completion is achieved, all material maintenance and user's manuals have been turned over to the Owner, and the Owner's designated personnel (whom Owner shall cause to attend the meeting specified below) have been instructed in the maintenance and operation of all applicable product. This maintenance shall include a complete turnover procedure at the time of Substantial Completion, including reasonable cleaning, testing and adjustment and at a meeting called by Contractor to explain such procedures and related matter to Owner and its designated representatives.

§ 3.5.6 Owner originated service calls which are demonstrated as not covered by warranty will be compensated at the Contractor's direct costs for materials and labor plus any agreed allowance for overhead and profit, provided they are approved in writing after submission of a detailed not-to-exceed estimate and schedule. Upon completion of the Project, the Owner will designate persons authorized to request service and will not compensate the Contractor for unauthorized calls.

§ 3.5.7 Eleven (11) months from the commencement of the warranty period, the Contractor shall schedule a walk-through inspection with the Owner and Architect to identify any warranty items to be corrected under such warranty period. The parties shall collaborate to prepare a list of warranty items within five (5) business days of the walk-through. The one (1) year Contractor's warranty period shall be extended for a period of thirty (30) days beyond the date the eleven (11) month walk-through inspection is actually performed. It is the intent of this Section to extend the warranty period by thirty (30) days beyond the date the eleven (11) month walk-through inspection is finally completed in order to give the Owner the benefit of the walk-through inspection prior to the expiration of the warranty period. The thirty (30) day extension period shall not begin to run until final completion of the walk-through inspection. Thus, if the walk-through inspection takes more than one day to complete, the thirty (30) day extension begins to run from the date the walkthrough is actually completed. If the Owner unreasonably refuses to schedule the eleven (11) month walk-through inspection, the Contractor shall notify the Owner in writing of a date on which the Contractor shall be available to perform the walk-through inspection, which date shall not be less than ten (10) days after the date of the Contractor's letter, and the thirty (30) day extension shall begin to run from the date of the proposed walk-through inspection. Under no circumstances shall the Contractor's warranty expire in less than one (1) full year.

§ 3.5.8 Nothing herein shall be a limitation of any of the Owner's legal or equitable rights or shall constitute a limitation or reduction of any statute of limitations.

§ 3.6 Taxes

The Contractor shall pay sales, consumer, use and similar taxes for the Work provided by the Contractor that are legally enacted when bids are received or negotiations concluded, whether or not yet effective or merely scheduled to go into effect. The Contractor and its subcontractors shall be responsible for payment of Social Security and Unemployment taxes for their respective employees. In addition, the Contractor and subcontractors shall pay any and all compulsory taxes required, or which may be imposed by any governmental agency relating to the performance of the Work.

§ 3.7 Permits, Fees, Notices and Compliance with Laws

§ 3.7.1 The Owner with the assistance of the Contractor shall secure and pay for the building permit application as well as for other applications, permits, fees, licenses, and inspections by government agencies necessary for proper execution and completion of the Work, unless such permits, fees, licenses, and inspections by government agencies necessary for proper execution and completion of the Work can only be secured by the licensed Contractor and/or Subcontractor. When such applications, permits, fees, licenses, and inspections by government agencies necessary for proper execution and completion of the Work are paid by the Contractor, the related fees are included in the Cost of the Work. Otherwise, if paid directly by the Owner, they shall not be included in the Cost of the Work.

§ 3.7.2 The Contractor shall comply with and give notices required by applicable laws, statutes, ordinances, codes, rules and regulations, and lawful orders of public authorities applicable to performance of the Work.

§ 3.7.3 If the Contractor performs Work knowing it to be contrary to applicable laws, statutes, ordinances, codes, rules and regulations, or lawful orders of public authorities, the Contractor shall assume appropriate responsibility for such Work and shall bear the costs attributable to correction, and shall indemnify the Owner therefore, including reasonable attorney and professional fees. The Owner shall not be responsible for any inspection fees due to re-inspection of rejected Work due to faulty or defective workmanship of the Contractor, or scheduling error by the Contractor. The Contractor shall be responsible for all such re-inspection fees and any professional fees and costs incurred by the Owner, subject to the provisions of §3.3.4 herein. The parties agree that the Architect shall be responsible for its design meeting applicable codes.

§ 3.7.4 Concealed or Unknown Conditions

If the Contractor encounters conditions at the site that are (1) subsurface or otherwise concealed physical conditions that differ materially from those indicated in the Contract Documents or (2) unknown physical conditions of an unusual nature that differ materially from those ordinarily found to exist in buildings of the same age and character as the building housing the Project, and/or in the case of improvements to raw land, and generally recognized as inherent in construction activities of the character provided for in the Contract Documents, the Contractor shall promptly

provide notice to the Owner and the Architect before conditions are disturbed and in no event later than 14 days after first observance of the conditions. The Architect will promptly investigate such conditions and, if the Architect determines that they differ materially and cause an increase or decrease in the Contractor's cost of, or time required for, performance of any part of the Work, will recommend that an equitable adjustment be made in the Contract Sum or Contract Time, or both. If the Architect determines that the conditions at the site are not materially different from those indicated in the Contract Documents and that no change in the terms of the Contract is justified, the Architect shall promptly notify the Owner and Contractor, stating the reasons. If either party disputes the Architect's determination or recommendation, that party may submit a Claim as provided in Article 15.

§ 3.7.5 If, in the course of the Work, the Contractor knowingly encounters and recognizes human remains or recognizes the existence of burial markers, archaeological sites or wetlands not indicated in the Contract Documents, the Contractor shall immediately suspend any operations that would affect them and shall notify the Owner and Architect. Upon receipt of such notice, the Owner shall promptly take any action necessary to obtain governmental authorization required to resume the operations. The Contractor shall continue to suspend such operations until otherwise instructed by the Owner but shall continue with all other operations that do not affect those remains or features. Requests for adjustments in the Contract Sum and Contract Time arising from the existence of such remains or features may be made as provided in Article 15.

§ 3.8 Allowances

§ 3.8.1 The Contractor shall include in the Contract Sum all Owner directed allowances for the use of funds stated in the Contract Documents. Items covered by allowances shall be supplied for such amounts and by such persons or entities as the Owner may direct, but the Contractor shall not be required to employ persons or entities to whom the Contractor has reasonable objection.

§ 3.8.2 Unless otherwise provided in the Contract Documents,

.1 allowances shall cover the cost to the Contractor of materials and equipment delivered at the site and all required taxes, less applicable trade discounts;

.2 Contractor's costs for unloading and handling at the site, labor, installation costs, overhead, profit, and other expenses contemplated for stated allowance amounts shall be included in the Contract Sum but not in the allowances; and

.3 whenever costs are more than or less than allowances, the Contract Sum shall be adjusted accordingly by Change Order. The amount of the Change Order shall reflect (1) the difference between actual costs and the allowances under Section 3.8.2.1 and (2) changes in Contractor's costs under Section 3.8.2.2.

§ 3.8.3 Materials and equipment under an allowance shall be selected by the Owner with reasonable promptness.

§ 3.9 Superintendent

§ 3.9.1 The Contractor shall employ a competent superintendent and necessary assistants who shall be in attendance at the Project site during performance of the Work. The superintendent shall represent the Contractor, and communications given to the superintendent shall be as binding as if given to the Contractor.

§ 3.9.2 The Contractor, as soon as practicable execution of the Agreement, shall notify the Owner of the name and qualifications of a proposed superintendent.

§ 3.9.3 The Contractor shall not employ a proposed superintendent to whom the Owner or Architect has made reasonable and timely objection. The Contractor shall not change the superintendent without the Owner's consent, which shall not unreasonably be withheld or delayed. The Owner shall have the right, at any time, to reasonably direct a change in Contractor's superintendent if their performance is unsatisfactory to the Owner. The Contractor shall replace said superintendent with a superintendent satisfactory to the Owner. No increase in the Contract Sum or Contract Time shall be allowed for any such substitution.

§ 3.9.4 If during the course of the Project, the superintendent changes, written notice shall be given to the Owner and Architect. Written notice shall include a resume of the new superintendent. Approval of such new superintendent shall be given in such manner as provided for in this Section 3.9.

§ 3.10 Contractor's Construction and Submittal Schedules

§ 3.10.1 The Contractor, promptly after being awarded the Contract, shall submit for the Owner's and Architect's

review and comment a Contractor's construction schedule for the Work ("Construction Schedule") and Cash-Flow Report. The schedule shall contain detail appropriate for the Project, including (1) the date of commencement of the Work, interim schedule milestone dates, and the date of Substantial Completion; (2) an apportionment of the Work by construction activity; and (3) the time required for completion of each portion of the Work. The schedule shall provide for the orderly progression of the Work to completion and shall not exceed time limits current under the Contract Documents (including, but not limited to any construction milestones set forth in the Agreement). The Cash-Flow Report and schedule shall be revised on a monthly basis or as requested by the Owner due to the conditions of the Work and Project and actual progress of the Work. In the event of a request by the Owner for a revised acceleration schedule solely for the Owner's convenience, the Contractor may request a Change Order.

§ 3.10.1.1 The Contractor will schedule and otherwise perform its Work as required so as not to interrupt or disturb the activities of the Owner or Owner's Separate Contractors.

§ 3.10.1.2 Should the Owner determine that sufficient progress is not being made on the Project, the Contractor shall submit a Recovery Construction Schedule upon request. Upon request, the Contractor shall further provide the Owner with the Construction Schedule's native information in an electronic format.

§ 3.10.1.3 The Milestone and Completion Dates set forth in the Contract Documents are subject to change only by properly issued Change Orders executed by the Owner, and no revision of the Construction Schedule shall be deemed to be an implicit extension of the Contract Time.

§ 3.10.2 The Contractor, promptly after being awarded the Contract and thereafter as necessary to maintain a current submittal schedule, shall submit a submittal schedule for the Architect's approval ("Submittal Schedule"). The Architect's approval shall not be unreasonably delayed or withheld. The Submittal Schedule shall (1) be coordinated with the Contractor's construction schedule, and (2) allow the Architect reasonable time to review submittals. The Architect shall be afforded sufficient time for first review and second review of submittals, if necessary. In the event of a rejection of any submittal, the Architect shall provide sufficient information as to allow the Contractor to understand the basis for the rejection. If the Contractor fails to submit a Submittal Schedule, or fails to provide submittals in accordance with the approved Submittal Schedule, or fails to correct and resubmit any submittal in a timely fashion, the Contractor shall not be entitled to any increase in Contract Sum or extension of Contract Time based on the time required for review of submittals. If there are material changes made by the Architect in the design during the Submittal process which do not arise out of errors or omissions in the Contractor's submittals, the Contractor may request a Change Order.

§ 3.10.3 The Contractor agrees the provision of review and comment by the Architect within the applicable standard of care, and the reasonable exercise of any rights by Architect or Owner, shall not be grounds for any claim against Owner, Architect, or other representative of the Owner by Contractor or any of its Subcontractors, alleging interference, lack of cooperation, delay, disruption, harassment, negligence or hindrance by Owner and/or Architect.

§ 3.10.4 The Contractor shall perform the Work in general accordance with the most recent Construction schedules submitted to the Owner and Architect and the approved Submittal Schedule.

§ 3.11 Documents and Samples at the Site

The Contractor shall maintain and make available, at the Project site, the Contract Documents, including record copies of Change Orders, Construction Change Directives, and other Modifications, in good order and marked currently to indicate field changes and selections made during construction, and the approved Shop Drawings, Product Data, Samples, and similar required submittals. These shall be in electronic form or paper copy, available to the Architect and Owner, and delivered to the Architect for submittal to the Owner upon completion of the Work as a record of the Work as constructed. [Drafting Note – Parties need agree as to how maintained at site]

§ 3.12 Shop Drawings, Product Data and Samples

§ 3.12.1 Shop Drawings are drawings, diagrams, schedules, and other data specially prepared for the Work by the Contractor or a Subcontractor, Sub-subcontractor, manufacturer, supplier, or distributor to illustrate some portion of the Work.

§ 3.12.2 Product Data are illustrations, standard schedules, performance charts, instructions, brochures, diagrams, and other information furnished by the Contractor to illustrate materials or equipment for some portion of the Work.

§ 3.12.3 Samples are physical examples that illustrate materials, equipment, or workmanship, and establish standards by which the Work will be judged.

§ 3.12.4 Shop Drawings, Product Data, Samples, and similar submittals are not Contract Documents. Their purpose is to demonstrate how the Contractor proposes to conform to the information given and the design concept expressed in the Contract Documents for those portions of the Work for which the Contract Documents require submittals. Review by the Architect is subject to the limitations of Section 4.2.7. Informational submittals upon which the Architect is not expected to take responsive action may be so identified in the Contract Documents. Submittals that are not required by the Contract Documents may be returned by the Architect without action.

§ 3.12.5 The Contractor shall review for compliance with the Contract Documents, approve, and submit to the Architect, Shop Drawings, Product Data, Samples, and similar submittals required by the Contract Documents, in accordance with the Submittal Schedule approved by the Architect or, in the absence of an approved Submittal Schedule, with reasonable promptness and in such sequence as to cause no delay in the Work or in the activities of the Owner or of Separate Contractors.

§ 3.12.6 By submitting Shop Drawings, Product Data, Samples, and similar submittals, the Contractor represents to the Owner and Architect that the Contractor has (1) reviewed and approved them, in writing (2) determined and verified materials, field measurements and field construction criteria related thereto, or will do so, and (3) checked and coordinated the information contained within such submittals with the requirements of the Work and of the Contract Documents. The Contractor's review and approval of all submittals shall be evidenced by the affixing of its stamp on the submittal. The Owner and Contractor shall agree on the language of Contractor's stamp.

§ 3.12.7 The Contractor shall perform no portion of the Work for which the Contract Documents require submittal and review of Shop Drawings, Product Data, Samples, or similar submittals, until the respective submittal has been approved by the Architect.

§ 3.12.8 The Work shall be in accordance with approved submittals except that the Contractor shall not be relieved of responsibility for deviations from the requirements of the Contract Documents by the Architect's approval of Shop Drawings, Product Data, Samples, or similar submittals, unless the Contractor has specifically notified the Architect in writing of such deviation at the time of submittal and (1) the Architect has given written approval to the specific deviation as a minor change in the Work, or (2) a Change Order or Construction Change Directive has been issued authorizing the deviation. The Contractor shall not be relieved of responsibility for errors or omissions in Shop Drawings, Product Data, Samples, or similar submittals, by the Architect's approval thereof. In collaboration with the Architect, the Contractor shall establish and implement procedures for expediting the processing and approval of the Shop Drawings, Product Data, Samples and other submittals.

§ 3.12.9 The Contractor shall direct specific attention, in writing or on resubmitted Shop Drawings, Product Data, Samples, or similar submittals, to revisions other than those requested by the Architect on previous submittals. In the absence of such notice, the Architect's approval of a resubmission shall not apply to such revisions.

§ 3.12.10 The Contractor shall not be required to provide professional services that constitute the practice of architecture or engineering unless such services are specifically required by the Contract Documents for a portion of the Work or unless the Contractor needs to provide such services in order to carry out the Contractor's responsibilities for construction means, methods, techniques, sequences, and procedures. The Contractor shall not be required to provide professional services in violation of applicable law.

§ 3.12.10.1 If professional design services or certifications by a design professional related to systems, materials, or equipment are specifically required of the Contractor by the Contract Documents, the Owner and the Architect will specify all performance and design criteria that such services must satisfy. The Contractor shall be entitled to rely upon the adequacy and accuracy of the performance and design criteria provided in the Contract Documents. The Contractor shall cause such services or certifications to be provided by an appropriately licensed design professional, who shall have and maintain reasonable limits of insurance as set forth in Exhibit _ to the Agreement, whose signature and seal shall appear on all drawings, calculations, specifications, certifications, Shop Drawings, and other submittals prepared by such professional. Shop Drawings, and other submittals related to the Work, designed, or certified by such professional, if prepared by others, shall bear such professional's written approval when submitted to the Architect.

The Owner and the Architect shall be entitled to rely upon the adequacy and accuracy of the services, certifications, and approvals performed or provided by such design professionals, provided the Owner and Architect have specified to the Contractor the performance and design criteria that such services must satisfy. Pursuant to this Section 3.12.10, the Architect will review and approve or take other appropriate action on submittals only for the limited purpose of checking for conformance with information given and the design concept expressed in the Contract Documents.

§ 3.12.10.2 If the Contract Documents require the Contractor's design professional to certify that the Work has been performed in accordance with the design criteria, the Contractor shall furnish such certifications to the Architect at the time and in the form specified by the Architect.

§ 3.12.11 Nothing in the Architect's or Owner's review of shop drawings and samples or submittals shall be construed as allowing substitutions not in accordance with the procedures for substitutions, the performance of additional work, or the allowance of any increased costs to the Owner unless reflected in a Change Order.

§ 3.12.12 If the Contractor intends that a change to the Contract be made by any information in a Shop Drawing, the Contractor shall affirmatively in narrative form state that the Shop Drawing depicts a change in the Work and shall submit a written request for Change Order in sufficient time for the Architect to understand that a Change Order is being requested before the time the Architect's approval of the Shop Drawing is required. Any notation, mark or other comment by the Architect on a submittal or in a response to a Request for Interpretation shall not constitute a change in the Contract. If the Contractor asserts that any notation, mark or comment by the Architect contained in a submittal or response to a Request for Interpretation will change the Contract, the Contractor shall immediately follow the procedures set forth in Article 15 and/or Section 7.2 to request and pursue a change in the Contract and the Contractor will not be entitled to assert any claim unless it has strictly complied with such procedures and this paragraph.

§ 3.12.13 The Architect's review of Shop Drawings, Product Data, Samples and similar submittals shall be limited to two (2) submissions under the scope of Basic Services and will be conducted only after the Contractor has coordinated said Documents to indicate field conditions, proposed Contractor deviations from the Contract Documents and other requirements, which effect design intent. For the Architect's unreasonable review of Shop Drawings, Product Data, Samples and similar submittals by the Contractor more than twice, a corresponding fee shall be deducted from the Contract Sum via a Change Order between the Owner and Contractor.

§ 3.13 Use of Site

§ 3.13.1 The Contractor shall confine operations at the site to areas permitted by applicable laws, statutes, ordinances, codes, rules and regulations, lawful orders of public authorities, and the Contract Documents and shall not unreasonably encumber the site with materials or equipment. **§ 3.13.2** Only materials and equipment that are to be used directly in the Work shall be brought to and stored on the Project site. Protection of construction materials and equipment stored at the Project site from weather, theft, damage and all other adversity is the responsibility of the Contractor.

§ 3.13.3 The Contractor and any entity for whom the Contractor is responsible shall not erect any sign on the Project site without the prior written consent of the Owner.

§ 3.13.4 Work shall be conducted so as not to impede traffic, obstruct any thoroughfare or access to property or means of egress, and so as not to interfere with the work of other Separate Contractors or emergency responders.

§ 3.13.5 During progress of the Work, Contractor shall provide lights, fences and barriers, danger, warning and detour signs and take such other precautions as may be necessary to protect life and property.

§ 3.13.6 Contractor shall protect Owner's property, all surrounding public and private properties, all its Work in place, and all work of Owner's Separate Contractors in place against damage, injury or loss arising in connection with the Work. Contractor shall promptly remedy any such damage, injury or loss.

§ 3.13.7 Contractor shall provide and maintain reasonable protection at all times for all exposed floors, walls, ceilings, fittings, fixtures, piping, glass, equipment, adjacent areas and other Work that may be subject to damage or theft of injury

of any kind during the progress of the Work. Any items damaged or injured shall be replaced or repaired by Contractor at its expense unless covered by insurance and in a manner entirely satisfactory to Architect and Owner.

§ 3.13.8 Contractor shall maintain and enforce regulations covering all fire hazards, including smoking, and shall provide approved fire extinguishers at proper locations.

§ 3.13.9 Contractor shall repair or replace, in a manner entirely satisfactory to Owner and Architect, all damage caused by Contractor resulting to curbs, sidewalks, roadways, lawns, drain- pipes, buildings, etc., as a result of this Project, even though they may be outside the limits of this Contract as shown on the Drawings. Existing facilities that have been marred or disturbed by Contractor's Work or failure to comply with the Contract Document shall be restored to its prior condition in a manner entirely satisfactory to Owner and Architect.

§ 3.14 Cutting and Patching

§ 3.14.1 The Contractor shall be responsible for cutting, fitting, or patching required to complete the Work or to make its parts fit together properly. All areas requiring cutting, fitting, or patching shall be restored to the condition existing prior to the cutting, fitting, or patching, unless otherwise required by the Contract Documents.

§ 3.14.2 The Contractor shall not damage or endanger a portion of the Work or fully or partially completed construction of the Owner or Separate Contractors by cutting, patching, or otherwise altering such construction, or by excavation. The Contractor shall not cut or otherwise alter construction by the Owner or a Separate Contractor except with written consent of the Owner and of the Separate Contractor. Consent shall not be unreasonably withheld. The Contractor shall not unreasonably withhold, from the Owner or a Separate Contractor, its consent to cutting or otherwise altering the Work.

§ 3.15 Cleaning Up

§ 3.15.1 The Contractor shall keep the premises and surrounding area free from accumulation of waste materials and rubbish caused by operations under the Contract. At completion of the Work, the Contractor shall remove waste materials, rubbish, the Contractor's tools, construction equipment, machinery, and surplus materials from and about the Project.

§ 3.15.2 If the Contractor fails to clean up as provided in the Contract Documents, the Owner may do so and the Owner shall be entitled to reimbursement from the Contractor.

§ 3.15.3 All areas of new or existing construction which are damaged during the Project shall be restored to their original condition by the Contractor.

§ 3.15.4 The Contractor shall be responsible for temporary dust and dirt control through the use of temporary enclosures and partitions.

§ 3.16 Access to Work

The Contractor shall provide the Owner and Architect with access to the Work in preparation and progress wherever located.

§ 3.17 Royalties, Patents and Copyrights

The Contractor shall pay all royalties and license fees. The Contractor shall defend suits or claims for infringement of copyrights and patent rights and shall hold the Owner and Architect harmless from loss on account thereof, but shall not be responsible for defense or loss when a particular design, process, or product of a particular manufacturer or manufacturers is required by the Contract Documents, or where the copyright violations are contained in Drawings, Specifications, or other documents prepared by the Owner or Architect. However, if an infringement of a copyright or patent is discovered by, or made known to, the Contractor, the Contractor shall be responsible for the loss unless the information is promptly furnished to the Architect.

§ 3.18 Indemnification

§ 3.18.1 To the fullest extent permitted by law, the Contractor shall indemnify and hold harmless the Owner, its officers, directors, employees, related entities, subsidiaries, successors, and assigns, (but excluding design professionals)(collectively "Indemnitees", and each an "Indemnitee") from and against liabilities, claims, damages,

losses, and expenses, including but not limited to attorneys' fees, arising out of or resulting from performance of the Work, provided that such claim, damage, loss, or expense is attributable to bodily injury, sickness, disease or death, or to economic injury or destruction of tangible property including the loss of use therefrom, but only to the extent caused by or alleged to be caused by the negligent acts or omissions or intentional conduct of the Contractor, a Subcontractor, anyone directly or indirectly employed by them, or anyone for whose acts they may be liable, regardless of whether or not such claim, damage, loss, or expense is caused in part by a party indemnified hereunder. Such obligation shall not be construed to negate, abridge, or reduce other rights or obligations of indemnity that would otherwise exist as to a party or person described in this Section 3.18. Notwithstanding anything to the contrary, nothing herein shall require the Contractor to indemnify an Indemnitee to the extent of such Indemnitee's own negligence or intentional acts, and, in the event a claim for which indemnification is required hereunder is asserted by one or more Indemnitees against any other Indemnitee, Contractor shall not be obligated to indemnify the Indemnitee against whom such claim is asserted unless Contractor is notified of such claim prior to resolution of same and afforded sufficient time to defend such claim.

§ 3.18.2 In claims against any person or entity indemnified under this Section 3.18 by an employee of the Contractor, a Subcontractor (of any tier), anyone directly or indirectly employed or retained by any of them, or anyone for whose acts they may be liable, the indemnification obligation under Section 3.18.1 or the Contract Documents shall not be limited by a limitation on amount or type of damages, compensation, or benefits payable by or for the Contractor or a Subcontractor (of any tier) under workers' compensation acts, disability benefit acts, or other employee benefit acts.

§ 3.18.3 The Contractor's indemnity obligations under this Paragraph 3.18 shall, but not by way of limitation, specifically include, without limitations, all fines, penalties and punitive damages arising out of, or in connection with, any (i) violation of or failure to comply with any governmental requirement by the Contractor or any person or entity for whom the Contractor is responsible, (ii) method of execution of the Work, or (iii) failure to obtain, or violation of, any permit or other approval of a public authority applicable to the Work by the Contractor or any entity for whom the Contractor is responsible.

§ 3.18.4 In the event that the Contractor fails or refuses to indemnify an Indemnitee hereunder, in addition to all other obligations and upon adjudication in favor of an Indemnitee, Contractor shall be responsible for any and all costs associated with bringing such action, including reasonable attorneys' fees.

§ 3.18.5 Without limiting the generality of this Section, the defense and indemnity obligations set forth in this Section 3.18 shall survive the expiration, completion or termination of this Agreement.

§ 3.19 Equal Employment Opportunity/Affirmative Action

§ 3.19.1 In performance of the Work, the Contractor agrees to abide by all laws governing Equal Employment Opportunity, or similar Acts, and accompanying rules and regulations and orders, and that it has or will develop an Affirmative Action Program to assure that all employees and applicants for employment are not discriminated against on the basis of race, sex, age, religion, creed, national origin or handicap unrelated to job function.

§ 3.20 Discrimination Prohibited

Discrimination Prohibited: According to 62 Pa.C.S.A. §3701, the Contractor agrees that:

§ 3.20.1 In hiring of employees for the performance of Work under the Contract or any subcontract, no Contractor or Subcontractor, or any person acting on behalf of the Contractor or Subcontractor shall, by reason of gender, race, creed or color, discriminate against any citizen of the Commonwealth who is qualified and available to perform the Work to which the employment relates.

§ 3.20.2 No Contractor or Subcontractor, or any person on their behalf shall in any manner discriminate against or intimidate any employee hired for the performance of Work under the Contract on account of gender, race, creed, or color.

§ 3.21 Human Relations Act

§ 3.21.1 The provisions of the Pennsylvania Human Relations Act, Act 222 of October 27, 1955 (P.L. 744) (43 P.S. Section 951, et seq.) of the Commonwealth of Pennsylvania prohibit discrimination because of race, color, religious creed, ancestry, age, sex, national origin, handicap or disability, by employers, employment agencies, labor organizations, contractors and others. The Contractor shall agree to comply with the provisions of this Act as amended

that are made part of this specification. Attention is directed to the language of the Commonwealth's non-discrimination clause in 16 PA. Code 349.101.

ARTICLE 4 ARCHITECT

§ 4.1 General

§ 4.1.1 The Architect is the person or entity retained by the Owner pursuant to Section 2.3.2 and identified as such in the Agreement. The term "Architect" shall mean the Architect or Architect's representative.

§ 4.1.2 Duties, responsibilities, and limitations of authority of the Architect as set forth in the Contract Documents shall not be restricted, modified, or extended without written consent of the Owner.

§ 4.2 Administration of the Contract

§ 4.2.1 The Architect will provide administration of the Contract as described in the Contract Documents and will be an Owner's representative during construction until the date the Architect issues the final Certificate for Payment. The Architect will have authority to act on behalf of the Owner only to the extent provided in the Contract Documents.

§ 4.2.2 The Architect will visit the site at intervals appropriate to the stage of construction, or as otherwise agreed with the Owner, to become generally familiar with the progress and quality of the portion of the Work completed, and to determine in general if the Work observed is being performed in a manner indicating that the Work, when fully completed, will be in accordance with the Contract Documents. However, the Architect will not be required to make exhaustive or continuous on-site inspections to check the quality or quantity of the Work. The Architect will not have control over, charge of, or responsibility for the construction means, methods, techniques, sequences or procedures, or for the safety precautions and programs in connection with the Work, since these are solely the Contractor's rights and responsibilities under the Contract Documents.

§ 4.2.3 On the basis of the site visits, the Architect will keep the Owner reasonably informed about the progress and quality of the portion of the Work completed, and promptly report to the Owner (1) known deviations from the Contract Documents, (2) known deviations from the most recent construction schedule submitted by the Contractor, and (3) defects and deficiencies observed in the Work. The Architect will not be responsible for the Contractor's failure to perform the Work in accordance with the requirements of the Contract Documents. The Architect will not have control over or charge of, and will not be responsible for acts or omissions of, the Contractor, Subcontractors, or their agents or employees, or any other persons or entities performing portions of the Work.

§ 4.2.4 Communications

The Owner and Contractor shall include the Architect in all communications that relate to or affect the Architect's services or professional responsibilities. The Owner shall promptly notify the Architect of the substance of any direct communications between the Owner and the Contractor otherwise relating to the Project. Communications by and with the Architect's consultants shall be through the Architect. Communications by and with Subcontractors and suppliers shall be through the Contractor. Communications by and with Separate Contractors shall be through the Owner. The Contract Documents may specify other communication protocols.

§ 4.2.5 Based on the Architect's evaluations of the Contractor's Applications for Payment, the Architect will review and certify the amounts due the Contractor and will issue Certificates for Payment in such amounts.

§ 4.2.6 The Architect and Owner each have authority to reject Work that does not conform to the Contract Documents. Whenever the Architect considers it necessary or advisable, the Architect and Owner will have authority to require inspection or testing of the Work in accordance with Sections 13.4.2 and 13.4.3, whether or not the Work is fabricated, installed, or completed. However, neither this authority of the Architect and the Owner nor a decision made in good faith either to exercise or not to exercise such authority shall give rise to a duty or responsibility of the Architect and/or Owner to the Contractor, Subcontractors, suppliers, their agents or employees, or other persons or entities performing portions of the Work. No inspections by the Architect or Owner shall relieve Contractor of any of its obligations under the Contract Documents.

§ 4.2.7 The Architect will review and approve, or take other appropriate action upon, the Contractor's submittals such as Shop Drawings, Product Data, and Samples, but only for the limited purpose of checking for conformance with information given and the design concept expressed in the Contract Documents. The Architect's action will be taken in accordance with the submittal schedule approved by the Architect or, in the absence of an approved submittal

schedule, with reasonable promptness while allowing sufficient time in the Architect's professional judgment to permit adequate review. Review of such submittals is not conducted for the purpose of determining the accuracy and completeness of other details such as dimensions and quantities, or for substantiating instructions for installation or performance of equipment or systems, all of which remain the responsibility of the Contractor as required by the Contract Documents. The Architect's review of the Contractor's submittals shall not relieve the Contractor of the obligations under Sections 3.3, 3.5, and 3.12. The Architect's review shall not constitute approval of safety precautions or of any construction means, methods, techniques, sequences, or procedures. The Architect's approval of a specific item shall not indicate approval of an assembly of which the item is a component.

§ 4.2.8 The Architect will prepare Change Orders and Construction Change Directives, and may order minor changes in the Work as provided in Section 7.4. The Architect will investigate and make determinations and recommendations regarding concealed and unknown conditions as provided in Section 3.7.4.

§ 4.2.9 The Contractor shall advise the Owner and Architect when a particular phase of the Work is ready for an inspection for Substantial Completion purposes. The Architect will conduct inspections to determine the date or dates of Substantial Completion and the date of final completion; issue Certificates of Substantial Completion pursuant to Section 9.8; receive and forward to the Owner, for the Owner's review and records, written warranties and related documents required by the Contract and assembled by the Contractor pursuant to Section 9.10; and issue a final Certificate for Payment pursuant to Section 9.10. If more than two (2) inspections are required for Substantial Completion or Final Completion, the Contractor shall reimburse (via Change Order or if necessary, a Construction Change Directive) the Owner for all expenses and costs associated with any additional inspections.

§ 4.2.10 If the Owner and Architect agree, the Architect will provide one or more Project representatives to assist in carrying out the Architect's responsibilities at the site. The Owner shall notify the Contractor of any change in the duties, responsibilities and limitations of authority of the Project representatives.

§ 4.2.11 The Architect will initially interpret matters concerning requirements of, the Contract Documents on written request of both the Owner or Contractor. The Architect's response to such requests will be made in writing within any time limits agreed upon or otherwise with reasonable promptness.

§ 4.2.12 Interpretations and decisions of the Architect will be consistent with the intent of, and reasonably inferable from, the Contract Documents and will be in writing or in the form of drawings. When making such interpretations and decisions, the Architect will endeavor to secure faithful performance by both Owner and Contractor, will not show partiality to either, and will not be liable for results of interpretations or decisions rendered in good faith.

§ 4.2.13 Intentionally omitted,.

§ 4.2.14 The Architect will review and respond to requests for information about the Contract Documents. The Architect's response to such requests will be made in writing within any time limits agreed upon or otherwise with reasonable promptness. If appropriate, the Architect will prepare and issue supplemental Drawings and Specifications in response to the requests for information.

ARTICLE 5 SUBCONTRACTORS

§ 5.1 Definitions

§ 5.1.1 A Subcontractor is a person or entity who has a direct contract with the Contractor to perform a portion of the Work at the site. The term "Subcontractor" is referred to throughout the Contract Documents as if singular in number and means a Subcontractor or an authorized representative of the Subcontractor. The term "Subcontractor" does not include a Separate Contractor or the subcontractors of a Separate Contractor.

§ 5.1.2 A Sub-subcontractor is a person or entity who has a direct or indirect contract with a Subcontractor to perform a portion of the Work at the site. The term "Sub-subcontractor" is referred to throughout the Contract Documents as if singular in number and means a Sub-subcontractor or an authorized representative of the Sub-subcontractor.

§ 5.2 Award of Subcontracts and Other Contracts for Portions of the Work

§ 5.2.1 Unless otherwise stated in the Contract Documents, the Contractor, as soon as practicable after award of the Contract, shall notify the Owner of the persons or entities proposed for each principal portion of the Work, including those who are to furnish materials or equipment fabricated to a special design of the Architect. Within 5 business days

of receipt of the information, the Architect may notify the Contractor whether the Owner (1) has reasonable objection to any such proposed person or entity or (2) requires additional time for review. Failure of the Owner to provide notice within the 5 business day period shall constitute notice of no reasonable objection. The Contractor shall advise the Owner of the need for approval of a subcontractor or supplier on an expedited basis.

§ 5.2.2 The Contractor shall not contract with a proposed person or entity to whom the Owner has made reasonable and timely objection. The Contractor shall not be required to contract with anyone to whom the Contractor has made reasonable objection.

§ 5.2.3 If the Owner has reasonable objection to a person or entity proposed by the Contractor, the Contractor shall propose another to whom the Owner has no reasonable objection. If the proposed but rejected Subcontractor was reasonably capable of performing the Work, the Contract Sum and Contract Time shall be increased or decreased by the difference, if any, occasioned by such change, and an appropriate Change Order shall be issued before commencement of the substitute Subcontractor's Work. However, no increase in the Contract Sum or Contract Time shall be allowed for such change unless the Contractor has acted promptly and responsively in submitting names as required.

§ 5.2.4 The Contractor shall not substitute a Subcontractor, person, or entity for one previously selected if the Owner or Architect makes reasonable objection to such substitution.

§ 5.3 Subcontractual Relations

By appropriate written agreement, the Contractor shall require each Subcontractor, to the extent of the Work to be performed by the Subcontractor, to be bound to the Contractor by terms of the Contract Documents, and to assume toward the Contractor all the obligations and responsibilities, including the responsibility for safety of the Subcontractor's Work that the Contractor, by these Contract Documents, assumes toward the Owner and Architect. Each subcontract agreement shall preserve and protect the rights of the Owner and Architect under the Contract Documents with respect to the Work to be performed by the Subcontractor so that subcontracting thereof will not prejudice such rights, and shall allow to the Subcontractor, unless specifically provided otherwise in the subcontract agreement, the benefit of all rights, remedies, and redress against the Contractor that the Contractor, by the Contract Documents, has against the Owner. Where appropriate, the Contractor shall require each Subcontractor to enter into similar agreements with Sub-subcontractors. The Contractor shall make available to each proposed Subcontractor, prior to the execution of the subcontract agreement, copies of the Contract Documents to which the Subcontractor will be bound, and, upon written request of the Subcontractor, identify to the Subcontractor terms and conditions of the proposed subcontract agreement that may be at variance with the Contract Documents. Subcontractors will similarly make copies of applicable portions of such documents available to their respective proposed Sub-subcontractors. The Contractor shall make available to each proposed Subcontractor, prior to the execution of the subcontract agreement, copies of the Contract Documents to which the Subcontractor will be bound, and, upon written request of the Subcontractor, identify to the Subcontractor terms and conditions of the proposed subcontract agreement that may be at variance with the Contract Documents. Subcontractors will similarly make copies of applicable portions of such documents available to their respective proposed Sub-subcontractors. Notwithstanding anything to the contrary in the Contract Documents, Contractor shall be fully responsible and liable for the acts and/or omissions of any tier of Subcontractors.

§ 5.3.2 All subcontracts shall be in writing and shall specifically provide that the Owner is an intended third-party beneficiary.

§ 5.4 Contingent Assignment of Subcontracts

§ 5.4.1 Each subcontract agreement for a portion of the Work is assigned by the Contractor to the Owner, provided that

.1 assignment is effective only after termination of the Contract by the Owner for cause pursuant to Section 14.2 and only for those subcontract agreements that the Owner accepts by notifying the Subcontractor and Contractor; and

.2 assignment is subject to the prior rights of the surety, if any, obligated under bond relating to the Contract.

When the Owner accepts the assignment of a subcontract agreement, the Owner assumes the Contractor's rights and obligations under the subcontract other than prior obligations of the Contractor to make payments that were the responsibility of the Contractor.

§ 5.4.2 Each subcontract shall specifically provide that the Owner shall only be responsible to the subcontractor for those obligations of the Contractor that accrue subsequent to the Owner's exercise of any rights under this conditional assignment.

§ 5.4.3 Upon assignment to the Owner under this Section 5.4, the Owner may further assign the subcontract to a successor contractor or other entity.

ARTICLE 6 CONSTRUCTION BY OWNER OR BY SEPARATE CONTRACTORS

§ 6.1 Owner's Right to Perform Construction and to Award Separate Contracts

§ 6.1.1 The term "Separate Contractor(s)" shall mean other contractors retained by the Owner under separate agreements. The Owner reserves the right to perform construction or operations related to the Project with the Owner's own forces, and with Separate Contractors retained under Conditions of the Contract substantially similar to those of this Contract, including those provisions of the Conditions of the Contract related to insurance and waiver of subrogation.

§ 6.1.2 When separate contracts are awarded for different portions of the Project or other construction or operations on the site, the term "Contractor" in the Contract Documents in each case shall mean the Contractor who executes each separate Owner-Contractor Agreement.

(Paragraphs deleted)

§ 6.2 Mutual Responsibility

§ 6.2.1 The Contractor shall afford the Owner and Separate Contractors reasonable opportunity for introduction and storage of their materials and equipment and performance of their activities, and shall connect and coordinate the Contractor's construction and operations with theirs as required by the Contract Documents and in accordance with the Construction Schedule.

§ 6.2.2 If part of the Contractor's Work depends for proper execution or results upon construction or operations by the Owner or a Separate Contractor, the Contractor shall, prior to proceeding with that portion of the Work, promptly notify the Architect and Owner in writing of apparent discrepancies or defects in the construction or operations by the Owner or Separate Contractor that would render it unsuitable for proper execution and results of the Contractor's Work. Failure of the Contractor to notify the Architect of apparent discrepancies or defects prior to proceeding with the Work shall constitute an acknowledgment that the Owner's or Separate Contractor's completed or partially completed construction is fit and proper to receive the Contractor's Work. The Contractor shall not be responsible for discrepancies or defects in the construction or operations by the Owner or Separate Contractor that are not apparent.

§ 6.2.3 The Contractor shall reimburse the Owner for costs the Owner incurs that are payable to a Separate Contractor because of the Contractor's delays, improperly timed activities, or defective construction. The Owner shall be responsible to the Contractor for unavoidable costs the Contractor incurs because of a Separate Contractor's delays, improperly timed activities, damage to the Work or defective construction.

§ 6.2.4 The Contractor shall promptly remedy damage that the Contractor wrongfully causes to completed or partially completed construction or to property of the Owner or of Separate Contractor as provided in Section 10.2.5.

§ 6.2.5 The Owner and each Separate Contractor shall have the same responsibilities for cutting and patching as are described for the Contractor in Section 3.14.

§ 6.2.6 The Contractor shall consult with its Subcontractors and other contractors as soon as possible after execution of the Contract to coordinate all work phases in order that the Project as a whole can be completed in a professional and expeditious manner.

§ 6.3 Owner's Right to Clean Up

If a dispute arises among the Contractor, Separate Contractors, and the Owner as to the responsibility under their respective contracts for maintaining the premises and surrounding area free from waste materials and rubbish, the Owner may clean up will allocate the cost among those responsible.

ARTICLE 7 CHANGES IN THE WORK

§ 7.1 General

§ 7.1.1 Changes in the Work may be accomplished after execution of the Contract, and without invalidating the Contract, by Change Order, Construction Change Directive or order for a minor change in the Work, subject to the limitations stated in this Article 7 and elsewhere in the Contract Documents.

§ 7.1.2 A Change Order shall be based upon agreement among the Owner, Contractor, and Architect. A Construction Change Directive requires agreement by the Owner and Architect and may or may not be agreed to by the Contractor. An order for a minor change in the Work may be issued by the Architect alone.

§ 7.1.3 Changes in the Work shall be performed under applicable provisions of the Contract Documents. The Contractor shall proceed promptly with changes in the Work, unless otherwise provided in the Change Order, Construction Change Directive, or order for a minor change in the Work.

§ 7.2 Change Orders

§ 7.2.1 A Change Order is a written instrument prepared by the Contractor and signed by the Owner, Contractor, and Architect stating their agreement upon all of the following:

.1 The change in the Work;
.2 The amount of the adjustment, if any, in the Contract Sum; and
.3 The extent of the adjustment, if any, in the Contract Time.

§ 7.2.2 The Contractor represents that any executed Change Order between the Owner and Contractor on this Project will include all costs associated with the additional Work described in the Change Order, including all costs of associated delay, interference, acceleration, inefficiency and overhead, as well as costs of material, labor and supervisions.

§ 7.2.3 Whenever the Contractor requests a Change Order, the Contractor shall submit a Change Order Request and shall provide documentation of labor and material costs in a form (to include Subcontractor quotes, bills of material, internal estimate worksheets, etc.) satisfactory to the Owner. Any Change Order Request for additional time shall be documented by a critical path analysis. Subcontractors will be allowed a maximum of 15% for overhead, profit, supervision, and miscellaneous expenses on Change Orders where it performs the Work with its own forces. In the case where the work is performed by a Second-tier Subcontractor, the maximum aggregate mark-up for overhead, profit, supervision, and miscellaneous expenses will be 15%. (Example: If the Second-Tier subcontractor includes a 10% mark-up, the Subcontractor is limited to no more than an additional 5% mark-up so that in the aggregate, the total allowable mark-up is 15%. If the Second-tier subcontractor includes a 15% mark-up, the Subcontractor shall not include any additional mark-up).

§ 7.2.4 Agreement on any Change Order shall constitute a final settlement on all matters relating to the change in the Work that is the subject of the Change Order, including, but not limited to, all direct and indirect costs associated with such change, delays, disruptions, interferences, inefficiencies, accelerations, hindrances, and any and all adjustments to the Contract Sum, the Project schedule, and Contract Time.

§ 7.3 Construction Change Directives

§ 7.3.1 A Construction Change Directive is a written order prepared by the Architect and signed by the Owner and Architect, directing a change in the Work prior to agreement on adjustment, if any, in the Contract Sum or Contract Time, or both. The Owner may by Construction Change Directive, without invalidating the Contract, order changes in the Work within the general scope of the Contract consisting of additions, deletions, or other revisions, the Contract Sum and Contract Time being adjusted accordingly.

§ 7.3.2 A Construction Change Directive shall be used in the absence of total agreement on the terms of a Change Order.

§ 7.3.3 If the Construction Change Directive provides for an adjustment to the Contract Sum, the adjustment shall be based on one of the following methods at the Owner's option:

.1 Mutual acceptance of a lump sum properly itemized and supported by sufficient substantiating data to permit evaluation;

.2 Unit prices stated in the Contract Documents or subsequently agreed upon which shall be used for both additions and deductions from the Contract Sum unless otherwise noted in the Contract Documents;

.3 Cost to be determined in a manner agreed upon by the parties and a mutually acceptable fixed or percentage fee; or

.4 As provided in Section 3.8 through 7.3

§ 7.3.4 If the Contractor does not respond promptly or disagrees with the method for adjustment in the Contract Sum, the Architect shall determine the adjustment on the basis of reasonable expenditures and savings of those performing the Work attributable to the change, including, in case of an increase in the Contract Sum, an amount for overhead and profit as set forth in the Agreement, or if no such amount is set forth in the Agreement, a reasonable amount. In such case, and also under Section 7.3.3.3, the Contractor shall keep and present, in such form as the Architect may prescribe, an itemized accounting together with appropriate supporting data. Unless otherwise provided in the Contract Documents, costs for the purposes of this Section 7.3.4 shall be limited to the following:

.1 Costs of labor, including applicable payroll taxes, fringe benefits required by agreement or custom, workers' compensation insurance, and other employee costs approved by the Architect;

.2 Costs of materials, supplies, and equipment, including cost of transportation, whether incorporated or consumed;

.3 Rental costs of machinery and equipment, exclusive of hand tools, whether rented from the Contractor or others;

.4 Costs of premiums for all bonds and insurance, permit fees, and sales, use, or similar taxes, directly related to the change; and

.5 Costs of supervision and field office personnel directly attributable to the change.

§ 7.3.5 If the Contractor disagrees with the adjustment in the Contract Time, the Contractor may make a Claim in accordance with applicable provisions of Article 15.

§ 7.3.6 Upon receipt of a Construction Change Directive, the Contractor shall promptly proceed with the change in the Work involved and advise the Architect and Owner in writing of the Contractor's agreement or disagreement with the method, if any, provided in the Construction Change Directive for determining the proposed adjustment in the Contract Sum or Contract Time.

§ 7.3.7 A Construction Change Directive signed by the Contractor indicates the Contractor's agreement therewith, including adjustment in Contract Sum and Contract Time or the method for determining them. Such agreement shall be effective immediately and shall be recorded as a Change Order.

§ 7.3.8 The amount of credit to be allowed by the Contractor to the Owner for a deletion or change that results in a net decrease in the Contract Sum shall be actual net cost as confirmed by the Owner. When both additions and credits covering related Work or substitutions are involved in a change, the allowance for overhead and profit shall be figured on the basis of net increase, if any, with respect to that change.

§ 7.3.9 Allowances for profit and overhead costs shall be applied only to that portion of the cost which constitutes a net increase in the Contract Sum. Allowances for profit and overhead costs shall be computed in accordance with 7.2.3 above.

§ 7.3.10 Pending final determination of the total cost of a Construction Change Directive to the Owner, the Contractor may request payment for Work completed under the Construction Change Directive in Applications for Payment. The Architect will make an interim determination for purposes of monthly certification for payment for those costs and certify for payment the amount that the Architect determines, in the Architect's professional judgment, to be reasonably justified. The Architect's interim determination of cost shall adjust the Contract Sum on the same basis as a Change Order, subject to the right of either party to disagree and assert a Claim in accordance with Article 15.

§ 7.3.11 When the Owner and Contractor agree with a determination made by the Architect concerning the adjustments in the Contract Sum and Contract Time, or otherwise reach agreement upon the adjustments, such agreement shall be effective immediately and the Architect will prepare a Change Order. Change Orders may be issued for all or any part of a Construction Change Directive.

§ 7.4 Minor Changes in the Work

The Architect or Owner may order minor changes in the Work that are consistent with the intent of the Contract Documents and do not involve an adjustment in the Contract Sum or an extension of the Contract Time. The Architect's or Owner's order for minor changes shall be in writing. If the Contractor believes that the proposed minor change in the Work will affect the Contract Sum or Contract Time, the Contractor shall notify the Architect or Owner and shall not proceed to implement the change in the Work. If the Contractor is directed to perform the Work set forth in the Architect's or Owner's order for a minor change, the Contractor shall make such Claim for an adjustment of the Contract Sum or Contract Time as provided in Article 15. If the Contractor performs the minor change without prior notice to the Architect and Owner that such change will affect the Contract Sum or Contract Time, the Contractor waives any adjustment to the Contract Sum or extension of the Contract Time.

ARTICLE 8 TIME

§ 8.1 Definitions

§ 8.1.1 Unless otherwise provided, Contract Time is the period of time, including authorized adjustments, allotted in the Contract Documents for Substantial Completion of the Work.

§ 8.1.2 The date of commencement of the Work is the date established in a written Notice to Proceed or as stated in the Contract Documents. All required documentation, such as insurance certificates shall be provided before the commencement of Work.

§ 8.1.3 The date of Substantial Completion is the date certified by the Architect in accordance with Section 9.8.

§ 8.1.4 The term "day" as used in the Contract Documents shall mean calendar day unless otherwise specifically defined.

§ 8.2 Progress and Completion

§ 8.2.1 Time limits stated in the Contract Documents are of the essence of the Contract. By executing the Agreement, the Contractor confirms that the Contract Time is a reasonable period for performing the Work.

§ 8.2.2 The Contractor shall not knowingly, except by agreement or instruction of the Owner in writing, commence the Work prior to the effective date of insurance required to be furnished by the Contractor and Owner.

§ 8.2.3 The Contractor shall proceed expeditiously with adequate forces and shall achieve Substantial Completion within the Contract Time.

§ 8.2.3.1 If the Contractor is not maintaining the pace of the Work in accordance with the Construction Schedule or otherwise consistent with the Contract Time, and such delays are not excusable as set forth in Section 8.3, then the Owner may require the Contractor to undertake a time recovery plan (including more personnel, overtime and/or additional shifts) at the Contractor's sole expense, to reasonably assure completion of the Work within the Contract Time.

§ 8.3 Delays and Extensions of Time

§ 8.3.1 If the Contractor is delayed at any time in the commencement or progress of the Work by (1) an act or neglect of the Owner or Architect, of an employee of either, or of a Separate Contractor; (2) by changes ordered in the Work; (3) by labor disputes impacting critical path activities, fire, unusual delay in deliveries, unavoidable casualties, adverse weather conditions documented in accordance with Section 15.1.6.2 which could not be anticipated, or other causes beyond the Contractor's reasonable control; (4) by delay authorized by the Owner pending mediation and binding dispute resolution; or (5) by other causes that the Contractor asserts, and the Owner determines, justify delay, then the Contract Time shall be extended with correlative General Conditions costs to be paid for such extension, to the extent such delay will impact the critical path as shown on the most recent Construction Schedule and if the performance of the Work is not, was not, or would not have been delayed by any other cause for which the Contractor is not entitled to an extension in the Contract Time under the Contract Documents. The Contractor further acknowledges and agrees

that adjustments in the Contract Time will be permitted for a delay only to the extent such delay (1) is not caused or could not have been anticipated by the Contractor, (2) could not be limited or avoided by Contractor's timely notice to the owner of the delay, and (3) is of a duration not less than one (1) day.

§ 8.3.1.1 Notwithstanding anything to the contrary in the Contract Documents, the Contractor acknowledges and agrees that the Work to be performed hereunder, the Contract Sum and Contract Time are based upon the Work being performed during the COVID-19 pandemic and Contractor's compliance with all rules, regulations and guidance relating to construction during COVID-19 promulgated by regulatory bodies including those of the state and municipality in which the Project is located, and federal bodies (collectively "COVID-19 Rules") and the Contractor shall be solely responsible for any failure to do so and shall indemnify the Owner from any third-party injuries, damages, losses and expenses resulting therefrom. The COVID-19 Rules will be observed at all possible and feasible times, while still allowing the required Work under these Contract Documents to be executed as solely directed or determined by the Contractor or one for whom the Contractor is responsible. In no event shall the Contract Time or Contract Sum be increased in connection with any impact arising out of the Contractor's failure to follow the COVID-19 Rules. In the event of a governmental shut down of the Project (including a location of materials being manufactured/supplied), or new COVID-19 Rules which become effective after the execution of this Agreement which materially limit the number of workers on site, or a significant delay in material deliveries or equipment due to COVID -19 that could not have been reasonably anticipated and/or avoided by the Contractor, the Contract Time and Contract Sum may be adjusted based upon direct, out-of-pocket, proven costs. In no event shall the Owner be responsible for inefficiency other than as directly attributable to COVID-19 Rules implemented after execution of the GMP Amendment, Eichleay damages, consequential damages or similar impact claims or remuneration. Contractor shall take such steps to procure materials and equipment in a timely manner so as to avoid any impact to the Contract Time or Contract Sum and in accordance with the Risk Register. Contractor may also request a substitute item if a specified material or equipment is not available as a result of the COVID-19 pandemic. Cost escalation due to unforeseeable circumstances attributed to COVID-19 will be presented by the Contractor to the Owner as a change order or a request for use of the Construction Contingency. The Owner will evaluate the submitted change order in accordance with the terms of this paragraph and the parties' Agreement, and the Risk Register.

§ 8.3.2 Claims relating to time shall be made in accordance with applicable provisions of Article 15.

(Paragraph deleted)
§ 8.3.3. Notwithstanding anything to the contrary in the Contract Documents, the Contractor and its Subcontractor's sole and exclusive remedy for any (i) delay in the commencement, prosecution or completion of the Work, (ii) hindrance or obstruction in the performance of the Work, (iii) loss of productivity or acceleration, or (iv) other similar claims (collectively referred to as "Delays") whether or not such Delays are foreseeable, shall be an extension of time in which to complete the Work if permitted under Subparagraph 8.3.1 and as follows. In the event of a Delay caused solely by the Owner, in addition to an extension of time, Contractor shall be entitled to its direct out-of-pocket costs associated with the Delay. In no event shall the Contractor or any Subcontractor be entitled to any other remedy or compensation or recovery of any damages, in connection with any Delay, including, without limitation, overhead, accelerations costs, consequential damages, lost opportunity costs, impact damages or other similar remuneration.

§ 8.3.4 The Contractor acknowledges and agrees that no extension of the Contract Time shall be granted on account of weather conditions except a state of emergency impacting the Project that has been declared by Governmental Authority which results in the closure of roads or except as permitted by the Owner.

ARTICLE 9 PAYMENTS AND COMPLETION

§ 9.1 Contract Sum

§ 9.1.1 The Contract Sum is stated in the Agreement and, including authorized adjustments, is the total amount payable by the Owner to the Contractor for performance of the Work under the Contract Documents.

§ 9.1.2 If unit prices are stated in the Contract Documents or subsequently agreed upon, and if quantities originally contemplated are materially changed so that application of such unit prices to the actual quantities causes substantial inequity to the Owner or Contractor, the applicable unit prices shall be equitably adjusted.

§ 9.2 Schedule of Values

The Contractor shall submit a preliminary schedule of values with the GMP Amendment. The schedule of values shall be prepared in the form, and supported by the data to substantiate its accuracy, required by the Architect or Owner. This schedule, unless objected to by the Architect or Owner, shall be used as a basis for reviewing the Contractor's Applications for Payment. The Schedule of Values shall be periodically updated to reflect actual costs (subject, at all times, to the GMP). The most recently approved Schedule of Values, unless objected to by the Architect or Owner, shall be used as a basis for reviewing the Contractor's subsequent Applications for Payment. The description of Work shall be sufficiently broken down to indicate labor and material costs associated with each area of Work as required by Owner. Any breakdown that fails to include sufficient detail, is unbalanced or exhibits "front-loading" of the value of the Work will be rejected.

§ 9.3 Applications for Payment

§ 9.3.1 At least ten days before the date established for each progress payment, the Contractor shall submit to the Architect an itemized Application for Payment prepared in accordance with the schedule of values, if required under Section 9.2, for completed portions of the Work. The application shall be notarized, if required, and supported by all data substantiating the Contractor's right to payment that the Owner or Architect reasonably require, such as copies of requisitions, and releases and waivers of liens from Subcontractors and suppliers, and shall reflect retainage if provided for in the Contract Documents.

§ 9.3.1.1 As provided in Section 7.3.9, such applications may include requests for payment on account of changes in the Work that have been properly authorized by Construction Change Directives, or by interim determinations of the Architect, but not yet included in Change Orders.

§ 9.3.1.2 Applications for Payment shall not include requests for payment for portions of the Work for which the Contractor does not intend to pay a Subcontractor or supplier, unless such Work has been performed by others whom the Contractor intends to pay.

§ 9.3.2 Unless otherwise provided in the Contract Documents, payments shall be made on account of materials and equipment delivered and suitably stored at the site for subsequent incorporation in the Work. If approved in advance in writing by the Owner, payment may similarly be made for materials and equipment suitably stored off the site at a location agreed upon in writing. Payment for materials and equipment stored on or off the site shall be conditioned upon compliance by the Contractor with procedures satisfactory to the Owner to establish the Owner's title to such materials and equipment or otherwise protect the Owner's interest, and shall include the costs of applicable insurance, storage, and transportation to the site, for such materials and equipment stored off the site.

§ 9.3.3 The Contractor warrants that title to all Work covered by an Application for Payment will pass to the Owner no later than the time of payment. The Contractor further warrants that upon submittal of an Application for Payment all Work for which Certificates for Payment have been previously issued and payments received from the Owner shall, to the best of the Contractor's knowledge, information, and belief, be free and clear of liens, claims, security interests, or encumbrances, in favor of the Contractor, Subcontractors, suppliers, or other persons or entities that provided labor, materials, and equipment relating to the Work.

§ 9.3.4 To the extent payment has been made by the Owner for amounts due, Owner shall be entitled to withhold payment to Contactor upon receipt of notice of any intent to file a lien in an amount sufficient to protect the interests of the Owner.

§ 9.3.5 At Substantial Completion or as provided by law, the Contractor may request a reduction of retainage in accordance with Section 9.8.5. Reduction in retainage will not be granted if the conditions defined in Section 9.5 exist, as determined by the Owner.

§ 9.4 Certificates for Payment

§ 9.4.1 The Architect will, within seven days after receipt of the Contractor's Application for Payment, either (1) issue to the Owner a Certificate for Payment in the full amount of the Application for Payment, with a copy to the Contractor; or (2) issue to the Owner a Certificate for Payment for such amount as the Architect and Owner determine is properly due, and notify the Contractor and Owner of the Architect's reasons for withholding certification in part as provided in Section 9.5.1; or (3) withhold certification of the entire Application for Payment, and notify the Contractor

and Owner of the Architect's reason for withholding certification in whole as provided in Section 9.5.1.**§ 9.4.2** The issuance of a Certificate for Payment will constitute a representation by the Architect to the Owner, based on the Architect's evaluation of the Work and the data in the Application for Payment, that, to the best of the Architect's knowledge, information, and belief, the Work has progressed to the point indicated, the quality of the Work is in accordance with the Contract Documents, and that the Contractor is entitled to payment in the amount certified. The foregoing representations are subject to an evaluation of the Work for conformance with the Contract Documents upon Substantial Completion, to results of subsequent tests and inspections, to correction of minor deviations from the Contract Documents prior to completion, and to specific qualifications expressed by the Architect. However, the issuance of a Certificate for Payment will not be a representation that the Architect has (1) made exhaustive or continuous on-site inspections to check the quality or quantity of the Work; (2) reviewed construction means, methods, techniques, sequences, or procedures; (3) reviewed copies of requisitions received from Subcontractors and suppliers and other data requested by the Owner to substantiate the Contractor's right to payment; or (4) made examination to ascertain how or for what purpose the Contractor has used money previously paid on account of the Contract Sum.

(Paragraph deleted)

§ 9.5 Decisions to Withhold Certification

§ 9.5.1 The Architect shall withhold a Certificate for Payment in whole or in part, to the extent reasonably necessary to protect the Owner, if in the Architect's opinion the representations to the Owner required by Section 9.4.2 cannot be made. If the Architect is unable to certify payment in the amount of the Application, the Architect will notify the Contractor and Owner as provided in Section 9.4.1. If the Contractor and Architect cannot agree on a revised amount, the Architect will promptly issue a Certificate for Payment for the amount for which the Architect is able to make such representations to the Owner. The Architect may also withhold a Certificate for Payment or, because of subsequently discovered evidence, may nullify the whole or a part of a Certificate for Payment previously issued, to such extent as may be necessary in the Architect's opinion to protect the Owner from loss for which the Contractor is responsible, including loss resulting from acts and omissions described in Section 3.3.2, because of

.1 defective Work not remedied after Contractor was provided with written notice to cure and failed to undertake and diligently pursue corrective action;

.2 third party claims filed or reasonable evidence indicating probable filing of such claims, unless security acceptable to the Owner is provided by the Contractor or unless the Contractor is unable to provide Owner with reasonable assurance of protection from financial liability;

.3 failure of the Contractor to make payments properly to Subcontractors or suppliers for labor, materials or equipment in accordance with the terms of this Agreement or Contractor's written third-party agreements;

.4 reasonable evidence that the Work cannot be completed for the unpaid balance of the Contract Sum;

.5 damage to the Owner or to a Separate Contractor;

.6 reasonable evidence that the Work will not be completed within the Contract Time, and that the unpaid balance would not be adequate to cover actual or liquidated damages for the anticipated delay; or

.7 persistent failure to carry out the Work in accordance with the Contract Documents.

.8 failure of the Contractor to provide the executed releases and waivers of liens and claims from the Contractor, Subcontractors, and material suppliers for Work included in previous Applications for Payment for which the Owner has issued prior payment;

. 9 unsatisfactory prosecution of the Work in accordance with the Contract Documents;

.10 Contractor's failure to comply with government statutes and the law governing performance of the Work;

.11 Contractor's failure to submit progress schedule updates or a recovery schedule as required by the Contract Documents; or

.12 Contractor's failure to provide such support for billed items as required by the Agreement.

§ 9.5.2 When either party disputes the Architect's decision regarding a Certificate for Payment under Section 9.5.1, in whole or in part, that party may submit a Claim in accordance with Article 15.

§ 9.5.3 When the reasons for withholding certification are removed, certification will be made for amounts previously withheld. In no event may Contractor stop performing Work in connection with a good faith dispute, so long as Owner pays amounts not in dispute.

§ 9.5.4 If the Architect withholds certification for payment under Section 9.5.1.3, the Owner may, at its sole option, issue joint checks to the Contractor and to any Subcontractor or supplier to whom the Contractor failed to make payment for Work properly performed or material or equipment suitably delivered. If the Owner makes payments by joint check, the Owner shall notify the Architect and the Contractor shall reflect such payment on its next Application for Payment.

§ 9.6 Progress Payments

§ 9.6.1 After the Architect has issued a Certificate for Payment, the Owner shall make payment in the manner and within the time provided in the Contract Documents, and shall so notify the Architect.

§ 9.6.2 The Contractor shall pay each Subcontractor promptly, but in no event later than the time prescribed by law, the amount to which the Subcontractor is entitled, reflecting percentages actually retained from payments to the Contractor on account of the Subcontractor's portion of the Work. The Contractor shall, by appropriate agreement with each Subcontractor, require each Subcontractor to make payments to Sub-subcontractors in a similar manner.

§ 9.6.3 The Architect will, on request, furnish to a Subcontractor, if practicable, information regarding percentages of completion or amounts applied for by the Contractor and action taken thereon by the Architect and Owner on account of portions of the Work done by such Subcontractor.

§ 9.6.4 The Owner has the right to request written evidence from the Contractor that the Contractor has properly paid Subcontractors and suppliers amounts paid by the Owner to the Contractor for subcontracted Work. If the Contractor fails to furnish such evidence within seven days, the Owner shall have the right to contact Subcontractors and suppliers to ascertain whether they have been properly paid. Neither the Owner nor Architect shall have an obligation to pay, or to see to the payment of money to, a Subcontractor or supplier, except as may otherwise be required by law.

§ 9.6.5 The Contractor's payments to suppliers shall be treated in a manner similar to that provided in Sections 9.6.2, 9.6.3 and 9.6.4.

§ 9.6.6 A Certificate for Payment, a progress payment, or partial or entire use or occupancy of the Project by the Owner shall not constitute acceptance of Work not in accordance with the Contract Documents.

§ 9.6.7 Unless the Contractor provides the Owner with a payment bond in the full penal sum of the Contract Sum, payments received by the Contractor for Work properly performed by Subcontractors or provided by suppliers shall be held by the Contractor for those Subcontractors or suppliers who performed Work or furnished materials, or both, under contract with the Contractor for which payment was made by the Owner. Nothing contained herein shall require money to be placed in a separate account and not commingled with money of the Contractor.

§ 9.6.8 Provided the Owner has fulfilled its payment obligations under the Contract Documents, the Contractor shall defend and indemnify the Owner from all loss, liability, damage or expense, including reasonable attorney's fees and litigation expenses, arising out of any lien claim or other claim for payment by any Subcontractor or supplier of any tier. Upon receipt of notice of a lien claim or other claim for payment, the Owner shall notify the Contractor. If approved by the applicable court, when required, the Contractor may substitute a surety bond or other security acceptable to the Owner for the property against which the lien or other claim for payment has been asserted.

§ 9.7 Failure of Payment

If the Architect does not issue a Certificate for Payment, through no fault of the Contractor, within fourteen (14) days after receipt of the Contractor's Application for Payment, or if the Owner does not pay the Contractor within seven days after the date established in the Contract Documents, the amount certified by the Architect or awarded by binding dispute resolution, then the Contractor may, upon seven additional days' notice to the Owner and Architect, stop the Work until payment of the amount owing has been received. The Contract Time shall be extended appropriately, and the Contract Sum shall be increased by the amount of the Contractor's reasonable costs of shutdown, delay and start-up, plus interest as provided for in the Contract Documents.

§ 9.7.2 Notwithstanding anything to the contrary, in no event shall the Contractor stop the Work in connection with any withholding of payment for an item in connection with a good faith dispute. The Owner shall make payment to the Contractor for Work not in dispute in accordance with the terms herein.

§ 9.8 Substantial Completion

§ 9.8.1 Substantial Completion is the stage in the progress of the Work when the Work or designated portion thereof is sufficiently complete in accordance with the Contract Documents so that the Owner can occupy or utilize the Work, which shall not be deemed to have occurred until Owner has received all applicable permits and approvals and other documents from any and all governmental authorities (excluding FDA) having jurisdiction over the Project necessary to permanently occupy or use the Work or designated portions thereof for its intended use. Under no circumstances shall the Work or any portion thereof be deemed to be Substantially Complete unless the Owner has unimpeded use of the portion of the Work and the Contractor has fully complied with the Contract Documents with only minor "punch list" items remaining to be completed by the Contractor. All punch list items shall reasonably be completed in not more than thirty (30) days. Other conditions precedent to Substantial Completion include the submission of Operation and Maintenance Manuals, warranties, guarantees, As-Builts and other documents required for Substantial Completion under the Contract Documents. The Work, or a designated portion thereof, shall be deemed substantially complete if Owner's failure to occupy or use is based on reasons unrelated to failure on the part of Contractor to perform in accordance with the terms of this Agreement.

§ 9.8.2 When the Contractor considers that the Work, or a portion thereof which the Owner agrees to accept separately, is substantially complete, the Contractor shall prepare and submit to the Architect and Owner a comprehensive list of items to be completed or corrected within thirty (30) days of Substantial Completion unless otherwise specified by the Architect and prior to final payment, commonly known as a "punch list" . Failure to include an item on such list does not alter the responsibility of the Contractor to complete all Work in accordance with the Contract Documents. The Owner shall be entitled to withhold one and one-half (1.5) times the value of the punch list items.

§ 9.8.3 Upon receipt of the Contractor's list, the Architect will make an inspection within a reasonable time to determine whether the Work or designated portion thereof is substantially complete. If the Architect's inspection discloses any item, whether or not included on the Contractor's list, which is not sufficiently complete in accordance with the Contract Documents so that the Owner can occupy or utilize the Work or designated portion thereof for its intended use, the Contractor shall, before issuance of the Certificate of Substantial Completion, complete or correct such item upon notification by the Architect. In such case, the Contractor shall then submit a request for another inspection by the Architect to determine Substantial Completion.

§ 9.8.4 When the Work or designated portion thereof is substantially complete, the Architect will prepare a Certificate of Substantial Completion that shall establish the date of Substantial Completion; establish responsibilities of the Owner and Contractor for security, maintenance, heat, utilities, damage to the Work and insurance; and fix the time within which the Contractor shall finish all items on the list accompanying the Certificate. Warranties required by the Contract Documents shall commence on the date of Substantial Completion of the Work or designated portion thereof unless otherwise provided in the Certificate of Substantial Completion. If the Contractor fails to complete the items on the punch list within the time prescribed, the Owner may perform the Work itself or others and the cost thereof shall be charged against the Contractor and deducted from the Contract Sum. If re-inspections of the Work are performed by the Architect for identification of items to be completed or corrected, then re-inspections will be performed at the Contractor's expense.

§ 9.8.5 The Certificate of Substantial Completion shall be submitted to the Owner and Contractor for their written acceptance of responsibilities assigned to them in the Certificate. Upon such acceptance, and consent of surety if any, the Owner shall make payment of retainage applying to the Work or designated portion thereof. Such payment shall be adjusted for Work that is incomplete or not in accordance with the requirements of the Contract Documents.

§ 9.9 Partial Occupancy or Use

§ 9.9.1 The Owner may occupy or use any completed or partially completed portion of the Work at any stage when such portion is designated by separate agreement with the Contractor, provided such occupancy or use is consented to by the insurer and authorized by public authorities having jurisdiction over the Project. Such partial occupancy or use may commence whether or not the portion is substantially complete, provided the Owner and Contractor have accepted in writing the responsibilities assigned to each of them for payments, retainage, if any, security, maintenance, heat, utilities, damage to the Work and insurance, and have agreed in writing concerning the period for correction of the Work and commencement of warranties required by the Contract Documents. When the Contractor considers a portion substantially complete, the Contractor shall prepare and submit a list to the Architect as provided under Section 9.8.2. Consent of the Contractor to partial occupancy or use shall not be unreasonably withheld. The stage of

the progress of the Work shall be determined by written agreement between the Owner and Contractor or, if no agreement is reached, by decision of the Architect.

§ 9.9.2 Immediately prior to such partial occupancy or use, the Owner, Contractor, and Architect shall jointly inspect the area to be occupied or portion of the Work to be used in order to determine and record the condition of the Work.

§ 9.9.3 Unless otherwise agreed upon, partial occupancy or use of a portion or portions of the Work shall not constitute acceptance of Work not complying with the requirements of the Contract Documents.

§ 9.10 Final Completion and Final Payment

§ 9.10.1 Upon receipt of the Contractor's notice that the Work is ready for final inspection and acceptance and upon receipt of a final Application for Payment, the Architect will promptly make such inspection. When the Architect finds the Work acceptable under the Contract Documents and the Contract fully performed, the Architect will promptly issue a final Certificate for Payment stating that to the best of the Architect's knowledge, information and belief, and on the basis of the Architect's on-site visits and inspections, the Work has been completed in accordance with the Contract Documents and that the entire balance found to be due the Contractor and noted in the final Certificate is due and payable. The Architect's final Certificate for Payment will constitute a further representation that conditions listed in Section 9.10.2 as precedent to the Contractor's being entitled to final payment have been fulfilled.

§ 9.10.2 Neither final payment nor any remaining retained percentage shall become due until the Contractor submits to the Architect and Owner (1) an affidavit that payrolls, bills for materials and equipment, and other indebtedness connected with the Work for which the Owner or the Owner's property might be responsible or encumbered (less amounts withheld by Owner) have been paid or otherwise satisfied, (2) a certificate evidencing that insurance required by the Contract Documents to remain in force after final payment is currently in effect, (3) a written statement that the Contractor knows of no reason that the insurance will not be renewable to cover the period required by the Contract Documents, (4) consent of surety, if any, to final payment, (5) documentation of any special warranties, such as manufacturers' warranties or specific Subcontractor warranties, and (6) if required by the Owner, other data establishing payment or satisfaction of obligations, such as receipts and releases and waivers of liens, claims, security interests, or encumbrances arising out of the Contract, to the extent and in such form as may be designated by the Owner, (7) all warranties and guarantees required by the Contract Documents, (8) a sworn conditional Final Release of Liens and Claims from the Contractor duly executed and acknowledged showing all subcontractors to be fully paid and similar final sworn statements from subcontractors and, where appropriate, from sub-subcontractors, and (9) all other documents required by the Agreement and other Contract Documents have been delivered to the Owner prior to final payment. If a Subcontractor refuses to furnish a release or waiver required by the Owner, the Contractor may furnish a bond satisfactory to the Owner to indemnify the Owner against such lien, claim, security interest, or encumbrance. If a lien, claim, security interest, or encumbrance remains unsatisfied after payments are made, the Contractor shall refund to the Owner all money that the Owner may be compelled to pay in discharging the lien, claim, security interest, or encumbrance, including all costs and reasonable attorneys' fees. Contractors shall provide unconditional Final Waiver from itself and all with lien rights within ten days of receipt of Final Payment.

§ 9.10.3 If, after Substantial Completion of the Work, final completion thereof is materially delayed through no fault of the Contractor or by issuance of Change Orders affecting final completion, and the Architect so confirms, the Owner shall, upon application by the Contractor and certification by the Architect, and without terminating the Contract, make payment of the balance due for that portion of the Work fully completed, corrected, and accepted. If the remaining balance for Work not fully completed or corrected is less than retainage stipulated in the Contract Documents, and if bonds have been furnished, the written consent of the surety to payment of the balance due for that portion of the Work fully completed and accepted shall be submitted by the Contractor to the Architect prior to certification of such payment. Such payment shall be made under terms and conditions governing final payment, except that it shall not constitute a waiver of Claims.

§ 9.10.4 The making of final payment shall constitute a waiver of Claims by the Owner except those arising from

.1 liens, Claims, security interests, or encumbrances arising out of the Contract and unsettled;
.2 failure of the Work to comply with the requirements of the Contract Documents;
.3 terms of special warranties required by the Contract Documents; or
.4 audits performed by the Owner, if permitted by the Contract Documents, after final payment.
.5 Latent failures of the Contractor to comply with the requirements of the Contract Documents; or
. 6 Insurance and indemnity obligations hereunder.

§ 9.10.5 Acceptance of final payment by the Contractor, a Subcontractor, or a supplier, shall constitute a waiver of claims by that payee except those previously made in writing and identified by that payee as unsettled at the time of final Application for Payment and those for indemnification or contribution from claims for bodily injury, death or property damages by or on behalf of third-parties as provided herein.

ARTICLE 10 PROTECTION OF PERSONS AND PROPERTY

(Paragraphs deleted)

§ 10.1 Safety Precautions and Programs. The Contractor shall be responsible for initiating, maintaining, and supervising all safety precautions and programs in connection with the performance of the Contract. The Owner assumes no responsibility or liability for the safety of the Project site. Contractor shall be responsible for providing a safe place for the performance of the Work.

§ 10.2 Safety of Persons and Property

§ 10.2.1 The Contractor shall take reasonable precautions for safety of, and shall provide reasonable protection to prevent damage, injury, or loss to

.1 employees on the Work and other persons who may be affected thereby;

.2 the Work and materials and equipment to be incorporated therein, whether in storage on or off the site, under care, custody, or control of the Contractor, a Subcontractor, or a Sub-subcontractor; and

.3 other property at the site or adjacent thereto, such as trees, shrubs, lawns, walks, pavements, roadways, structures, and utilities not designated for removal, relocation, or replacement in the course of construction.

§ 10.2.2 The Contractor shall comply with, and give notices required by applicable laws, statutes, ordinances, codes, rules and regulations, and lawful orders of public authorities, bearing on safety of persons or property or their protection from damage, injury, or loss.

§ 10.2.3 The Contractor shall implement, erect, and maintain, as required by existing conditions and performance of the Contract, reasonable safeguards for safety and protection, including posting danger signs and other warnings against hazards; promulgating safety regulations; and notifying the owners and users of adjacent sites and utilities of the safeguards.

§ 10.2.4 When use or storage of explosives or other hazardous materials or equipment, or unusual methods are necessary for execution of the Work, the Contractor shall provide the Owner with advance written notice and shall exercise utmost care and carry on such activities under supervision of properly qualified personnel.

§ 10.2.5 The Contractor shall promptly remedy damage and loss (other than damage or loss insured under property insurance required by the Contract Documents) to property referred to in Sections 10.2.1.2 and 10.2.1.3 caused in whole or in part by the Contractor, a Subcontractor, a Sub-subcontractor, or anyone directly or indirectly employed by any of them, or by anyone for whose acts they may be liable and for which the Contractor is responsible under Sections 10.2.1.2 and 10.2.1.3. The Contractor may make a Claim for the cost to remedy the damage or loss to the extent such damage or loss is attributable to acts or omissions of the Owner or Architect or anyone directly or indirectly employed by either of them, or by anyone for whose acts either of them may be liable, and not attributable to the fault or negligence of the Contractor. The foregoing obligations of the Contractor are in addition to the Contractor's obligations under Section 3.18.

§ 10.2.6 The Contractor shall designate a responsible member of the Contractor's organization at the site whose duty shall be the prevention of accidents. This person shall be the Contractor's superintendent unless otherwise designated by the Contractor in writing to the Owner and Architect.

§ 10.2.7 The Contractor shall not permit any part of the construction or site to be loaded so as to cause damage or create an unsafe condition.

§ 10.2.8 Injury or Damage to Person or Property

If either party suffers injury or damage to person or property because of an act or omission of the other party, or of others for whose acts such party is legally responsible, notice of the injury or damage, whether or not insured, shall be

given to the other party within a reasonable time not exceeding 21 days after discovery. The notice shall provide sufficient detail to enable the other party to investigate the matter.

§ 10.2.9 The Contractor shall promptly report in writing to the Owner all accidents, other than minor accidents for which no medical treatment is required, arising out of, or in connection with the Work which cause death, personal injury or property damage, giving full details and statements of any witnesses whether or not the Owner has actual knowledge of the accident. In addition, if death or serious personal injuries or serious damage are caused, the accident shall be reported immediately by telephone or messenger to the Owner and Architect.

§ 10.3 Hazardous Materials and Substances

§ 10.3.1 The Contractor is responsible for compliance with any requirements included in the Contract Documents regarding hazardous materials or substances. If the Contractor encounters a hazardous material or substance not addressed in the Contract Documents and if reasonable precautions will be inadequate to prevent foreseeable bodily injury or death to persons resulting from a material or substance, including but not limited to asbestos or polychlorinated biphenyl (PCB), encountered on the site by the Contractor, the Contractor shall, upon recognizing the condition, immediately stop Work in the affected area and shall provide written notification to the Owner and Architect of the condition.

§ 10.3.2 Upon receipt of the Contractor's notice, the Owner shall obtain the services of a licensed laboratory to verify the presence or absence of the material or substance reported by the Contractor and, in the event such material or substance is found to be present, to cause it to be rendered harmless. Unless otherwise required by the Contract Documents, the Owner shall furnish in writing to the Contractor and Architect the names and qualifications of persons or entities who are to perform tests verifying the presence or absence of the material or substance or who are to perform the task of removal or safe containment of the material or substance. The Contractor and the Architect will promptly reply to the Owner in writing stating whether or not either has reasonable objection to the persons or entities proposed by the Owner. If either the Contractor or Architect has an objection to a person or entity proposed by the Owner, the Owner shall propose another to whom the Contractor and the Architect have no reasonable objection. When the material or substance has been rendered harmless, Work in the affected area shall resume upon written agreement of the Owner and Contractor. By Change Order, the Contract Time shall be extended appropriately and the Contract Sum shall be increased by the amount of the Contractor's reasonable additional costs of shutdown, delay, and start-up.

§ 10.3.3 To the fullest extent permitted by law, the Owner shall indemnify and hold harmless the Contractor, Subcontractors, Architect, Architect's consultants, and agents and employees of any of them from and against claims, damages, losses, and expenses, including but not limited to attorneys' fees, arising out of or resulting from performance of the Work in the affected area if in fact the material or substance presents the risk of bodily injury or death as described in Section 10.3.1 and has not been rendered harmless, provided that such claim, damage, loss, or expense is attributable to bodily injury, sickness, disease or death, or to injury to or destruction of tangible property (other than the Work itself), except to the extent that such damage, loss, or expense is due to the fault or negligence of the party seeking indemnity.

§ 10.3.4 The Owner shall not be responsible under this Section 10.3 for hazardous materials or substances the Contractor brings to the site unless such materials or substances are required by the Contract Documents. The Contractor shall provide the Owner with advance written notice of the use or storage of hazardous materials or equipment or unusual methods in execution of the Work and shall exercise the utmost care and carry on such activities under supervision of properly qualified personnel. The Owner shall be responsible for hazardous materials or substances required by the Contract Documents, except to the extent of the Contractor's fault or negligence in the use and handling of such materials or substances. Unless required by the Contract Documents, the Contractor shall not be required to perform without its consent, any Work relating to a hazardous material or substance, provided that such Contractor consent shall not be unreasonably withheld.

§ 10.3.5 The Contractor shall reimburse the Owner for the cost and expense the Owner incurs (1) for remediation of hazardous materials or substances the Contractor brings to the site and negligently handles, or (2) where the Contractor fails to perform its obligations under Section 10.3.1, except to the extent that the cost and expense are due solely to the Owner's fault or negligence.

§ 10.3.6 If, without negligence on the part of the Contractor, the Contractor is held liable by a government agency for the cost of remediation of a hazardous material or substance solely by reason of performing Work as required by the Contract Documents, the Owner shall reimburse the Contractor for all cost and expense thereby incurred.

§ 10.4 Emergencies

In an emergency affecting safety of persons or property, the Contractor shall act, at the Contractor's discretion, to prevent threatened damage, injury, or loss. Additional compensation or extension of time claimed by the Contractor on account of an emergency shall be determined as provided in Article 15 and Article 7.

ARTICLE 11 INSURANCE AND BONDS – SEE INSURANCE ADDENDUM ATTACHED HERETO AND INCORPORATED HEREIN.

§ 11.1 – See Exhibit B, Insurance, as amended

(Paragraphs deleted)

§ 11.2 All bond premiums paid by Subcontractors providing labor, materials or equipment of to the Project with a value in excess of $150,000 shall be a Cost of the Work. The Owner shall be named as a dual Obligee. The Contractor may request to bond others based upon the circumstances, which request shall not be unreasonably refused by the Owner.

ARTICLE 12 UNCOVERING AND CORRECTION OF WORK

§ 12.1 Uncovering of Work

§ 12.1.1 If a portion of the Work is covered contrary to the Architect's or Owner's request or to requirements specifically expressed in the Contract Documents, it must, if requested in writing by the Architect or Owner, be uncovered for the Architect's or Owner's examination and be replaced at the Contractor's expense. Including but not limited to testing and re-inspection costs, without change in the Contract Time.

§ 12.1.2 If a portion of the Work has been covered that the Architect or Owner has not specifically requested to examine prior to its being covered, the Architect or Owner may request to see such Work and it shall be uncovered by the Contractor. If such Work is in accordance with the Contract Documents, the Contractor shall be entitled to an equitable adjustment to the Contract Sum and Contract Time as may be appropriate. If such Work is not in accordance with the Contract Documents, the costs of uncovering the Work, and the cost of correction, shall be at the Contractor's expense, including but not limited to testing and re-inspection costs.

§ 12.2 Correction of Work

§ 12.2.1 Before Substantial Completion

The Contractor shall promptly correct Work rejected by the Architect or Owner or any governmental authority (excluding FDA) or failing to conform to the requirements of the Contract Documents, discovered before Substantial Completion and whether or not fabricated, installed or completed. Costs of correcting such rejected Work, including additional testing and inspections, the cost of uncovering and replacement, and compensation for the Architect's services and expenses made necessary thereby, shall be at the Contractor's expense.

§ 12.2.2 After Substantial Completion

§ 12.2.2.1 In addition to the Contractor's obligations under Section 3.5, if, within one year after the date of Substantial Completion of the Work or designated portion thereof or after the date for commencement of warranties established under Section 9.9.1, or by terms of any applicable special warranty required by the Contract Documents, any of the Work is found to be not in accordance with the requirements of the Contract Documents, the Contractor shall correct it promptly after receipt of notice from the Owner to do so, unless the Owner has previously given the Contractor a written acceptance of such condition. The Owner shall give such notice promptly after discovery of the condition. During the one-year period for correction of Work, if the Owner fails to notify the Contractor and give the Contractor an opportunity to make the correction, the Owner waives the rights to make a claim for breach of warranty. If the Contractor fails to correct nonconforming Work within a reasonable time during that period after receipt of notice from the Owner or Architect, the Owner may correct it in accordance with Section 2.5. Materials, part, and/or components employed in the warranty Work shall be of quality greater than and no less than equally to that of fully conforming equipment, components, materials and/or parts originally furnished by Contractor as part of its Work.

§ 12.2.2.2 The one-year period for correction of Work shall be extended with respect to portions of Work first performed after Substantial Completion by the period of time between Substantial Completion and the actual completion of that portion of the Work.

§ 12.2.2.3 Upon completion of any Work under or pursuant to this Paragraph 12.2, the one-year correction period in connection with the Work requiring correction shall be renewed and recommence as to the specific item(s) replaced and/or repaired.

§ 12.2.2.4 In the event any Work, material or equipment is replaced or repaired as a consequence of latent defects or failure to meet the terms of the Contract Documents, all warranties with respect to only such Work, material or equipment replaced or repaired shall continue following repair or replacement of such Work, material or equipment for an additional period equivalent to the original period of warranty for such Work, material or equipment as to the extent this is a reoccurring event.

§ 12.2.3 The Contractor shall remove from the site portions of the Work that are not in accordance with the requirements of the Contract Documents and are neither corrected by the Contractor nor accepted by the Owner.

§ 12.2.4 The Contractor shall bear the cost of correcting destroyed or damaged construction of the Owner or Separate Contractors, whether completed or partially completed, caused by the Contractor's correction or removal of Work that is not in accordance with the requirements of the Contract Documents.

§ 12.2.5 Nothing contained in this Section 12.2 shall be construed to establish a period of limitation with respect to other obligations the Contractor has under the Contract Documents. Establishment of the one-year period for correction of Work as described in Section 12.2.2 relates only to the specific obligation of the Contractor to correct the Work, and has no relationship to the time within which the obligation to comply with the Contract Documents may be sought to be enforced, nor to the time within which proceedings may be commenced to establish the Contractor's liability with respect to the Contractor's obligations other than specifically to correct the Work.

§ 12.3 Acceptance of Nonconforming Work

If the Owner prefers to accept Work that is not in accordance with the requirements of the Contract Documents, the Owner may do so instead of requiring its removal and correction, in which case the Contract Sum will be reduced as appropriate and equitable. Such adjustment shall be effected whether or not final payment has been made. The Owner's acceptance of the Work or any portion thereof that is not in accordance with the requirements of the Contract Documents shall be effective only when the Owner's acceptance of such specifically identified deficiency is memorialized in writing and signed by an agent of the Owner authorized by law to do so.

ARTICLE 13 MISCELLANEOUS PROVISIONS

§ 13.1 Governing Law

The Contract shall be governed by the law of the Commonwealth of Pennsylvania without application to its choice of law provisions.

§ 13.2 Successors and Assigns

§ 13.2.1 The Owner and Contractor respectively bind themselves, their partners, successors, assigns, and legal representatives to covenants, agreements, and obligations contained in the Contract Documents. Except as provided in Section 13.2.2, or set forth elsewhere in the Contract Documents, the Contractor shall not transfer, sell or assign the Contract as a or any portion thereof or its rights, title or interest therein, without written consent of the Owner. If the Contractor attempts to make an assignment without such consent, that party shall nevertheless remain legally responsible for all obligations under the Contract.

§ 13.2.2 The Owner may, without consent of the Contractor, assign the Contract to an institutional lender providing construction financing for the Project, if the lender assumes the Owner's rights and obligations under the Contract Documents. The Contractor shall execute all consents reasonably required to facilitate the assignment. The Owner may also without the consent of the Contractor, assign the Contract to a successor in interest or a related or affiliated entity.

§ 13.3 Rights and Remedies

§ 13.3.1 Except as expressly provided in the Contract Documents, duties and obligations imposed by the Contract Documents and rights and remedies available thereunder shall be in addition to and not a limitation of duties, obligations, rights, and remedies otherwise imposed or available by law.

§ 13.3.2 No action or failure to act by the Owner, Architect, or Contractor shall constitute a waiver of a right or duty afforded them under the Contract, nor shall such action or failure to act constitute approval of or acquiescence in a breach thereunder, except as may be specifically agreed upon in writing.

§ 13.4 Tests and Inspections

§ 13.4.1 Tests, inspections, and approvals of portions of the Work shall be made as required by the Contract Documents and by applicable laws, statutes, ordinances, codes, rules, and regulations or lawful orders of public authorities. Unless otherwise provided, the Contractor shall make arrangements for such tests, inspections, and approvals with an independent testing laboratory or entity acceptable to the Owner, or with the appropriate public authority, and shall bear all related costs of tests, inspections, and approvals. The Contractor shall give the Architect and Owner timely notice of when and where tests and inspections are to be made so that the Architect and Owner may be present for such procedures. The Owner shall bear costs of tests, inspections, or approvals that do not become requirements until after bids are received or negotiations concluded. The Owner shall directly arrange and pay for tests, inspections, or approvals where building codes or applicable laws or regulations so require.

§ 13.4.2 If the Architect, Owner, or public authorities having jurisdiction determine that portions of the Work require additional testing, inspection, or approval not included under Section 13.4.1, the Architect will, upon written authorization from the Owner, instruct the Contractor to make arrangements for such additional testing, inspection, or approval, by an entity acceptable to the Owner, and the Contractor shall give timely notice to the Architect and Owner of when and where tests and inspections are to be made so that the Architect may be present for such procedures. Such costs, except as provided in Section 13.4.3, shall be at the Owner's expense.

§ 13.4.3 If procedures for testing, inspection, or approval under Sections 13.4.1 and 13.4.2 reveal failure of the portions of the Work to comply with requirements established by the Contract Documents, all costs made necessary by such failure, including those of repeated procedures and compensation for the Architect's services and expenses, in addition to the procedures and compensation the independent testing and inspection firm's services and expenses, shall be at the Contractor's expense.

§ 13.4.4 Required certificates of testing, inspection, or approval shall, unless otherwise required by the Contract Documents, be secured by the Contractor and promptly delivered to the Architect.

§ 13.4.5 If the Architect is to observe tests, inspections, or approvals required by the Contract Documents, the Architect will do so promptly and, where practicable, at the normal place of testing.

§ 13.4.6 Tests or inspections conducted pursuant to the Contract Documents shall be made promptly to avoid unreasonable delay in the Work.

§ 13.5 Interest

Payments due and unpaid under the Contract Documents shall bear interest from the date payment is due at the rate the parties agree upon in writing.

ARTICLE 14 TERMINATION OR SUSPENSION OF THE CONTRACT

§ 14.1 Termination by the Contractor

§ 14.1.1 Provided the Contractor can demonstrate that it has been materially harmed thereby, the Contractor may terminate the Contract if the Work is stopped for a period of 60 consecutive days through no act or fault of the Contractor, a Subcontractor, a Sub-subcontractor, their agents or employees, or any other persons or entities performing portions of the Work, for any of the following reasons:

.1 Issuance of an order of a court or other public authority having jurisdiction that requires all Work to be stopped;

.2 An act of government, such as a declaration of national emergency, that requires all Work to be stopped;

.3 Because the Architect has not issued a Certificate for Payment and has not notified the Contractor of the reason for withholding certification as provided in Section 9.4.1, or because the Owner has not made payment on a Certificate for Payment within the time stated in the Contract Documents; or

.4 The Owner has failed to furnish to the Contractor reasonable evidence as required by Section 2.2.

The Contractor acknowledges and agrees that it executed this Agreement during a pandemic and that any act or order associated therewith shall not serve as a basis for termination no matter the length of the stoppage.

§ 14.1.2 The Contractor may terminate the Contract if, through no act or fault of the Contractor, a Subcontractor, a Sub-subcontractor, their agents or employees, or any other persons or entities performing portions of the Work, repeated suspensions, delays, or interruptions of the entire Work by the Owner as described in Section 14.3, constitute in the aggregate more than 100 percent of the total number of days scheduled for completion, or 120 days in any 365-day period, whichever is more.

§ 14.1.3 If one of the reasons described in Section 14.1.1 or 14.1.2 exists, the Contractor may, upon thirty days' notice to the Owner and Architect, terminate the Contract and recover from the Owner payment for Work executed and profit thereon,, and reasonable out-of-pocket costs incurred by reason of such termination, and no further remuneration.

§ 14.1.4 If the Work is stopped for a period of 90 consecutive days through no act or fault of the Contractor, a Subcontractor, a Sub-subcontractor, or their agents or employees or any other persons or entities performing portions of the Work because the Owner has repeatedly failed to fulfill the Owner's obligations under the Contract Documents with respect to matters important to the progress of the Work, the Contractor may, upon 15 additional days' notice to the Owner and the Architect, terminate the Contract and recover from the Owner as provided in Section 14.1.3.

§ 14.2 Termination by the Owner for Cause

§ 14.2.1 The Owner may terminate the Contract if the Contractor

.1 refuses or fails to supply enough properly skilled workers or proper materials;

.2 fails to make payment to Subcontractors or suppliers in accordance with the respective agreements between the Contractor and the Subcontractors or suppliers;

.3 disregards applicable laws, statutes, ordinances, codes, rules and regulations, or lawful orders of a public authority applicable to Contractor's performance of its Work; or

.4 otherwise is guilty of material breach of a provision of the Contract Documents

.5 shall institute proceedings or consent to proceedings requesting relief or arrangement under the Federal Bankruptcy Code or any similar or applicable federal or state law; or if a petition under any federal or state bankruptcy or insolvency law is filed against the Contractor and such petition is not dismissed within sixty (60) days from the date of said filing; or if the Contractor admits in writing, his inability to pay his debts generally as they become due, or if it makes a general assignment for the benefit of its creditors, or if a receiver, liquidator, trustee or assignee is appointed on account of its bankruptcy or insolvency; or if a receiver of all or any substantial portion of the Contractor's properties is appointed.

§ 14.2.2 When any of the reasons described in Section 14.2.1 exist, , the Owner may, without prejudice to any other rights or remedies of the Owner and after giving the Contractor and the Contractor's surety, if any, seven days' notice, terminate employment of the Contractor and may, subject to any prior rights of the surety:

.1 Exclude the Contractor from the site and take possession of all materials, equipment, tools, and construction equipment and machinery thereon owned by the Contractor;

.2 Accept assignment of subcontracts pursuant to Section 5.4; and

.3 Finish the Work by whatever reasonable method the Owner may deem expedient. Upon written request of the Contractor, the Owner shall furnish to the Contractor a detailed accounting of the costs incurred by the Owner in finishing the Work.

§ 14.2.3 When the Owner terminates the Contract for one of the reasons stated in Section 14.2.1, the Contractor shall not be entitled to receive further payment until the Work is finished. The Owner's right to terminate the Agreement pursuant to this Subparagraph 14.2 shall be in addition to and not in limitation of any rights or remedies existing hereunder or pursuant hereto or at law or in equity.**§ 14.2.4** If such costs, damages and expenses incurred by the Owner in finishing the Work, including, but not limited to, compensation for the Architect's services and expenses, and professional fees and expenses, and other damages incurred by the Owner exceed the unpaid balance, the Contractor shall pay the difference to the Owner. This obligation for payment shall survive termination of the Contract.
(Paragraph deleted)

§ 14.2.4.1 Upon determination that a termination of this Contract under this Section was wrongful, or improper for any reason, such termination shall automatically be deemed converted to a termination by the

Owner for convenience and the Contractor's sole remedy for such wrongful termination shall be limited to the recoveries specified under Section 14.3.

§ 14.3 Suspension by the Owner for Convenience

§ 14.3.1 The Owner may, without cause, order the Contractor in writing to suspend, delay or interrupt the Work, in whole or in part for such period of time as the Owner may determine. Any suspension by the Owner for convenience does not constitute grounds for termination by the Contractor under Section 14.1.

§ 14.3.2 The Contract Sum and Contract Time shall be adjusted for increases in the cost and time caused by suspension, delay, or interruption under Section 14.3.1. Adjustment of the Contract Sum shall include profit. No adjustment shall be made to the extent

.1 that performance is, was, or would have been, so suspended, delayed, or interrupted, by another cause for which the Contractor is responsible; or

.2 that an equitable adjustment is made or denied under another provision of the Contract.

§ 14.4 Termination by the Owner for Convenience

§ 14.4.1 The Owner may, at any time, terminate the Contract for the Owner's convenience and without cause, even though Contractor has not failed to perform any part of the Contract. Termination by the Owner under this Paragraph shall be by a written notice of termination delivered to the Contractor specifying the extent of termination and the effective date.

§ 14.4.2 Upon receipt of notice from the Owner of such termination for the Owner's convenience, the Contractor shall

.1 cease operations as directed by the Owner in the notice;

.2 take actions necessary, or that the Owner may direct, for the protection and preservation of the Work; and

.3 except for Work directed to be performed prior to the effective date of termination stated in the notice, terminate all existing subcontracts and purchase orders and enter into no further subcontracts and purchase orders.

.4 Proceed to complete the performance of the Work not terminated, if any. Deliver drawings, specifications, instruments of service, warranties, operation and maintenance manuals, project closeout documents and other necessary information to the Owner.

§ 14.4.3 Upon such termination the Contractor shall recover as its sole remedy payment for Work properly performed prior to the effective date of termination and for items properly and timely fabricated off the Project site, delivered and stored in accordance with the Owner's instructions and any out-of-pocket termination costs such as restocking fees and non-cancellable/nonrefundable items. The Contractor hereby waives and forfeits all other claims for payment and damages, including, without limitation, anticipated and/or unearned profits, consequential or indirect damages.

§ 14.4.4 All obligations of the Contractor under the Contract with respect to completion of the Work, including but not limited to all warranties, guarantees and indemnities, shall apply to all Work completed or Substantially Completed by the Contractor prior to a convenience termination by the Owner. Notwithstanding the above, any convenience termination by the Owner or payments to the Contractor shall be without prejudice to any claims or legal remedies that the Owner may have against the Contractor for any cause.

ARTICLE 15 CLAIMS AND DISPUTES

§ 15.1 Claims

§ 15.1.1 Definition

A Claim is a demand or assertion by one of the parties seeking, as a matter of right, payment of money, a change in the Contract Time, or other relief with respect to the terms of the Contract. The term "Claim" also includes other disputes and matters in question between the Owner and Contractor arising out of or relating to the Contract. The responsibility to substantiate Claims shall rest with the party making the Claim. This Section 15.1.1 does not require the Owner to file a Claim in order to impose liquidated damages in accordance with the Contract Documents.

§ 15.1.1.1 The parties agree that upon the receipt of a Claim, within ten (10) business days, Stacy Percoski on behalf of Contractor and Kate Romano on behalf of Owner shall meet in an effort to resolve the same. Should such meeting be unsuccessful in resolving the Claim, within fifteen (15) business days, Jeff Jenkins on behalf of Contractor and Suma

Krishnan on behalf of the Owner shall meet within ten (10) business days. Upon failure to resolve the Claim at such meeting, the dispute resolution provisions herein shall then be followed.

§ 15.1.2 Time Limits on Claims

The Owner and Contractor shall commence all Claims and causes of action against the other and arising out of or related to the Contract, whether in contract, tort, breach of warranty or otherwise, in accordance with the requirements of the binding dispute resolution method selected in the Agreement and within the period specified by applicable law., The Owner and Contractor waive all Claims and causes of action not commenced in accordance with this Section 15.1.2.

§ 15.1.3 Notice of Claims

§ 15.1.3.1 Claims by either the Owner or Contractor, where the condition giving rise to the Claim is first discovered prior to expiration of the period for correction of the Work set forth in Section 12.2.2, shall be initiated by notice to the other party and to the Initial Decision Maker with a copy sent to the Architect, if the Architect is not serving as the Initial Decision Maker. Claims by either party. Claims by the Contractor under this Section 15.1.3.1 shall be initiated within 21 days after occurrence of the event giving rise to such Claim or within 21 days after it first recognizes the condition giving rise to the Claim, whichever is later. The Claim shall identify all causes of action, basis for requested relief including all facts and events, and an itemization of the claim amount including supporting documentation of the Claim amount.

§ 15.1.3.2 Payment of a Change Order shall constitute accord and satisfaction of all Claims in connection with the change or changes to the Contract Documents addressed by the Change Order, and it is understood and agreed that a signed Change Order shall be the complete and full integrated agreement for all related costs including but not limited to delay, inefficiency, overtime, and/or acceleration costs, and that there are no oral or written understandings, representations or agreements, directly or indirectly, connected with the Change Order that are not affirmatively stated on the signed Change Order. The Contractor's execution of a Change Order constitutes a representation that it will make no further Claims for damages inconsistent with this paragraph.

§ 15.1.3.3 Claims by either the Owner or Contractor, where the condition giving rise to the Claim is first discovered after expiration of the period for correction of the Work set forth in Section 12.2.2, shall be initiated by notice to the other party. In such event, no decision by the Initial Decision Maker is required.

§ 15.1.4 Continuing Contract Performance

§ 15.1.4.1 Pending final resolution of a Claim, except as otherwise agreed in writing or as provided in Section 9.7 and Article 14, the Contractor shall proceed diligently with performance of the Contract and the Owner shall continue to make payments in accordance with the Contract Documents.

§ 15.1.4.2 The Contract Sum and Contract Time shall be adjusted in accordance with the Initial Decision Maker's decision, subject to the right of either party to proceed in accordance with this Article 15. The Architect will issue Certificates for Payment in accordance with the decision of the Initial Decision Maker. [Drafting Note - Architect not issuing CO?]

§ 15.1.5 Claims for Additional Cost

If the Contractor wishes to make a Claim for an increase in the Contract Sum, notice as provided in Section 15.1.3 shall be given before proceeding to execute the portion of the Work that is the subject of the Claim. Prior notice is not required for Claims relating to an emergency endangering life or property arising under Section 10.4.

§ 15.1.5.1 If the Contractor believes additional cost is involved for reasons including, but not limited to, (1) a written interpretation from the Architect, (2) an order by the Owner to stop the Work where the Contractor was not at fault, (3) a written order for a minor change in the Work issued by the Architect, (4) failure of payment by the Owner, (5) termination of the Agreement by the Owner, (6) Owner's suspension, or (7) other reasonable grounds, a timely Claim shall be filed in accordance with this Section 15.1.3.

§ 15.1.6 Claims for Additional Time

§ 15.1.6.1 If the Contractor wishes to make a Claim for an increase in the Contract Time, notice as provided in Section 15.1.3 shall be given. The Contractor's Claim shall include an estimate of cost and of probable effect of delay on progress of the Work. In the case of a continuing delay, only one Claim is necessary.

§ 15.1.6.2 If adverse weather conditions are the basis for a Claim for additional time, such Claim shall be documented by data substantiating that weather conditions were abnormal for the period of time, where they were beyond a fifteen (15) year coverage for the area could not have been reasonably anticipated, and had an adverse effect on the scheduled construction.

§ 15.1.6.3 The Contractor's Construction Schedule must reflect anticipated adverse weather delays in all weather-dependent activities.

§ 15.1.6.4 Upon acknowledgement of the Notice to Proceed and continuing throughout the Contract, the Contractor will record in a daily log the occurrence of adverse weather and resultant impact to normally scheduled critical path Work. Actual adverse weather delay days must prevent work on critical activities for 50 percent or more of the Contractor's scheduled work- day in order to constitute an adverse weather delay day. The number of actual adverse weather delay days shall include days impacted by actual adverse weather (even if adverse weather occurred in a previous month), be calculated chronologically from the first to the last day of each month, and be recorded as full days. If the number of actual adverse weather delay days exceeds the number of days anticipated in sub-subparagraph 15.1.6.3 above, the Architect will convert any qualifying delays to calendar days, giving full consideration for equivalent fair weather work days, and issue a no-cost Change Order for additional days, to be executed by the Owner, Architect and Contractor. This no-cost Change Order shall be the sole remedy for delays associated with weather.

§ 15.1.7 Waiver of Claims for Consequential Damages

The Contractor and Owner waive Claims against each other for consequential damages arising out of or relating to this Contract. This mutual waiver

(Paragraphs deleted)

is applicable, without limitation, to all consequential damages due to either party's termination in accordance with Article 14.

§ 15.2 Miscellaneous

§ 15.2.1 In the event of a dispute giving rise to a Claim, representatives of the parties shall meet in an effort to reach a resolution. Stacy Percoski shall participate on behalf of the Contractor and Kate Romano shall participate on behalf of the Owner. If unable to do resolve the Claim, officers of the parties shall meet within fifteen (15) days thereafter to review the Claim and reach a resolution. Jeff Jenkins shall participate on behalf of the Contractor and Suma Krishnan shall participate on behalf of the Owner. If unable to do resolve the Claim, the Claim shall be subject to the dispute resolution provisions of Section 15.3 and 15.4. .

§ 15.2.2 In the event of a Claim against the Contractor, the Owner may, but is not obligated to, notify the surety, if any, of the nature and amount of the Claim. If the Claim relates to a possibility of a Contractor's default, the Owner may, but is not obligated to, notify the surety, and request the surety's assistance in resolving the controversy.

§ 15.2.3 If a Claim relates to or is the subject of a mechanic's lien, the party asserting such Claim may proceed in accordance with applicable law to comply with the lien notice or filing deadlines.

(Paragraphs deleted)

§ 15.3 Mediation

§ 15.3.1 Claims, disputes, or other matters in controversy arising out of or related to the Contract, except those waived as provided for in Sections 9.10.4, 9.10.5, and 15.1.7, shall be subject to mediation as a condition precedent to binding dispute resolution.

§ 15.3.2 The parties shall endeavor to resolve their Claims by mediation with a mutually acceptable mediator, or if unable to agree upon one, shall be administered by the American Arbitration Association in accordance with its Construction Industry Mediation Procedures in effect on the date of the Agreement. A request for mediation shall be made in writing, delivered to the other party to the Contract, and filed with the person or entity administering the mediation. The request may be made concurrently with the filing of binding dispute resolution proceedings but, in such event, mediation shall proceed in advance of binding dispute resolution proceedings, which shall be stayed pending mediation for a period of 60 days from the date of filing, unless stayed for a longer period by agreement of the parties or court order.

(Paragraphs deleted)

§ 15.4 Litigation or Arbitration

§ 15.4.1 Any and all claims shall be subject to litigation or arbitration at the option of the Owner. The Contractor shall advise the Owner of its intent to proceed with a Claim and request the Owner to advise as to its selection of arbitration or litigation. Failure of the Owner to respond within ten (10) business days shall be deemed to be the selection of litigation. Any arbitration shall be filed with the American Arbitration Association in accordance with its Construction Industry Arbitration Rules in effect on the date of the Agreement and shall be conducted in the place where the Project is located.

§ 15.4.1.1 In the event of arbitration, a demand for arbitration shall be made no earlier than concurrently with the filing of a request for mediation, but in no event shall it be made after the date when the institution of legal or equitable proceedings based on the Claim would be barred by the applicable statute of limitations. For statute of limitations purposes, receipt of a written demand for arbitration by the person or entity administering the arbitration shall constitute the institution of legal or equitable proceedings based on the Claim.

§ 15.4.2 The award rendered by the arbitrator or arbitrators shall be final, and judgment may be entered upon it in accordance with applicable law in any court having jurisdiction thereof.

§ 15.4.3 The foregoing agreement to arbitrate and other agreements to arbitrate with an additional person or entity duly consented to by parties to the Agreement, shall be specifically enforceable under applicable law in any court having jurisdiction thereof.

§ 15.4.4 Consolidation or Joinder

§ 15.4.4.1 In the event of arbitration, subject to the rules of the American Arbitration Association or other applicable arbitration rules, either party may consolidate an arbitration conducted under this Agreement with any other arbitration to which it is a party provided that (1) the arbitrations to be consolidated substantially involve common questions of law or fact, and (3) the arbitrations employ materially similar procedural rules and methods for selecting arbitrator(s).

§ 15.4.4.2 In the event of arbitration, subject to the rules of the American Arbitration Association or other applicable arbitration rules, either party may include by joinder persons or entities substantially involved in a common question of law or fact whose presence is required if complete relief is to be accorded in arbitration

§ 15.4.4.3 In the event of arbitration, the Owner and Contractor grant to any person or entity made a party to an arbitration conducted under this Section 15.4, whether by joinder or consolidation, the same rights of joinder and consolidation as those of the Owner and Contractor under this Agreement.

KRYSTAL BIOTECH, INC.

DocuSigned by: krish krishnan
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OWNER *(Signature)*

DS AP DS KK

THE WHITING-TURNER CONTRACTING COMPANY

DocuSigned by: Samuel R. Wells
E814C2E756BE45B...

CONSTRUCTION MANAGER *(Signature)*

DS

Exhibit 31.1

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

I, Krish S. Krishnan, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the Condensed financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2021

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

Exhibit 31.2

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

I, Kathryn A. Romano, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the Condensed financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2021

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

Exhibit 32.1

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

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

1. the Quarterly Report on Form 10-Q for the three months ended June 30, 2021, (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: August 9, 2021

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

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

1. the Quarterly Report on Form 10-Q for the three months ended June 30, 2021, (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: August 9, 2021

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