Section 1: 10-Q (FORM 10-Q)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2019

OR

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

For the transition period from to

Commission File Number 001-35366

FORTRESS BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-5157386**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address including zip code of principal executive offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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

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

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	FBIO	Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	FBIOP	Nasdaq Capital Market

As of May 8, 2019, there were 65,230,630 shares of Common Stock of the issuer outstanding.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Quarterly Report on Form 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 116,444	$ 65,508
Accounts receivable	8,022	5,498
Short-term investments (certificates of deposit)	5,044	17,604
Inventory	629	678
Other receivables - related party	2,129	2,095
Prepaid expenses and other current assets	4,281	6,735
Current assets held for sale	–	13,089
Total current assets	136,549	111,207
Property and equipment, net	11,833	12,019
Operating lease right-of-use asset, net	22,618	–
Restricted cash	16,074	16,074
Long-term investment, at fair value	11,056	–
Intangible asset	1,183	1,417
Other assets	1,225	276
Total assets	**$ 200,538**	**$ 140,993**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 37,073	$ 34,067
Accounts payable and accrued expenses - related party	16	149
Interest payable	1,013	1,232
Interest payable - related party	97	97
Notes payable, short-term - related party (net of debt discount of $223 and $336 at March 31, 2019 and December 31, 2018, respectively)	9,277	9,164
Partner company convertible note, short-term, at fair value	–	9,914
Operating lease liabilities – short-term	1,481	–
Derivative warrant liability	–	991
Total current liabilities	48,957	55,614
Notes payable, long-term (net of debt discount of $6,385 and $4,567 at March 31, 2019 and December 31, 2018, respectively)	73,607	60,425
Operating lease liabilities – long-term	24,989	–
Other long-term liabilities	2,276	5,211
Total liabilities	**149,829**	**121,250**

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	March 31, 2019 (Unaudited)	December 31, 2018
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 1,000,000 shares issued and outstanding as of March 31, 2019 December 31, 2018; liquidation value of $25.00 per share	1	1
Common stock, $.001 par value, 100,000,000 shares authorized, 63,126,521 and 57,845,447 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	63	58
Common stock issuable, 475,225 and 744,332 shares as of March 31, 2019 and December 31, 2018, respectively	765	659
Additional paid-in-capital	414,870	397,408
Accumulated deficit	(394,882)	(396,274)
Total stockholders' equity attributed to the Company	20,817	1,852
Non-controlling interests	29,892	17,891
Total stockholders' equity	50,709	19,743
Total liabilities and stockholders' equity	**$ 200,538**	**$ 140,993**

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
($ in thousands except for share and per share amounts)
(Unaudited)

	For the Three Months Ended March 31,	
	2019	**2018**
Revenue		
Product revenue, net	$ 6,125	$ 5,509
Revenue - from a related party	352	394
Net revenue	6,477	5,903
Operating expenses		
Cost of goods sold - product revenue	1,884	1,472
Research and development	23,273	24,958
Research and development - licenses acquired	450	97
General and administrative	13,478	13,548
Total operating expenses	39,085	40,075
Loss from operations	(32,608)	(34,172)
Other income (expenses)		
Interest income	438	278
Interest expense and financing fee	(2,469)	(2,403)
Change in fair value of derivative liability	–	23
Change in fair value of subsidiary convertible note	–	250
Change in fair value of investments	–	(118)
Gain on deconsolidation of Caelum	18,384	–
Total other income (expense)	16,353	(1,970)
Loss from continuing operations	(16,255)	(36,142)
Discontinued operations		
Loss from discontinued operations, net of tax	–	(2,076)
Total loss from discontinued operations	–	(2,076)
Net loss	**(16,255)**	**(38,218)**
Less: net loss attributable to non-controlling interests	17,647	17,200
Net income (loss) attributable to common stockholders	**$ 1,392**	**$ (21,018)**
Loss from continuing operations per common share - basic and diluted	$ (0.34)	$ (0.85)
Loss from discontinued operations per common share - basic and diluted	$ –	$ (0.05)
Net income (loss) per common share attributable to common stockholders - basic	$ 0.03	$ (0.49)
Net income (loss) per common share attributable to common stockholders - diluted	$ 0.02	$ (0.49)
Weighted average common shares outstanding - basic	48,506,994	42,518,403
Weighted average common shares outstanding - diluted	63,811,136	42,518,403

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Stockholders' Equity
($ in thousands)
(Unaudited)

	Series A Preferred Stock		Common Stock		Common Shares	Additional Paid-In	Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Issuable	Capital	Deficit	Interests	Equity
Balance at December 31, 2018	**1,000,000**	**$ 1**	**57,845,447**	**$ 58**	**$ 659**	**$ 397,408**	**$ (396,274)**	**$ 17,891**	**$ 19,743**
Stock-based compensation expense	-	-	-	-	-	3,309	-	-	3,309
Issuance of restricted stock	-	-	1,609,325	2	-	(2)	-	-	-
Issuance of subsidiaries' common shares for license expenses	-	-	-	-	(164)	164	-	-	-
Issuance of common stock for at-the-market offering, net	-	-	2,927,427	3	-	6,139	-	-	6,142
Preferred A dividends declared and paid	-	-	-	-	-	(586)	-	-	(586)
Partner company's sale of stock, net	-	-	-	-	-	31,499	-	-	31,499
Partner company's at-the-market offering, net	-	-	-	-	-	355	-	-	355
Issuance of partner company warrants in conjunction with Horizon Notes						888			888
Common shares issuable for 2017 Subordinated Note Financing interest expense	-	-	-	-	484	-	-	-	484
Common shares issued for 2017 Subordinated Note Financing interest expense	-	-	744,322	-	(495)	495	-	-	-
Common shares issuable for Opus interest expense	-	-	-	-	281	-	-	-	281
Non-controlling interest in subsidiaries	-	-	-	-	-	(24,799)	-	24,799	-
Deconsolidation of Caelum non-controlling interest	-	-	-	-	-	-	-	4,849	4,849
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	(17,647)	(17,647)
Net income attributable to common stockholders	-	-	-	-	-	-	1,392	-	1,392
Balance at March 31, 2019	**1,000,000**	**$ 1**	**63,126,521**	**$ 63**	**$ 765**	**$ 414,870**	**$ (394,882)**	**$ 29,892**	**$ 50,709**

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Stockholders' Equity
($ in thousands)
(Unaudited)

	Series A Preferred Stock		Common Stock		Common Shares	Additional Paid-In	Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Issuable	Capital	Deficit	Interests	Equity
Balance at December 31, 2017	**1,000,000**	**$ 1**	**50,991,285**	**$ 51**	**$ 500**	**$ 364,148**	**$ (312,127)**	**$ 67,929**	**$ 120,502**
Stock-based compensation expense	-	-	-	-	-	4,795	-	-	4,795
Issuance of restricted stock	-	-	1,472,440	1	-	(1)	-	-	-
Issuance of subsidiaries' common shares for license expenses	-	-	-	-	-	22	-	-	22
Subsidiary's offering, net	-	-	-	-	-	20,844	-	-	20,844
Exercise of subsidiary's warrants for cash	-	-	-	-	-	96	-	-	96
Issuance of common stock for at-the-market offering	-	-	64,797	-	-	318	-	-	318
At-the-market offering cost	-	-	-	-	-	(6)	-	-	(6)
Common shares issuable for 2017 Subordinated Note Financing interest expense	-	-	-	-	489	-	-	-	489
Common shares issued for 2017 Subordinated Note Financing interest expense	-	-	158,015	-	(500)	500	-	-	-
Preferred A dividends declared and paid	-	-	-	-	-	(586)	-	-	(586)
–Disposal of National	-	-	-	-	-	(710)	-	-	(710)
Non-controlling interest in subsidiaries	-	-	-	-	-	(15,166)	-	15,166	-
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	(17,200)	(17,200)
Net loss attributable to common stockholders	-	-	-	-	-	-	(21,018)	-	(21,018)
Balance at March 31, 2018	**1,000,000**	**$ 1**	**52,686,537**	**$ 52**	**$ 489**	**$ 374,254**	**$ (333,145)**	**$ 65,895**	**$ 107,546**

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
($ in thousands)
(Unaudited)

	For the Three Months Ended March 31,	
	2019	**2018**
Cash Flows from Operating Activities:		
Net loss	$ (16,255)	$ (38,218)
Net loss on discontinued operations	–	(2,076)
Loss from continuing operations	(16,255)	(36,142)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation expense	481	196
Amortization of debt discount	622	661
Amortization of product revenue license fee	234	133
Amortization of operating lease right-of-use assets	381	–
Stock-based compensation expense	3,309	4,795
Common shares issuable for Opus interest expense	281	–
Common shares issuable for 2017 Subordinated Note Financing interest expense	484	489
Change in fair value of investments	–	118
Change in fair value of derivative liability	–	(23)
Change in fair value of partner company convertible note	–	(250)
Gain on deconsolidation of Caelum	(18,384)	–
Research and development-licenses acquired, expense	450	97
Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:		
Accounts receivable	(2,524)	(556)
Inventory	49	(51)
Other receivables - related party	(34)	(326)
Prepaid expenses and other current assets	2,483	(1,466)
Other assets	(949)	(343)
Current assets held for sale	–	(3,383)
Noncurrent assets held for sale	–	427
Current liabilities held for sale	–	4,040
Accounts payable and accrued expenses	3,664	6,195
Accounts payable and accrued expenses - related party	(133)	(98)
Interest payable	(21)	17
Interest payable - related party	–	(12)
Lease liabilities	(351)	–
Other long-term liabilities	888	19
Net cash used in continuing operating activities	(25,325)	(25,463)
Net cash used in discontinued operating activities	–	(2,381)
Net cash used in operating activities	(25,325)	(27,844)

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

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows (Continued)
($ in thousands)
(Unaudited)

Cash Flows from Investing Activities:		
Purchase of research and development licenses	-	(75)
Purchase of property and equipment	(300)	(765)
Purchase of short-term investment (certificates of deposit)	-	(25,000)
Redemption of short-term investment (certificates of deposit)	12,560	24,000
Deconsolidation of Caelum	(1,201)	-
Net cash provided by (used in) continuing investing activities	11,059	(1,840)
Net cash provided by discontinued investing activities	13,089	-
Net cash provided by (used in) investing activities	24,148	(1,840)
Cash Flows from Financing Activities:		
Payment of Preferred A dividends	(586)	(586)
Inter-company costs related to the issuance of Series A preferred stock	–	1,298
Proceeds from at-the-market offering	6,251	229
Payment of cost related to at-the-market offering	(109)	(6)
Proceeds from partner company's sale of stock	34,999	23,011
Payment of costs related to partner company's sale of stock	(3,500)	(2,167)
Proceeds from partner company's at-the-market offering	366	-
Payment of costs related to partner company's at-the-market offering	(11)	-
Proceeds from exercise of partner companies' warrants	–	96
Payment of debt issuance costs associated with 2017 Subordinated Note Financing	–	(255)
Proceeds from 2018 Venture Notes	–	21,707
Payment of debt issue costs associated with 2018 Venture Notes	(67)	(1,814)
Proceeds from partner company's Horizon Notes	15,000	–
Payment of debt issuance costs associated with partner company's Horizon Notes	(230)	–
Payment of partner company's Convertible Notes	–	(1,858)
Net cash provided by financing activities	52,113	39,655
Net increase in cash and cash equivalents and restricted cash	50,936	9,971
Cash and cash equivalents and restricted cash at beginning of period	81,582	110,958
Cash and cash equivalents and restricted cash at end of period	$ 132,518	$ 120,929
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,100	$ 394
Cash paid for interest - related party	$ –	$ 853
Supplemental disclosure of non-cash financing and investing activities:		
Settlement of restricted stock units into common stock	$ 2	$ 1
Receivable from ATM issuances	$ –	$ 89
Unpaid debt offering costs	$ 1,202	$ –
Common shares issuable for license acquired	$ 164	$ –
Common shares issued for 2017 Subordinated Note Financing interest expense	$ 495	$ 500
Issuance of partner company warrants in conjunction with Horizon Notes	$ 888	$ –
Unpaid fixed assets	$ 191	$ 2,321
Inter-company costs related to the issuance of Series A preferred stock	$ –	$ 1,298

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

1. Organization and Description of Business

Fortress Biotech, Inc. ("Fortress" or the "Company") is a biopharmaceutical company dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates, which the Company does at the Fortress level, at its majority-owned and majority-controlled subsidiaries and joint ventures, and at entities the Company founded and in which it maintains significant minority ownership positions. Fortress has a talented and experienced business development team, comprising scientists, doctors and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. Fortress through its partner companies has executed such arrangements in partnership with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, St. Jude Children's Research Hospital and University College London.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, Fortress leverages its business, scientific, regulatory, legal and finance expertise to help the partners achieve their goals. Partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, and public and private financings; to date, three partner companies are publicly-traded, and two have consummated strategic partnerships with industry leaders Alexion Pharmaceuticals, Inc. and InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited).

As of March 31, 2019, several of the Fortress partner companies maintain licenses to product candidate intellectual property, including Aevitas Therapeutics, Inc. ("Aevitas"), Avenue Therapeutics, Inc. ("Avenue"), Caelum Biosciences, Inc. ("Caelum"), Cellvation, Inc. ("Cellvation"), Checkpoint Therapeutics, Inc. ("Checkpoint"), Cyprium Therapeutics, Inc. ("Cyprium"), Helocyte, Inc. ("Helocyte"), Journey Medical Corporation ("Journey" or "JMC"), Mustang Bio, Inc. ("Mustang"), and Tamid Bio, Inc. ("Tamid").

Liquidity and Capital Resources

Since inception, the Company's operations have been financed primarily through the sale of equity and debt securities and proceeds from the exercise of warrants and stock options. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and prepare regulatory filings and obtain regulatory approvals for its existing and new product candidates. The Company's current cash and cash equivalents are sufficient to fund operations for at least the next 12 months. However, the Company will need to raise additional funding through strategic relationships, public or private equity or debt financings, sale of a partner company, grants or other arrangements to fully develop and prepare regulatory filings and obtain regulatory approvals for the existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for the potential products, sales and marketing capabilities. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plan and plans for expansion of its general and administrative infrastructure will be curtailed.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the unaudited condensed consolidated financial statements have read or have access to the audited financial statements for the preceding fiscal year for each of the companies: Avenue, Checkpoint and Mustang. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 18, 2019, from which the Company derived the balance sheet data at December 31, 2018, as well as Checkpoint's Form 10-K filed with the SEC on March 18, 2019, Mustang's Form 10-K, filed with the SEC on March 18, 2019, and Avenue's Form 10-K, filed with the SEC on March 12, 2019.

The Company's unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries: Avenue, Aevitas, CB Securities Corporation, Cellvation, Coronado SO Co., Checkpoint, Cyprium, Escala Therapeutics, Inc., GeneXion Oncology, Inc., Helocyte, Immune Limited, JMC, Mustang, Tamid, Fortress Biotech China, Inc., FBIO Acquisition Corp. IV, FBIO Acquisition Corps. VI - XIV, and JG Pharma, Inc., a subsidiary of JMC. All intercompany balances and transactions have been eliminated.

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting period.

Use of Estimates

The Company's unaudited condensed consolidated financial statements include certain amounts that are based on management's best estimates and judgments. The Company's significant estimates include, but are not limited to, useful lives assigned to long-lived and intangible assets, fair value measurements, stock-based compensation, common stock issued to acquire licenses, investments, accrued expenses, derivative warrant liabilities, revenue with customers, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates.

Discontinued Operations

At December 31, 2018, the Company determined that its National segment met the discontinued operations criteria set forth in Accounting Standards Codification (ASC) Subtopic 205-20-45, *Presentation of Financial Statements*. As such, the National segment results have been classified as discontinued operations in the accompanying Condensed Consolidated Balance Sheets and Condensed Consolidated Statements of Operations. See Note 3 for more information relating to the Company's discontinued operations.

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2018 Annual Report other than the adoption of the Financial Accounting Standards Board (FASB) Accounting Standard Updates (ASU) ASU 2016-02, *Leases*, and 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*.

Leases

Effective January 1, 2019, the Company accounts for its leases under ASC 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases, and are recorded on the condensed consolidated balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. For finance leases, interest on the lease liability and the amortization of the right-of-use asset results in front-loaded expense over the lease term. Variable lease expenses are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elects to combine lease and non-lease components. The Company continues to account for leases in the prior period financial statements under ASC Topic 840.

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates.

For stock-based compensation awards to non-employees, prior to the adoption of ASU 2018-07 on January 1, 2019, the Company remeasured the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards were recognized as compensation expense in the period of change. Subsequent to the adoption of ASU 2018-07, the Company recognizes non-employees compensation costs over the requisite service period based on a measurement of fair value for each stock award.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model or 409A valuations, as applicable. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Recently Adopted Accounting Pronouncements

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule became effective on November 5, 2018. The Company included the required presentation of changes in stockholders' equity in this Form 10-Q.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU No. 2018-07 as of January 1, 2019. As a result of the adoption of ASU 2018-07, the grant date fair value of non-employee awards will be fixed as of December 31, 2018, rather than the prior methodology that recognized a variable cost based on the fair value of such shares as of their vesting dates. The Company recorded non-employees' awards as of January 1, 2019 prospectively. The Company's implementation of this standard as of January 1, 2019 did not have a material impact on its condensed consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The adoption of this ASU on January 1, 2019 did not have a material impact on its condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method by recording a right of use asset of $23.0 million, a lease liability of $26.8 million and eliminated deferred rent of approximately $3.8 million; there was no effect on opening retained earnings, and the Company continues to account for leases in the prior period financial statements under ASC Topic 840. In adopting the new standard, the Company elected to apply the practical expedients regarding the identification of leases, lease classification, indirect costs, and the combination of lease and non-lease components.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326)*: Measurement of Credit Losses on Financial Instruments. ASU 2016-13 requires that expected credit losses relating to financial assets are measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective on January 1, 2020 and may be adopted earlier. The Company is currently evaluating the impact, if any, that ASU 2016-13 will have on its condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* , which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its condensed consolidated financial statements.

3. Discontinued Operations

The following is a summary of revenue and expenses of National for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,	
($ in thousands)	**2019**	**2018**
Revenue	$ –	$ 49,522
Operating expenses		
Commissions, compensation and fees	–	43,561
Clearing fees	–	743
Communications	–	760
Occupancy	–	955
Licenses and registration	–	637
Professional fees	–	1,393
Underwriting costs	–	145
Interest	–	2
Depreciation and amortization	–	859
Other administrative expenses	–	1,781
Total operating expenses	–	50,836
Gain (loss) from operations	–	(1,314)
Other income (expenses)		
Change in fair value of derivative liabilities	–	(1,088)
Interest expense and financing fees	–	320
Interest income	–	6
Total other expenses	–	(762)
Total loss from discontinued operations	$ –	$ (2,076)

As of March 31, 2019, the Company received $13.1 million or $3.25 per share, for its remaining ownership of National, as such as of March 31, 2019 the Company had no asset available for sale on its condensed consolidated balance sheets. In connection with this sale, the Company classified the assets and liabilities related to National, included on its condensed consolidated balance sheet as of March 31, 2019 and December 31, 2018, as held for sale as presented in the table below:

($ in thousands)	**March 31, 2019**	**December 31, 2018**
ASSETS		
Current assets		
Current assets held for sale	$ –	$ 13,089
Total current assets held for sale	–	13,089
Total assets held for sale	$ –	$ 13,089

The table below depicts the cash flows from the transaction for the three months ended March 31, 2019 and 2018, respectively:

	Three months ended March 31,	
($ in thousands)	**2019**	**2018**
Operating activities		
Effect of elimination entry on discontinued operations presentation	$ –	$ (305)
Net loss on discontinued operations	–	(2,076)
Total cash used in discontinued operating activities	$ –	$ (2,381)
Investing activities		
Proceeds from sale of National	$ 13,089	$ –
Total cash provided by discontinued investing activities	$ 13,089	$ –

4. Collaboration and Stock Purchase Agreements

Caelum

Agreement with Alexion

In January 2019, our partner company Caelum Biosciences, Inc. (“Caelum”) signed an agreement with Alexion Pharmaceuticals, Inc. (“Alexion”) to advance the development of CAEL-101. Under the terms of the agreement, Alexion purchased a 19.9% minority equity interest in Caelum for $30 million. Additionally, Alexion has agreed to make potential payments to Caelum upon the achievement of certain developmental milestones, in exchange for which Alexion obtained a contingent exclusive option to acquire the remaining equity in the company for pre-negotiated economics.

In connection with the Alexion agreement, the Company deconsolidated its holdings in Caelum immediately prior to the execution of the agreement. The following table provides a summary of the assets and liabilities of Caelum impacted by the deconsolidation:

($ in thousands)	**January 2019**
ASSETS	
Current assets	
Cash and cash equivalents	$ 1,201
Prepaid expenses and other current assets	6
Total current assets held for sale	$ 1,207
LIABILITIES	
Current liabilities	
Accounts payable and accrued expenses	$ 2,246
Interest payable	198
Interest payable - related party	106
Note payable - related party	929
Note payable	9,914
Warrant liability	991
Other current liabilities	14,384
Net liabilities impacted by deconsolidation	**$ 13,177**

In connection with this transaction the Company recorded a gain resulting from the deconsolidation of Caelum on its condensed consolidated financial statements for the three months ended March 31, 2019:

($ in thousands)	**Gain on deconsolidation of Caelum**
Fair value of Caelum	$ 11,056
Net liabilities deconsolidated	13,177
Non-controlling interest share	(4,849)
Write off of MSA fees due Fortress	(1,000)
Gain on deconsolidation of Caelum	**$ 18,384**

Avenue

Agreement with InvaGen

On November 12, 2018, the Company's partner company Avenue entered into a Stock Purchase and Merger Agreement ("SPMA") with InvaGen Pharmaceuticals Inc. ("InvaGen") and Madison Pharmaceuticals Inc., a newly-formed, wholly-owned subsidiary of InvaGen. Pursuant to the SPMA, and following approval by Avenue's stockholders on February 8, 2019, InvaGen purchased a number of shares of Avenue common stock representing 33.3% of Avenue's fully-diluted capital stock for net proceeds to Avenue of $31.5 million (after deducting fees and other offering-related costs).

Upon the achievement of certain closing conditions (including most notably U.S. Food and Drug Administration approval for IV Tramadol, Avenue's product candidate), InvaGen will be obligated to acquire Avenue via reverse subsidiary merger (the "Merger Transaction"). Under the Merger Transaction, InvaGen will pay $180 million (subject to certain potential reductions) to the holders of Avenue's capital stock (other than InvaGen itself).

Subject to the terms and conditions described in the SPMA, InvaGen may also provide interim financing to Avenue in an amount of up to $7.0 million during the time period between February 8, 2019 and the Merger Transaction. Any amounts drawn on the interim financing will be deducted from the aggregate consideration payable to Company stockholders by virtue of the Merger Transaction.

Prior to the closing of the Merger Transaction, Avenue will enter into a Contingent Value Rights Agreement (the "CVR Agreement") with a trust company as rights, pursuant to which holders of common shares of Avenue, other than InvaGen (each, a "Holder"), will be entitled to receive on Contingent Value Right ("CVR") for each share held immediately prior to the Merger Transaction.

Each CVR represents the right of its holder to receive a contingent cash payment pursuant to the CVR Agreement upon the achievement of certain milestones. If, during the period commencing on the day following the closing of the Merger Transaction until December 31, 2028, IV Tramadol generates at least $325 million or more in Net Sales (as defined in the CVR Agreement) in a calendar year, each Holder shall entitled to receive their pro rata share of (i) if the product generated less than $400 million in Net Sales during such calendar year, 10% of Gross Profit (as defined in the CVR Agreement), (ii) if the product generated between $400 million and $500 million in Net Sales during such calendar year, 12.5% of Gross Profit, or (iii) if the product generated more than $500 million in Net Sales during such calendar year, 15% of Gross Profit. Additionally, at any time beginning on January 1, 2029 that IV Tramadol has generated at least $1.5 billion in aggregate Net Sales, then with respect to each calendar year in which IV Tramadol generates $100 million or more in Net Sales, each Holder shall be entitled to receive their pro rata share of an amount equal to 20% of the Gross Profit generated by IV Tramadol. These additional payments will terminate on the earlier of December 31, 2036 and the date (which may be extended by up to 6 months) that any person has received approval from the FDA for an Abbreviated New Drug Application or an FDA AP-rated 505(b)(2) NDA using IV Tramadol.

5. Property and Equipment

Fortress' property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	March 31, 2019	December 31, 2018
Computer equipment	3	$ 648	$ 648
Furniture and fixtures	5	1,142	1,128
Machinery & equipment	5	3,242	3,143
Leasehold improvements	5-15	9,359	9,271
Construction in progress [1]	N/A	487	393
Total property and equipment		14,878	14,583
Less: Accumulated depreciation		(3,045)	(2,564)
Property and equipment, net		$ 11,833	$ 12,019

Note 1: Relates to the Mustang cell processing facility.

Fortress' depreciation expense for the three months ended March 31, 2019 and 2018, was approximately $0.5 million and $0.2 million, respectively, and was recorded in both research and development expense and general and administrative expense in the Condensed Consolidated Statements of Operations.

6. Fair Value Measurements

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as accounts payable, accrued expenses and other current liabilities.

Fair Value of Caelum

The Company valued its investment in Caelum in accordance with ASC Topic 820, *Fair Value Measurements and Disclosures*, and estimated the fair value to be $11.1 million based on a per share value of $1.549. The following inputs were utilized to derive the value: risk free rate of return of 2.24%, volatility of 70% and a discount for lack of marketability of 27.9%.

In connection with the DOSPA Caelum's convertible notes automatically converted into common shares of Caelum and the warrant liability payable to the placement agent in connection with the placement of the convertible notes was also issued.

Caelum Warrant Liability

The Caelum warrant liability and convertible notes did not exist as of March 31, 2019. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Caelum's warrant liability that are categorized within Level 3 of the fair value hierarchy as of December 31, 2018 is as follows:

	December 31, 2018
Risk-free interest rate	2.905% – 2.909%
Expected dividend yield	–%
Expected term in years	3.84 – 3.96
Expected volatility	70%

($ in thousands)	Fair Value of Derivative Warrant Liability
Beginning balance at January 1, 2019	$ 991
Issuance of warrant due to conversion of note	(991)
Ending balance at March 31, 2019	$ –

Caelum Convertible Notes

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Caelum's convertible notes that are categorized within Level 3 of the fair value hierarchy as of December 31, 2018 is as follows:

	December 31, 2018
Risk-free interest rate	2.302%
Expected dividend yield	–%
Expected term in years	0.32
Expected volatility	67%

($ in thousands)	Caelum Convertible Notes, at fair value
Beginning balance at January 1, 2019	$ 9,914
Conversion of the convertible notes	(9,914)
Ending balance at March 31, 2019	$ –

The following tables classify into the fair value hierarchy of Fortress' financial instruments, measured at fair value as of March 31, 2019 and December 31, 2018:

	Fair Value Measurement as of March 31, 2019			
($ in thousands)	Level 1	Level 2	Level 3	Total
Assets				
Fair value of investment in Caelum	$ –	$ –	$ 11,056	$ 11,056
Total	$ –	$ –	$ 11,056	$ 11,056

	Fair Value Measurement as of December 31, 2018			
($ in thousands)	Level 1	Level 2	Level 3	Total
Liabilities				
Caelum warrant liability	$ –	$ –	$ 991	$ 991
Caelum convertible notes, at fair value	–	–	9,914	9,914
Total	$ –	$ –	$ 10,905	$ 10,905

The table below provides a roll-forward of the changes in fair value of Level 3 financial instruments as of March 31, 2019:

($ in thousands)	Caelum Convertible Note	Warrant liability	Total
Balance at December 31, 2018	$ 9,914	$ 991	$ 10,905
Conversion of convertible notes	(9,914)	–	(9,914)
Issuance of warrant	–	(991)	(991)
Balance at March 31, 2019	$ –	$ –	$ –

As of March 31, 2019, no transfers occurred between Level 1, Level 2 and Level 3 instruments.

7. Licenses Acquired

In accordance with ASC 730-10-25-1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use. The licenses purchased by Fortress, Aevitas, Avenue, Cellvation, Checkpoint, Cyprium, Helocyte, Mustang and Tamid require substantial completion of research and development, and regulatory and marketing approval efforts in order to reach technological feasibility. As such, for the three months ended March 31, 2019 and 2018, the purchase price of licenses acquired was classified as research and development-licenses acquired in the Condensed Consolidated Statements of Operations as reflected in the table below:

	For the Three Months Ended March 31,	
($ in thousands)	**2019**	**2018**
Partner companies:		
Helocyte	$ –	$ 21
Mustang	450	75
Cellvation	–	1
Total	$ 450	$ 97

Mustang

In February 2019, Mustang announced that it partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital ("Nationwide") to develop the C134 oncolytic virus (MB-108) for the treatment of glioblastoma multiforme ("GBM"). Mustang intends to combine MB-108 with MB-101 (IL13R2-specific CAR) to potentially enhance efficacy in treating GBM. Mustang paid $0.2 million in consideration for the license for exclusive, worldwide rights to develop and commercialize products that incorporate data, know-how and/or C134 virus that were developed at Nationwide. Additional payments are due to Nationwide upon achievement of development and commercialization milestones totaling $152.8 million. Royalty payments in the low-single digits are due on net sales of licensed products.

For the three months ended March 31, 2019 and 2018, Mustang recorded the following expense in research and development for licenses acquired:

	For the Three Months Ended March 31,	
($ in thousands)	**2019**	**2018**
City of Hope (COH) – CD123	$ 250	$ –
City of Hope manufacturing	–	75
Nationwide Children's Hospital – C134 (MB-108)	200	–
Total	$ 450	$ 75

8. Sponsored Research and Clinical Trial Agreements

Aevitas

In 2018, Aevitas entered into a Sponsored Research Agreement (SRA) with the University of Massachusetts ("UMass SRA") for certain continued research and development activities related to the development of adeno-associated virus ("AAV") gene therapies in complement-mediated diseases and with the Trustees of the University of Pennsylvania ("UPenn SRA") for certain continued research and development activities related to the development of AAV gene therapies in complement-mediated diseases. For the three months ended March 31, 2019 and 2018, Aevitas recorded the following expense in research and development for sponsored research and clinical trial agreements:

($ in thousands)	For the Three Months Ended March 31, 2019	2018
UMass – AAV	$ –	$ 100
UPenn – AAV	250	–
Total	$ 250	$ 100

Cellvation

For the three months ended March 31, 2019 and 2018, respectively, Cellvation recorded expense of $0.1 million and $0.1 million, respectively, in connection with its sponsored research arrangement with the University of Texas. The expense was recorded in research and development expense in the Company's condensed consolidated statements of operations.

Mustang

For the three months ended March 31, 2019 and 2018, Mustang recorded the following expense in research and development for sponsored research and clinical trial agreements:

($ in thousands)	For the Three Months Ended March 31, 2019	2018
City of Hope (COH)	$ 500	$ 500
COH – CD123 (MB-102)	303	150
COH – IL13Rα2 (MB-101)	342	360
COH – manufacturing	114	114
Fred Hutch-CD20 (MB-106)	267	266
BIDMC – CRISPR	69	–
Total	$ 1,595	$ 1,390

9. Intangibles, net

The table below provides a summary of the JMC intangible asset as of March 31, 2019 and December 31, 2018, respectively:

($ in thousands)	Estimated Useful Lives (in years)	March 31, 2019	December 31, 2018
Ceracade®	3	$ 300	$ 300
Luxamend®	3	50	50
Targadox®	3	1,250	1,250
Exelderm®	3	1,200	1,200
Total		2,800	2,800
Accumulated amortization		1,617	1,383
Net intangible assets		$ 1,183	$ 1,417

The table below provides a summary for the three months ended March 31, 2019, of JMC recognized expense related to its product licenses, which was recorded in costs of goods sold on the Condensed Consolidated Statement of Operations:

($ in thousands)	**Intangible Assets**
Beginning balance at January 1, 2019	$ 1,417
Amortization expense	(234)
Ending balance at March 31, 2019	$ 1,183

The future amortization of these intangible assets is as follows:

($ in thousands)	**Ceracade®**	**Targadox®**	**Exelderm®**	**Total Amortization**
For the nine-months ending December 31, 2019	$ 8	$ 208	$ 300	$ 516
December 31, 2020	–	–	400	400
December 31, 2021	–	–	267	267
Total	$ 8	$ 208	$ 967	$ 1,183

10. Debt and Interest

Debt

Total debt consists of the following as of March 31, 2019 and December 31, 2018:

($ in thousands)	**March 31, 2019**	**December 31, 2018**	**Interest rate**	**Maturity**
IDB Note	$ 14,929	$ 14,929	2.25%	Aug - 2020
2017 Subordinated Note Financing	3,254	3,254	8.00%	March - 2020
2017 Subordinated Note Financing	13,893	13,893	8.00%	May - 2020
2017 Subordinated Note Financing	1,820	1,820	8.00%	June - 2020
2017 Subordinated Note Financing	3,018	3,018	8.00%	August - 2020
2017 Subordinated Note Financing	6,371	6,371	8.00%	September - 2020
2018 Venture Debt	6,517	6,517	8.00%	February - 2021
2018 Venture Debt	15,190	15,190	8.00%	March - 2021
Opus Credit Facility[1]	9,500	9,500	12.00%	September - 2019
Mustang Horizon Notes[2]	15,000	–	9.00%	October - 2022
Caelum Convertible Note, at fair value[1]	–	1,000	8.00%	January - 2019
Caelum Convertible Note, at fair value[1]	–	6,800	8.00%	February - 2019
Caelum Convertible Note, at fair value[1]	–	2,114	8.00%	March - 2019
Total notes payable	89,492	84,406		
Less: Discount on notes payable	6,608	4,903		
Total notes payable	$ 82,884	$ 79,503		

Note 1: Classified as short-term on the Company's Consolidated Balance Sheet as of December 31, 2018.
Note 2: Interest rate is 9.0% plus one-month LIBOR Rate in excess of 2.5%

Mustang Horizon Notes

On March 29, 2019, Mustang entered into a $20.0 million venture debt financing agreement (the "Loan Agreement") with Horizon Technology Finance Corporation ("Horizon"), the proceeds of which will provide Mustang with additional working capital to continue development of its gene and cell therapies. In accordance with the Loan Agreement, $15.0 million of the $20.0 million loan was funded on the Closing Date, with the remaining $5.0 million fundable upon Mustang achieving certain predetermined milestones.

Each advance under the Horizon Loan Agreement will mature 42 months from the first day of the month following the funding of the advance. The first three advances will mature on October 1, 2022 (the "Loan Maturity Date"). Each advance accrues interest at a per annum rate of interest equal to 9.00% plus the amount by which the one-month LIBOR Rate, as reported in the Wall Street Journal, exceeds 2.50%. The Loan Agreement provides for interest-only payments commencing May 1, 2019 through and including October 1, 2020. The interest-only period may be extended to April 1, 2021 if Mustang satisfies the Interest Only Extension Milestone (as defined in the Loan Agreement). Thereafter, commencing May 1, 2021, amortization payments will be payable monthly in eighteen installments of principal and interest. At its option, upon ten business days' prior written notice to Horizon, Mustang may prepay all or any portion greater than or equal to $500,000 of each of the outstanding advances by paying the entire principal balance (or portion thereof) and all accrued and unpaid interest, subject to a prepayment charge of 4.0% of the then outstanding principal balance of each advance if such advance is prepaid on or before the Loan Amortization Date (as defined in the Loan Agreement), 3% if such advance is prepaid after the Loan Amortization Date applicable to such Loan, but on or prior to twelve months following the Loan Amortization Date, and 2% thereafter. In addition, a final payment equal to $0.3 million for each advance (i.e., $0.8 million in aggregate with respect to the initial $15.0 million) is due on the maturity date or other date of payment in full. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding.

Each advance of the loan is secured by a lien on substantially all of the assets of Mustang, other than Intellectual Property and Excluded Collateral (in each case as defined in the Loan Agreement), and contains customary covenants and representations, including a liquidity covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Loan Agreement include, among other things, without limitation, and subject to customary grace periods, (1) Mustang's failure to make any payments of principal or interest under the Loan Agreement, promissory notes or other loan documents, (2) Mustang's breach or default in the performance of any covenant under the Loan Agreement, (3) the occurrence of a material adverse change, (4) Mustang making a false or misleading representation or warranty in any material respect, (5) Mustang's insolvency or bankruptcy, (6) certain attachments or judgments on the Mustang's assets, (7) the occurrence of any material default under certain agreements or obligations of Mustang involving indebtedness in excess of $0.3 million or (8) failing to maintain minimum monthly cash balances which range from approximately $8.0 to $13.0 million over the term of the loan. If an event of default occurs, Horizon is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Loan Agreement also contains warrant coverage of 5% of the total amount of the facility. Four warrants (the "Warrants") were issued by Mustang to Horizon to purchase a combined 288,184 shares of Mustang's common stock with an exercise price of $3.47 and a fair value of $0.9 million. The Warrant is exercisable for ten years from the date of issuance. Horizon may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. The shares of Mustang's common stock will, upon request by Horizon, be registered and freely tradeable following a period of six months after issuance.

Mustang paid Horizon an initial commitment fee of $0.2 million and reimbursed Horizon for $30,000 of legal fees in connection with the Loan Agreement. Mustang incurred approximately $1.2 million of legal and other direct costs incurred in connection with the Loan Agreement.

All fees, warrants, and costs paid to Horizon and all direct costs incurred by Mustang are recognized as a debt discount to the funded loans and are amortized to interest expense using the effective interest method over the term of the Loan Agreement.

Interest Expense

The following table shows the details of interest expense for all debt arrangements during the periods presented. Interest expense includes contractual interest and amortization of the debt discount and amortization of fees represents fees associated with loan transaction costs, amortized over the life of the loan:

	Three Months Ended March 31,					
	2019			2018		
($ in thousands)	*Interest*	*Fees [1]*	Total	*Interest*	*Fees [1]*	Total
IDB Note	$ 83	$ -	$ 83	$ 84	$ -	$ 84
2017 Subordinated Note Financing	1,028	363	1,391	1,048	325	1,373
Opus Credit Facility	281	113	394	281	319	600
2018 Venture Notes	429	146	575	56	17	73
LOC Fees	15	–	15	7	–	7
Helocyte Convertible Note	–	–	–	68	–	68
Caelum Convertible Note	–	–	–	196	–	196
Mustang Horizon Notes	11	–	11	–	–	–
Other	–	–	–	2	–	2
Total Interest Expense and Financing Fee	$ 1,847	$ 622	$ 2,469	$ 1,742	$ 661	$ 2,403

Note 1: amortization of fees

11. Leases

On October 3, 2014, the Company entered into a 15-year lease for office space at 2 Gansevoort Street, New York, NY 10014, at an average annual rent of $2.7 million. The Company took possession of this space, which serves as its principal executive offices, in December 2015, and took occupancy in April 2016. Total rent expense, over the full term of the lease for this space will approximate $40.7 million. In conjunction with the lease, the Company entered into Desk Space Agreements with two related parties: OPPM and TGTX, to occupy 10% and 45%, respectively, of the office space that requires them to pay their share of the average annual rent of $0.3 million and $1.1 million, respectively. The total net rent expense will approximate $16.0 million over the lease term. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. Additionally, the Company has reserved the right to execute desk space agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by us.

In October 2015, the Company entered into a 5-year lease for approximately 6,100 square feet of office space in Waltham, MA at an average annual rent of approximately $0.2 million. The Company took occupancy of this space in January 2016.

Journey

In June 2017, Journey extended its lease for 2,295 square feet of office space in Scottsdale, AZ by one year, at an average annual rent of approximately $55,000. Journey originally took occupancy of this space in November 2014. In August 2018, Journey amended their lease and entered into a new two-year extension for 3,681 square feet of office space in the same location in Scottsdale, AZ at an annual rate of approximately $94,000. The term of this amended lease commenced on December 1, 2018 and will expire on November 30, 2020.

Mustang

On October 27, 2017, Mustang entered into a lease agreement with WCS - 377 Plantation Street, Inc., a Massachusetts nonprofit corporation (“Landlord”). Pursuant to the terms of the lease agreement, Mustang agreed to lease 27,043 square feet from the Landlord, located at 377 Plantation Street in Worcester, MA (the “Facility”), through November 2026, subject to additional extensions at Mustang’s option. Base rent, net of abatements of $0.6 million over the lease term, totals approximately $3.6 million, on a triple-net basis. Mustang has made improvements to the facility of approximately $3.9 million.

The Facility initiated cell processing operations for both personalized CAR T and gene therapies in late 2018.

The Company leases copiers under agreements classified as operating leases that expire on various dates through 2021.

Most of the Company's lease liabilities result from the lease of its New York City, NY office, which expires in 2031 and Mustang's Worcester, MA cell processing facility lease which expires in 2026. Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right of use assets as the Company is not reasonably certain to exercise the options. The Company does not act as a lessor or have any leases classified as financing leases. At March 31, 2019, the Company had operating lease liabilities of $26.5 million and right of use assets of $22.6 million, which were included in the condensed balance sheet.

During the three months ended March 31, 2019, the Company recorded $0.8 million as lease expense to current period operations.

($ in thousands)	**As of March 31, 2019**
Lease cost	
Operating lease cost	$ 796
Shared lease costs	(477)
Variable lease cost	26
Total lease cost	$ 345

The following tables summarize quantitative information about the Company's operating leases, under the adoption of *Topic 842*:

($ in thousands)	**Three Months Ended March 31, 2019**
Operating cash flows from operating leases	$ (767)
Right-of-use assets exchanged for new operating lease liabilities	$ 22,618
Weighted-average remaining lease term – operating leases (years)	6.7
Weighted-average discount rate – operating leases	6.2%

($ in thousands)	**Future Lease Liability**
Nine months ended December 31, 2019	$ 1,871
Year ended December 31, 2020	3,351
Year ended December 31, 2021	3,114
Year ended December 31, 2022	3,084
Year ended December 31, 2023	3,137
Other	23,463
Total operating lease liabilities	38,020
Less: present value discount	(11,550)
Net operating lease liabilities, short-term and long-term	$ 26,470

At December 31, 2018, the total future minimum lease payments under all leases were:

($ in thousands)	
2019	$ 3,070
2020	3,289
2021	3,084
2022	3,084
2023	3,137
Beyond	23,466
Total minimum lease payments	$ 39,130

12. Accrued Liabilities and other Long-Term Liabilities

Accrued expenses and other long-term liabilities consisted of the following:

($ in thousands)	March 31, 2019	December 31, 2018
Accrued expenses:		
Professional fees	$ 1,262	$ 1,434
Salaries, bonuses and related benefits	5,592	5,843
Accrued expenses - related party	16	–
Research and development	4,855	3,805
Research and development - milestones	–	200
Research and development - manufacturing	826	826
Research and development - clinical supplies	215	160
Research and development - license maintenance fees	489	519
Dr. Falk Pharma settlement	300	300
Accrued royalties payable	1,233	1,108
Accrued coupon expense	993	838
Other	4,546	1,327
Total accrued expenses	$ 20,327	$ 16,360
Other long-term liabilities:		
Deferred expenses related to build-out[1]	2,276	5,211
Total other long-term liabilities	$ 2,276	$ 5,211

Note 1: As of March 31, 2019, balance consists of deferred charges related to build-out of the New York facility, and as of December 31, 2018, balance consists of deferred rent and deferred build out charges.

13. Non-Controlling Interests

Non-controlling interests in consolidated entities are as follows:

	As of March 31, 2019	For the three months ended March 31, 2019	As of March 31, 2019	
($ in thousands)	NCI equity share	Net loss attributable to non-controlling interests	Non-controlling interests in consolidated entities	Non-controlling ownership
Aevitas	$ (1,125)	$ (138)	$ (1,263)	36.1%
Avenue [2]	23,702	(8,000)	(15,702)	77.2%
Caelum [3]	–	–	–	60.1%
Cellvation	(670)	(53)	(723)	21.1%
Checkpoint [1]	8,754	(3,932)	4,822	68.1%
Coronado SO	(290)	–	(290)	13.0%
Cyprium	(279)	(43)	(322)	10.6%
Helocyte	(4,045)	(48)	(4,093)	19.3%
JMC	(227)	24	(203)	6.9%
Mustang [2]	22,211	(5,419)	16,792	58.9%
Tamid	(492)	(38)	(530)	23.4%
Total	$ 47,539	$ (17,647)	$ 29,892	

($ in thousands)	As of December 31, 2018 NCI equity share	For the twelve months ended December 31, 2018 Net loss attributable to non-controlling interests	As of December 31, 2018 Non-controlling interests in consolidated entities	Non-controlling ownership
Aevitas	$ (474)	$ (606)	$ (1,080)	36.1%
Avenue [2]	13,326	(13,735)	(409)	64.81%
Caelum	(2,436)	(2,413)	(4,849)	36.8%
Cellvation	(457)	(185)	(642)	21.1%
Checkpoint [1]	31,648	(23,470)	8,178	69.3%
Coronado SO	(290)	–	(290)	13.0%
Cyprium	(210)	(62)	(272)	10.8%
Helocyte	(3,372)	(684)	(4,056)	19.8%
JMC	(475)	245	(230)	6.9%
Mustang [2]	38,631	(16,628)	22,003	60.5%
Tamid	(211)	(251)	(462)	23.4%
Total	$ 75,680	$ (57,789)	$ 17,891	

Note 1: Checkpoint is consolidated with Fortress' operations because Fortress maintains voting control through its ownership of Checkpoint's Class A Common Shares which provide super-majority voting rights.

Note 2: Avenue and Mustang are consolidated with Fortress' operations because Fortress maintains voting control through its ownership of Preferred Class A Shares which provide super-majority voting rights.

Note 3: Effective January 30, 2019, Caelum ceased to be a controlled Fortress entity and as such is no longer consolidated.

14. Net Income (Loss) per Common Share

The following table sets forth the computation of earnings per share (amounts in thousands except share and per share data):

	Three Months Ended March 31, 2019	2018
Net income (loss) attributable to common stockholders	$ 1,392	$ (21,018)
Weighted average shares outstanding - basic	48,506,994	42,518,403
Preferred stock, Series A	1,000,000	–
Stock options	378,835	–
Warrants	60,000	–
Unvested restricted stock	12,622,076	–
Unvested restricted stock units	1,243,231	–
Weighted average shares outstanding - diluted	63,811,136	42,518,403
Per share data:		
Basic	$ 0.03	$ (0.49)
Diluted	$ 0.02	$ (0.49)

Basic income (loss) per share is calculated by dividing income (loss) by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Diluted income (loss) per share is computed by dividing income (loss) by the weighted-average number of common stock and common stock equivalents outstanding for the period.

The Company's common stock equivalents, including unvested restricted stock, options, and warrants have been excluded from the computation of diluted income (loss) per share for the three months ended March 31, 2018 as the effect would be to reduce the income (loss) per share. Therefore, the weighted average common stock outstanding used to calculate both basic and diluted income (loss) per share is the same for the quarter ended March 31, 2018.

The following shares of potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding, as the effect of including such securities would be anti-dilutive at the end of the three months ended March 31, 2018:

	March 31, 2018
Warrants to purchase Common Stock	894,189
Opus warrants to purchase Common Stock	1,880,000
Options to purchase Common Stock	1,085,501
Convertible Preferred Stock	1,000,000
Unvested Restricted Stock	11,050,943
Unvested Restricted Stock Units	1,778,154
Total	17,688,787

15. Stockholders' Equity

Stock-based Compensation

The following table summarizes the stock-based compensation expense from stock option, employee stock purchase programs and restricted Common Stock awards and warrants for the three months ended March 31, 2019 and 2018:

	For the Three Months Ended March 31,	
($ in thousands)	**2019**	**2018**
Employee awards	$ 935	$ 942
Executive awards of Fortress partner companies' stock	352	518
Non-employee awards	(2)	23
Fortress partner companies:		
Avenue	751	349
Checkpoint	798	1,137
Mustang	432	1,995
Other	43	(169)
Total stock-based compensation	$ 3,309	$ 4,795

For the three months ended March 31, 2019 and 2018, approximately $0.6 million and $2.3 million, respectively, of stock-based compensation expense was included in research and development expenses in connection with equity grants made to employees and consultants and approximately $2.7 million and $2.5 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

Stock Options

The following table summarizes Fortress stock option activities excluding activity related to Fortress partner companies:

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Options vested and expected to vest at December 31, 2018	1,085,501	$ 3.75	$ –	2.93
Exercised	–	–	–	–
Options vested and expected to vest at March 31, 2019	1,085,501	$ 3.75	$ 155,322	2.68
Options vested and exercisable	1,085,501	$ 3.75	$ 155,322	2.68

As of March 31, 2019, Fortress had no unrecognized stock-based compensation expense related to options.

Restricted Stock and Restricted Stock Units

The following table summarizes Fortress restricted stock awards and restricted stock units activities, excluding activities related to Fortress Companies:

	Number of shares	Weighted average grant price
Unvested balance at December 31, 2018	12,645,982	$ 2.72
Restricted stock granted	1,516,408	0.86
Restricted stock vested	(220,000)	2.82
Restricted stock units forfeited	(43,333)	4.56
Restricted stock units vested	(33,750)	3.59
Unvested balance at March 31, 2019	13,865,307	$ 2.51

As of March 31, 2019 and 2018, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately $14.8 million and $2.5 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 5.4 years and 2.4 years, respectively.

Warrants

The following table summarizes Fortress warrant activities, excluding activities related to Fortress Companies:

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Outstanding as of December 31, 2018	2,754,189	$ 3.28	$ –	3.49
Granted	–	–	–	–
Forfeited	–	–	–	–
Outstanding as of March 31, 2019	2,754,189	$ 3.28	$ 24,600	3.25
Exercisable as of March 31, 2019	849,189	$ 3.92	$ 24,600	2.89

Employee Stock Purchase Plan

Eligible employees can purchase the Company's Common Stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period. The ESPP is compensatory and results in stock-based compensation expense.

As of March 31, 2019, 356,507 shares have been purchased and 643,493 shares are available for future sale under the Company's ESPP. Share-based compensation expense recorded was approximately $20,000 and $38,000, respectively, for the three months ended March 31, 2019 and 2018.

Capital Raises

At-the-Market Offering

Pursuant to the terms of the Company's Amended and Restated At Market Issuance Sales Agreement, or Sales Agreement, with B. Riley FBR, Inc. ("B. Riley," f/k/a MLV & Co. LLC, and FBR Capital Markets & Co.) (the "ATM"), for the three-month period ended March 31, 2019, the Company issued approximately 2.9 million shares of common stock at an average price of $2.14 per share for gross proceeds of $6.3 million. In connection with these sales, the Company paid aggregate fees of approximately $0.1 million.

These shares were sold pursuant to the current shelf registration statement on Form S-3; approximately $10.2 million of the shelf remains available for sale at March 31, 2019.

Checkpoint Therapeutics, Inc.

Checkpoint At-the-Market Offering

In November 2017, Checkpoint filed a shelf registration statement on Form S-3 (the "Checkpoint S-3"), which was declared effective in December 2017. Under the Checkpoint S-3, Checkpoint may sell up to a total of $100 million of its securities. In connection with the Checkpoint S-3, Checkpoint entered into an At-the-Market Issuance Sales Agreement (the "Checkpoint ATM") with Cantor Fitzgerald & Co., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the Checkpoint ATM, Checkpoint pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the three months ended March 31, 2019, Checkpoint sold a total of 90,269 shares of its common stock under the Checkpoint ATM for aggregate total gross proceeds of approximately $0.4 million at an average selling price of $4.05 per share. Pursuant to the Founders Agreement, Checkpoint issued 2,254 shares of common stock to Fortress for the ATM offering noted above.

Approximately $68.6 million of the shelf remains available for sale under the Checkpoint S-3, following the offerings noted above. Checkpoint may offer the securities under the Checkpoint S-3 from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interests of its stockholders.

16. Commitments and Contingencies

Indemnification

In accordance with its certificate of incorporation, bylaws and indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance to address such claims. Pursuant to agreements with clinical trial sites, the Company provides indemnification to such sites in certain conditions.

Legal Proceedings

In the ordinary course of business, the Company and its subsidiaries may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers, partners and/or third parties (including tort claims for personal injury arising from clinical trials of the Company's product candidates and property damage) alleging deficiencies in performance, breach of contract, etc., and seeking resulting alleged damages.

17. Related Party Transactions

Other Related Parties

The Company's Chairman, President and Chief Executive Officer, individually and through certain trusts over which he has voting and dispositive control, beneficially owned approximately 15.3% of the Company's issued and outstanding Common Stock as of March 31, 2019. The Company's Executive Vice Chairman, Strategic Development owns approximately 14.9% of the Company's issued and outstanding Common Stock at March 31, 2019.

Shared Services Agreement with TGTX

TGTX and the Company entered into an arrangement to share the cost of certain research and development employees. The Company's Executive Vice Chairman, Strategic Development, is Executive Chairman and Interim Chief Executive Officer of TGTX. Under the terms of the Agreement, TGTX will reimburse the Company for the salary and benefit costs associated with these employees based upon actual hours worked on TGTX related projects. For the three months ended March 31, 2019 and 2018, the Company invoiced TGTX $0.1 million and $0.3 million, respectively. At March 31, 2019, the amount receivable from TGTX related to this arrangement approximated $0.1 million.

Desk Space Agreements with TGTX and OPPM

In connection with the Company's Desk Space Agreements with TGTX and Opus Point Partners Management, LLC ("OPPM"), as of March 31, 2019, the Company had paid $0.7 million in rent under the Desk Space Agreements, and invoiced TGTX and OPPM approximately $0.3 million and $0.1 million, respectively, for their prorated share of the rent base. At March 31, 2019, the amount due from TGTX approximated $0.4 million and the amount due from OPPM approximated $0.4 million.

Opus Credit Facility

On March 12, 2018, the Company and OPHIF amended and restated the Opus Credit Facility (the "A&R Opus Credit Facility"). The A&R Opus Credit Facility extends the maturity date of the notes issued under the Opus Credit Facility from September 14, 2018 by one year to September 14, 2019. The A&R Opus Credit Facility also permits the Company to make portions of interest and principal repayments in the form of shares of the Company's common stock and/or in common stock of the Company's publicly-traded subsidiaries, subject to certain conditions. Fortress retains the ability to prepay the Notes at any time without penalty. The notes payable under the A&R Opus Credit Facility continue to bear interest at 12% per annum. For the three months ended March 31, 2019 and 2018, the Company paid nil and $0.3 million, respectively.

Founders Agreements

The Company has entered into Founders Agreements and, in some cases, Exchange Agreements with certain of its subsidiaries as described in the Company's Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019. The following table summarizes, by subsidiary, the effective date of the Founders Agreements and PIK dividend or equity fee payable to the Company in accordance with the terms of the Founders Agreements, Exchange Agreements and the subsidiaries' certificates of incorporation.

Fortress Partner Company	Effective Date [1]	PIK Dividend as a % of fully diluted outstanding capitalization	Class of Stock Issued
Helocyte	March 20, 2015	2.5%	Common Stock
Avenue	February 17, 2015	0.0%[2]	Common Stock
Mustang	March 13, 2015	2.5%	Common Stock
Checkpoint	March 17, 2015	0.0%[3]	Common Stock
Cellvation	October 31, 2016	2.5%	Common Stock
Caelum	January 1, 2017	0.0%[4]	Common Stock
Cyprium	March 13, 2017	2.5%	Common Stock
Aevitas	July 28, 2017	2.5%	Common Stock
Tamid	November 30, 2017 [5]	2.5%	Common Stock

Note 1: Represents the effective date of each subsidiary's Founders Agreement. Each PIK dividend and equity fee is payable on the annual anniversary of the effective date of the original Founders Agreement or has since been amended to January 1 of each calendar year.

Note 2: Concurrently with the execution and delivery of the Stock Purchase and Merger Agreement ("SPMA") entered into between, Avenue, the Company and InvaGen Pharmaceuticals Inc. ("InvaGen") (together, the "SPMA Parties"), the SPMA Parties entered into a waiver agreement (the "Waiver Agreement"), pursuant to which the Company irrevocably waived its right to receive the annual dividend of Avenue's common shares under the terms of the Class A preferred stock and any fees, payments, reimbursements or other distributions under the management services agreement between the Company and Avenue and the Founders Agreement, for the period from the effective date of the Waiver Agreement to the termination of InvaGen's rights under the SPMA. Pursuant to the Waiver Agreement, immediately prior to the closing of the Merger Transaction contemplated under the SPMA, the Company will convert all of its preferred shares into common shares pursuant to the terms of the certificate of incorporation of Avenue, as amended from time to time.

Note 3: Instead of a PIK dividend, Checkpoint pays the Company an annual equity fee in shares of Checkpoint's common stock equal to 2.5% of Checkpoint's fully diluted outstanding capitalization.

Note 4: Effective January 31, 2019 the Caelum Founders Agreement and MSA with Fortress were terminated in conjunction with the execution of a Development Option and Share Purchase Agreement ("DOSPA") between Caelum and Alexion Therapeutics, Inc. (See Note 4).

Note 5: Represents the Trigger Date, the date that the Fortress partner company first acquires, whether by license or otherwise, ownership rights in a product.

Management Services Agreements

The Company has entered in Management Services Agreements (the "MSAs") with certain of its subsidiaries as described in the Company's Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019. The following table summarizes, by subsidiary, the effective date of the MSA and the annual consulting fee payable by the subsidiary to the Company in quarterly installments:

Fortress partner company	Effective Date	Annual MSA Fee (Income)/Expense
Helocyte	March 20, 2015	$ 500
Avenue [1]	February 17, 2015	–
Mustang	March 13, 2015	500
Checkpoint	March 17, 2015	500
Cellvation	October 31, 2016	500
Caelum[2]	January 1, 2017	–
Cyprium	March 13, 2017	500
Aevitas	July 28, 2017	500
Tamid	November 30, 2017	500
Fortress		(3,500)
Consolidated (Income)/Expense		$ –

Note 1: Concurrently with the execution and delivery of the SPMA entered into between, Avenue, the Company and InvaGen Pharmaceuticals Inc. ("InvaGen") (together, the "SPMA Parties"), the SPMA Parties entered into a waiver agreement (the "Waiver Agreement"), pursuant to which the Company irrevocably waived its right to receive the annual dividend of Avenue's common shares under the terms of the Class A preferred stock and any fees, payments, reimbursements or other distributions under the management services agreement between the Company and Avenue and the Founders Agreement, for the period from the effective date of the Waiver Agreement to the termination of InvaGen's rights under the SPMA. Pursuant to the Waiver Agreement, immediately prior to the closing of the Merger Transaction contemplated under the SPMA, the Company will convert all of its preferred shares into common shares pursuant to the terms of the certificate of incorporation of Avenue, as amended from time to time. (See Note 4).

Note 2: Effective January 31, 2019 the Caelum Founders Agreement and MSA with Fortress were terminated in conjunction with the execution of a DOSPA between Caelum and Alexion Therapeutics, Inc. and $1.0 million of fees accrued under the MSA were written off (See Note 4).

18. Segment Information

The Company operates in two reportable segments, Dermatology Product Sales and Pharmaceutical and Biotechnology Product Development. The accounting policies of the Company's segments are the same as those described in Note 2. Prior to the sale of National the Company operated in three segments, one of which included National, see Note 3. The following tables summarize, for the periods indicated, operating results, from continued operations by reportable segment:

($ in thousands) **Three Months Ended March 31, 2019**	Dermatology Products Sales	Pharmaceutical and Biotechnology Product Development	Consolidated
Net Revenue	$ 6,125	$ 352	$ 6,477
Direct cost of goods	(1,884)	–	(1,884)
Sales and marketing costs	(3,493)	–	(3,493)
Research and development	–	(23,723)	(23,723)
General and administrative	(387)	(9,598)	(9,985)
Segment income (loss) from operations	$ 361	$ (32,969)	$ (32,608)
Segment assets	$ 11,079	$ 189,459	$ 200,538

($ in thousands) **Three Months Ended March 31, 2018**	**Dermatology Products Sales**	**Pharmaceutical and Biotechnology Product Development**	**Consolidated**
Net Revenue	$ 5,509	$ 394	$ 5,903
Direct cost of goods	(1,472)	–	(1,472)
Sales and marketing costs	(2,764)	–	(2,764)
Research and development	–	(25,055)	(25,055)
General and administrative	(397)	(10,387)	(10,784)
Segment income (loss) from operations	$ 876	$ (35,048)	$ (34,172)
Segment assets	$ 11,163	$ 189,560	$ 200,723
Assets held for sale			64,352
Total consolidated			$ 265,075

19. Revenues from Contracts and Significant Customers

Disaggregation of Total Revenues

The Company has three marketed products, Targadox®, Luxamend®, Ceracade® and Exelderm®. Substantially all of the Company's product revenues are recorded in the U.S. Substantially all of the Company's collaboration revenues are from its collaboration with TGTX. Revenues by product and collaborator are summarized as follows (in thousands):

	Three months ended March 31,	
	2019	**2018**
Targadox®	$ 5,700	$ 5,498
Other branded revenue	425	11
Total product revenues	$ 6,125	$ 5,509
TGTX	352	394
Total Revenue	$ 6,477	$ 5,903

Significant Customers

For the three months ended March 31, 2019, one of the Company's Dermatology Products customers accounted for more than 10.0% of its total gross product revenue in the amount of $19.9 million.

For the three months ended March 31, 2018, three of the Company's Dermatology Products customers each accounted for more than 10.0% of its total gross product revenue in the amount of $4.4 million and $3.9 million and $2.0 million, respectively.

At March 31, 2019, one of the Company's Dermatology Products customers accounted for more than 10.0% of its total accounts receivable balance in the amount of $7.7 million.

At March 31, 2018, two of the Company's Dermatology Products customers each accounted for more than 10.0% of its total accounts receivable balance in the amount of $3.0 million and $2.1 million, respectively.

20. Incomes taxes

The Company and its subsidiaries are subject to US federal and state income taxes. Income tax expense is the total of the current year income tax due or refundable and the change in deferred tax assets and liabilities. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of Management, it is more likely than not that some portion, or all, of the deferred tax asset will not be realized.

The Company files a consolidated income tax return with subsidiaries for which the Company has an 80% or greater ownership interest. Subsidiaries for which the Company does not have an 80% or more ownership are not included in the Company's consolidated income tax group and file their own separate income tax return. As a result, certain corporate entities included in these financial statements are not able to combine or offset their taxable income or losses with other entities' tax attributes.

Income tax expense for the three months ended March 31, 2019 and 2018 is based on the estimated annual effective tax rate.

21. Subsequent Events

Capital Raises

Mustang At-the-Market Offering

Pursuant to the terms of the Company's Amended and Restated At Market Issuance Sales Agreement, or Sales Agreement, with B. Riley FBR, Inc. ("B. Riley," f/k/a MLV & Co. LLC, and FBR Capital Markets & Co.) (the "ATM"), subsequent to the quarter ended March 31, 2019, the Company issued approximately 3.5 million shares of common stock at an average price of $6.42 per share for gross proceeds of $22.5 million. In connection with these sales, the Company paid aggregate fees of approximately $0.4 million.

These shares were sold pursuant to Mustang's current shelf registration statement on Form S-3; approximately $20.9 million of the shelf remains available for sale as of the date of filing.

Mustang Public Offering of Common Stock

On April 30, 2019, Mustang announced the pricing of an underwritten public offering, whereby it sold 6,875,000 shares of its common stock, (plus a 30-day option to purchase up to an additional 1,031,250 shares of common stock, which has been exercised) at a price of $4.00 per share for gross proceeds of approximately $31.6 million, before deducting underwriting discounts and commissions and offering expenses. The shares were sold under a Registration Statement (No. 333-226175) on Form S-3, filed by Mustang with the Securities and Exchange Commission. The offering closed on May 2, 2019, with the over-allotment closing on May 8, 2019.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this Form 10-Q. Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," "may," "plan", "seek" or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially, from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading "Risk Factors" herein and in our Annual Report on Form 10-K for the year ended December 31, 2018.

Overview

We are a biopharmaceutical company dedicated to acquiring, developing and commercializing pharmaceutical and biotechnology products and product candidates, which we do at the Fortress level, at our majority-owned and majority-controlled subsidiaries and joint ventures, and at entities we founded and in which we maintain significant minority ownership positions. We have a talented and experienced business development team, comprising scientists, doctors and finance professionals, who identify and evaluate promising products and product candidates for potential acquisition by new or existing partner companies. We have executed such arrangements in collaboration with some of the world's foremost universities, research institutes and pharmaceutical companies, including City of Hope National Medical Center, St. Jude Children's Research Hospital and University College London.

Following the exclusive license or other acquisition of the intellectual property underpinning a product or product candidate, we leverage our business, scientific, regulatory, legal and finance expertise to help our partners achieve their goals. Our partner companies then assess a broad range of strategic arrangements to accelerate and provide additional funding to support research and development, including joint ventures, partnerships, out-licensings, and public and private financings.

Recent Events

Marketed Dermatology Products

In the quarter ended March 31, 2019, through our partner company Journey Medical Corporation ("Journey" or "JMC"), our seven marketed products generated net revenue of $6.1 million.

IV Tramadol

IV Tramadol is currently in development at our partner, Avenue Therapeutics, Inc. ("Avenue"). In February 2019, Avenue's shareholders approved the first stage closing of the equity subscription and contingent acquisition by InvaGen, a subsidiary of Cipla Limited, a leading pharmaceutical company. In connection with this transaction, InvaGen acquired approximately 5.8 million shares of Avenue Therapeutics' common stock at $6.00 per share, representing a 33.3% stake in Avenue's capital stock on a fully diluted basis and Avenue received total gross consideration of $35.0 million before deducting offering costs of $2.7 million.

Avenue is currently running a second pivotal Phase 3 efficacy and safety study of IV tramadol in patients with post-operative pain following abdominoplasty procedure. Based on the enrollment pace of similar studies, we anticipate that Avenue will have topline data from this second Phase 3 trial by the end of the second quarter in 2019. Avenue also initiated an open-label, single-arm safety study in December 2017. The results of this study showed that IV Tramadol with a side effect profile consistent with known pharmacology.

If primary endpoints are met in connection with the study, Avenue plans to submit a new drug application, or an NDA, for IV Tramadol to treat moderate to moderately severe postoperative pain pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FDCA) by the end of 2019.

CAEL-101

In January 2019, Caelum Biosciences Inc. ("Caelum") signed a Development, Option and Stock Purchase Agreement ("DOSPA") with Alexion Pharmaceuticals, Inc. ("Alexion") to advance the development of CAEL-101. Under the terms of the DOSPA, Alexion acquired a minority equity interest in Caelum and an exclusive option to acquire the remaining equity in the company based on Phase 2 data for pre-negotiated economics. Alexion will make payments to Caelum totaling $60 million, including the purchase price for the equity and milestone-dependent development funding payments. The collaboration also provides for potential additional payments of up to $500 million, including the upfront, regulatory and commercial milestone payments, in the event Alexion exercises the acquisition option. For the quarter ended March 31, 2019, Caelum had received $30 million from Alexion under the terms of the DOSPA and issued approximately 4.1 million class B preferred shares.

Triplex

The multicenter Phase 2 study of Triplex for cytomegalovirus ("CMV") control in allogeneic stem cell transplant recipients has concluded, and its primary endpoint was met. The full dataset was accepted for oral presentation at the 45 th Annual Meeting of the European Society for Blood and Marrow Transplantation ("EBMT") held in Frankfurt, Germany March 24-27, 2019. Our partner company Helocyte, Inc. ("Helocyte") is developing this program in collaboration with COH.

MB-107 (XSCID Gene Therapy)

In April 2019 St. Jude Children's Research Hospital ("St. Jude") published Phase 1/2 clinical data in the New England Journal of Medicine that underscores the potential of MB-107 as a novel approach for newly diagnosed infants with X-linked severe combined immunodeficiency ("XSCID"). It is anticipated that the investigational new drug application ("IND") will be transferred from St. Jude's to Mustang Bio, Inc. ("Mustang") by the end of 2019, after which patients' cells from all three participating clinical trial sites will be processed at Mustang's Worcester, Mass., facility.

In August 2018, our partner company Mustang announced that it entered into an exclusive worldwide license agreement with St. Jude for the development of a potentially first-in-class *ex vivo* lentiviral gene therapy for the treatment of XSCID, also known as bubble boy disease. The therapy is currently being evaluated in a Phase 1/2 multicenter trial in infants under the age of two. This study is the world's first lentiviral gene therapy trial for infants with XSCID. The therapy is also being investigated in patients over the age of two in a second Phase 1/2 trial at the National Institutes of Health ("NIH"). Mustang believes these may be registration trials.

Cosibelimab (formerly CK-301, an anti-PD-L1 antibody)

In January 2019, our partner company Checkpoint Therapeutics, Inc. ("Checkpoint") announced that the ongoing multi-center clinical trial of Cosibelimab, a fully human anti-PD-L1 antibody, was expanded to enroll patients in three endometrial and colorectal cohorts intended to support potential requests for accelerated approval and Biologics License Application ("BLA") submissions to the FDA. The ongoing trial is also enrolling cohorts of patients with NSCLC and cutaneous squamous cell carcinoma.

In May 2019, Checkpoint announced interim results of the ongoing multi-center clinical trial of Cosibelimab.

CUTX-101

In January 2019, our partner company Cyprium Therapeutics, Inc. ("Cyprium") received notification from the U.S. FDA that the sponsorship of the Investigational New Drug ("IND") application for CUTX-101 ("Copper Histidinate"), a product candidate for the treatment of Menkes disease, was transferred to Cyprium. CUTX-101 is currently in a Phase 3 clinical trial.

Oncolytic Virus C134 (MB-108)

In February 2019, Mustang announced that they partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital to develop the C134 oncolytic virus (MB-108) for the treatment of glioblastoma multiforme ("GBM"). Mustang intends to combine MB-108 with MB-101 (IL13Rα2-specific CAR) to potentially enhance efficacy in treating GBM.

Mustang Capital Raises

Horizon Notes

In April 2019, Mustang announced that it had entered into a $20 million debt financing agreement with Horizon Technology Finance Corporation (NASDAQ: HRZN) ("Horizon"), a leading specialty finance company that provides capital in the form of secured loans to venture-backed companies in the technology, life sciences, healthcare information and services and cleantech industries. $15 million of the $20 million loan funded upon closing, and the remaining $5 million may be funded upon the achievement by Mustang of certain predetermined milestones. Each advance of the loan will be repaid in 42 monthly payments consisting of 18 monthly payments of interest only, followed by 24 monthly payments of principal and accrued interest, payable monthly in arrears. The interest-only period may be extended to 24 months contingent upon Mustang achieving certain milestones. In connection with the debt financing, Mustang issued Horizon warrants to purchase up to 288,184 of its common shares at an exercise price of $3.47 per share.

At-the-Market Offering

Pursuant to the terms of the Company's Amended and Restated At Market Issuance Sales Agreement, or Sales Agreement, with B. Riley FBR, Inc. ("B. Riley," f/k/a MLV & Co. LLC, and FBR Capital Markets & Co.) (the "ATM"), subsequent to the quarter ended March 31, 2019, the Company issued approximately 3.5 million shares of common stock at an average price of $6.42 per share for gross proceeds of $22.5 million. In connection with these sales, the Company paid aggregate fees of approximately $0.4 million.

These shares were sold pursuant to Mustang's current shelf registration statement on Form S-3; approximately $20.9 million of the shelf remains available for sale as of the date of filing.

Public Offering of Common Stock

On April 30, 2019, Mustang announced the pricing of an underwritten public offering, whereby it sold 6,875,000 shares of its common stock, (plus a 30-day option to purchase up to an additional 1,031,250 shares of common stock, which has been exercised) at a price of $4.00 per share for gross proceeds of approximately $31.6 million, before deducting underwriting discounts and commissions and offering expenses. The shares were sold under a Registration Statement (No. 333-226175) on Form S-3, filed by Mustang with the Securities and Exchange Commission. The offering closed on May 2, 2019, with the over-allotment closing on May 8, 2019.

Sale of National

In February 2019, we sold our remaining 4.0 million shares in National Holdings Corporation, to NHC Holdings, LLC, a wholly-owned subsidiary of B. Riley Financial, Inc. at $3.25 per share for proceeds of $13.1 million. The aggregate purchase price totaled approximately $22.9 million for our 56.1% stake and following the February closing we no longer owned shares in National.

Reportable Business Segments

For presentation purposes, Results of Operations is presented on a detailed revenue and expense basis rather than on a reportable business segment basis. Our operations are subject to wide fluctuations due to our early stage of development. The following provides a summary of revenues and expenses for the periods presented.

Results of Operations

General

For the three months ended March 31, 2019, we generated $6.5 million of net revenue, of which $0.4 million of revenue relates to Checkpoint's collaborative agreements with TG Therapeutics Inc. ("TGTX") and $6.1 million of revenue relates primarily to the sale of Journey branded products. At March 31, 2019, we had an accumulated deficit of $394.9 million. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our and our subsidiaries' current product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

For the three months ended March 31, 2019, we had $1.9 million of costs of goods sold in connection with the sale of Journey's marketed products, compared to $1.5 million at March 31, 2018.

Research and Development Expenses

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

For the three months ended March 31, 2019 and 2018, research and development expenses were approximately $23.3 million and $25.0 million, respectively. Additionally, during the three months ended March 31, 2019 and 2018, we expensed approximately $0.5 million and $0.1 million, respectively, in costs related to the acquisition of licenses. Noncash, stock-based compensation expense included in research and development for the three months ended March 31, 2019 and 2018, was $0.6 million and $2.3 million, respectively.

Research and development costs associated with the development of our licenses, net of noncash stock-based compensation expenses, for the three months ended March 31, 2019 and 2018, by entity, are as follows:

	Quarter Ended March 31,		% of total	
($ in millions)	**2019**	**2018**	**2019**	**2018**
Research & Development				
Fortress	$ 544	$ 1,896	2%	8%
Partner Companies:				
Avenue	10,060	9,193	44%	41%
Checkpoint	4,385	6,190	19%	27%
Mustang	6,801	2,778	30%	12%
Other[1]	839	2,554	4%	11%
Total Research & Development	**$ 22,629**	**$ 22,611**	**100%**	**100%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Helocyte and Tamid

Noncash stock-based compensation expense for the three months ended March 31, 2019 and 2018, by entity is as follows:

	Quarter Ended March 31,		% of total	
($ in millions)	**2019**	**2018**	**2019**	**2018**
Research & Development				
Noncash stock-based compensation				
Fortress	$ 167	$ 306	26%	13%
Partner Companies:				
Avenue	182	133	28%	6%
Checkpoint	196	680	30%	29%
Mustang	96	1,452	15%	62%
Other[1]	3	(224)	0%	-10%
Total Research & Development	**$ 644**	**$ 2,347**	**100%**	**100%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Helocyte and Tamid

General and Administrative Expenses

General and administrative expenses consist principally of sales and marketing costs, personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development expenses. For the three months ended March 31, 2019 and 2018, general and administrative expenses were approximately $13.5 million and $13.5 million, respectively. Noncash, stock-based compensation expense included in general and administrative expenses for the three months March 31, 2019 and 2018, was $2.7 million and $2.5 million, respectively.

Included in the remaining $10.8 million and $11.1 million figures for the three months ended March 31, 2019 and 2018, respectively are the following partner company expenses:

	Quarter Ended March 31,		% of Total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
General & Administrative				
Fortress	$ 3,477	$ 3,951	32%	36%
Partner Companies:				
Avenue	550	757	5%	7%
Checkpoint	967	1,034	9%	9%
JMC[1]	3,885	3,133	36%	28%
Mustang	1,549	1,504	14%	14%
Other[2]	385	721	4%	6%
Total General & Administrative	**$ 10,813**	**$ 11,100**	**100%**	**100%**

Note 1: Includes cost of outsourced sales force

Note 2: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

Noncash stock-based compensation expense included in general and administrative expense for the three months ended March 31, 2019 and 2018, by entity is as follows:

	Quarter Ended March 31,		% of Total	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
General & Administrative				
Non cash stock-based compensation				
Fortress	$ 1,118	$ 1,177	42%	48%
Partner Companies:				
Avenue	569	216	21%	9%
Checkpoint	602	457	23%	19%
Mustang	336	543	13%	22%
Other[1]	40	55	2%	2%
Total General & Administrative	**$ 2,665**	**$ 2,448**	**100%**	**100%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

Comparison of three months ended March 31, 2019 and 2018

($ in thousands, except per share amounts)	For the Three Months Ended March 31, 2019	2018	Change $	Change %
Revenue				
Product revenue, net	$ 6,125	$ 5,509	$ 616	11%
Revenue - from a related party	352	394	(42)	-11%
Net revenue	6,477	5,903	574	10%
Operating expenses				
Cost of goods sold - product revenue	1,884	1,472	412	28%
Research and development	23,273	24,958	(1,685)	-7%
Research and development - licenses acquired	450	97	(353)	364%
General and administrative	13,478	13,548	(70)	—1%
Total operating expenses	39,085	40,075	(990)	-2%
Loss from operations	(32,608)	(34,172)	(1,564)	-5%
Other income (expenses)				
Interest income	438	278	160	58%
Interest expense and financing fee	(2,469)	(2,403)	(66)	3%
Change in fair value of derivative liabilities	-	23	(23)	-100%
Change in fair value of subsidiary convertible note	-	250	(250)	-100%
Change in fair value of investments	-	(118)	118	-100%
Gain from deconsolidation of Caelum	18,384	-	18,384	100%
Total other income (expenses)	16,353	(1,970)	18,323	-930%
Loss from continuing operations	(16,255)	(36,142)	19,887	-55%
Discontinued operations:				
Loss from discontinued operations, net of tax	-	(2,076)	2,067	-100%
Total loss from discontinued operations	-	(2,076)	2,076	-100%
Net loss	**(16,255)**	**(38,218)**	**21,963**	**-57%**
Less: net loss attributable to non-controlling interest	(17,647)	(17,200)	(447)	3%
Net income (loss) attributable to common stockholders	**$ 1,392**	**$ (21,018)**	**$ 22,410**	**-107%**

Net revenues increased $0.6 million or 10% from the three months ended March 31, 2018 to the three months ended March 31, 2019. The increase in net revenue is related to an increase in product revenue of $0.6 million associated with Journey's marketed products, offset by a decrease of less than $0.1 million in collaboration revenue between Checkpoint and TGTX.

Cost of goods sold increased by $0.4 million or 28% from the three months ended March 31, 2018 to the three months ended March 31, 2019 due to the increase in Journey marketed products revenue in the first quarter of 2019 as compared to the first quarter of 2018.

Research and development expenses decreased $1.7 million or 7% from the three months ended March 31, 2018 to the three months ended March 31, 2019. The following table shows the change in research and development spending by Fortress and its partner companies:

($ in millions)	Quarter Ended March 31, 2019	2018	Change $	Change %
Research & Development				
Stock-based compensation				
Fortress	$ 167	$ 306	$ (139)	-45%
Partner Companies:				
Avenue	182	133	49	37%
Checkpoint	196	680	(484)	-71%
Mustang	96	1,452	(1,356)	-93%
Other[1]	3	(224)	230	-101%
Sub-total stock-based compensation	644	2,347	(1,701)	-73%
Other Research & Development				
Fortress	544	1,896	(1,352)	-71%
Partner Companies:				
Avenue	10,060	9,193	867	9%
Checkpoint	4,385	6,190	(1,805)	-29%
Mustang	6,801	2,778	4,023	145%
Other[1]	839	2,554	(1,717)	-67%
Total Research & Development	**$ 23,273**	**$ 24,958**	**$ (1,685)**	**-7%**

Note 1: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

The decrease in stock-based compensation is due to overall vesting of grants for Mustang and Checkpoint, as well as the decrease in value attributed to marking to market grants held by non-employees due to the stock price decreases.

The decrease in Fortress research and development spending is due to the lower research and development headcount subsequent to the transfer of Fortress research and development employees to TGTX, a related party, in the quarter ended September 30, 2018. Checkpoint's decrease in research and development spending is attributable to the manufacturing costs related to the PD-L1 GMP batch incurred in the quarter ended March 31, 2018 and not replicated in the current quarter. Mustang's increase in research and development spending is attributable to the fitting out of the cell processing facility, the purchase of lab supplies, increased headcount, and increased costs incurred under sponsored research agreements with City of Hope. The decrease in "Other" is attributable to Caelum's deconsolidation and Helocyte's sponsored research activities with City of Hope not replicated in 2019.

General and administrative expenses decreased $0.1 million, or 1%, from the quarter ended March 31, 2018 to the quarter ended March 31, 2019. The following table shows the change in general and administrative spending by Fortress and its partner companies:

	Quarter Ended March 31,		Change	
($ in thousands)	**2019**	**2018**	$	%
General & Administrative				
Stock-based compensation				
Fortress	$ 1,118	$ 1,177	$ (59)	-5%
Partner Companies:				
Avenue	569	216	353	163%
Checkpoint	602	457	145	32%
Mustang	336	543	(208)	-38%
Other[2]	40	55	(14)	-25%
Sub-total stock-based compensation	2,665	2,448	217	9%
Other G&A				
Fortress	3,477	3,951	(474)	-12%
Partner Companies:				
Avenue	550	757	(207)	-27%
Checkpoint	967	1,034	(67)	-6%
JMC[1]	3,885	3,133	752	24%
Mustang	1,550	1,504	46	3%
Other[2]	384	721	(337)	-47%
Total General & Administrative	**$ 13,478**	**$ 13,548**	**$ (70)**	**-1%**

Note 1: Includes cost of outsourced sales force

Note 2: Includes the following partner companies: Aevitas, Caelum (2018 only), Cellvation, Cyprium, Escala, Helocyte and Tamid

For the quarter ended March 31, 2019, the decrease in general and administrative expenses of $0.1 million or 1% is primarily attributable to Fortress' decreased headcount and travel costs of $0.2 million and Avenue's decrease in investor relations and marketing costs of $0.2 million offset by Journey's sales and marketing cost increases of $0.5 million.

Total other income or expense increased $18.3 million, or 930%, from a loss of $2.0 million for the quarter ended March 31, 2018 to income of $16.4 million for the quarter ended March 31, 2019, primarily due to the gain on the deconsolidation of Caelum of $18.4 million.

Net loss attributable to non-controlling interests increased $0.4 million, or 3%, from the quarter ended March 31, 2018 to the quarter ended March 31, 2019. This increase reflects the partner companies' share of net loss, which increased despite the decrease in net loss of $22.0 million or 57% from the quarter ended March 31, 2018 to the quarter ended March 31, 2019 due to the fact that Caelum was deconsolidated.

Liquidity and Capital Resources

We will require additional financing to fully develop and prepare regulatory filings and obtain regulatory approvals for our existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for our potential products, and sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt securities. We believe that our current cash and cash equivalents is sufficient to fund operations for at least the next twelve months. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We may seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, sales of stakes in partner companies, the contingent acquisitions of Avenue and Caelum, or through other sources of financing.

Cash Flows for the Three Months Ended March 31, 2019 and 2018

	Three Months Ended March 31,	
($ in thousands)	**2019**	**2018**
Statement of cash flows data:		
Total cash (used in)/provided by:		
Operating activities	$ (25,325)	$ (27,844)
Investing activities	24,148	(1,840)
Financing activities	52,113	39,655
Net increase in Cash and cash equivalents and restricted cash	$ 50,936	$ 9,971

Components of cash flows from publicly-traded partner companies are comprised of:

($ in thousands)	For the Three Months Ended March 31, 2019				
	Fortress[1]	**Avenue**	**Checkpoint**	**Mustang**	**Total**
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (4,876)	$ (5,568)	$ (8,203)	$ (6,678)	$ (25,325)
Investing activities	11,952	-	-	12,196	24,148
Financing activities	5,800	32,345	355	13,613	52,113
Net increase in cash and cash equivalents and restricted cash	$ 12,876	$ 26,777	$ (7,848)	$ 19,131	$ 50,936

	For the Three Months Ended March 31, 2018				
	Fortress[1]	**Avenue**	**Checkpoint**	**Mustang**	**Total**
Statement of cash flows data:					
Total cash (used in)/provided by:					
Operating activities	$ (10,253)	$ (6,819)	$ (5,207)	$ (5,565)	$ (27,844)
Investing activities	(89)	10,000	-	(11,751)	(1,840)
Financing activities	18,714	-	20,845	96	39,655
Net increase in cash and cash equivalents and restricted cash	$ 8,372	$ 3,181	$ 15,638	$ (17,220)	$ 9,971

Note 1: Includes Fortress and non-public subsidiaries

Operating Activities

Net cash used in operating activities decreased $2.5 million from the three months ended March 31, 2018, compared to the three months ended March 31, 2019. The increase was primarily due to the decrease of $19.9 million in net loss from continuing operations, primarily offset by the gain from the deconsolidation of Caelum of $18.4 million and a $0.4 million increase of expense related to research and development-licenses acquired.

Investing Activities

Net cash provided by investing activities increased $26.0 million from the three months ended March 31, 2018, compared to the three months ended March 31, 2019. The increase is primarily due to $13.1 million received from the sale of National, a decrease in the purchase of short-term investments of $25.0 million, offset by the $11.4 million redemption of certificates of deposit held by Mustang, a decrease of $0.5 million in the purchase of property and equipment as the build-out of the cell processing facility in Worcester, Massachusetts by Mustang slows, $1.2 million decrease in cash due to deconsolidation of Caelum, as well as a decrease of $0.1 million in funds used to purchase research and development licenses.

Financing Activities

Net cash provided by financing activities was $39.7 million for the three months ended March 31, 2018, compared to $52.1 million of net cash provided by financing activities for the three months ended March 31, 2019. During the three months ended March 31, 2019, net proceeds from subsidiaries' offerings were $31.5 million, and net proceeds from Mustang's Horizon Notes was $15.0 million. Additionally, $0.6 million was paid in Preferred A dividends, and $6.1 million was received in net proceeds from the Company's at-the-market offering and $0.4 million was received in net proceeds from a partner company's at-the-market offerings.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in their market price. Market risk is inherent in all financial instruments. Market risk may be exacerbated in times of trading illiquidity when market participants refrain from transacting in normal quantities and/or at normal bid-offer spreads. Our exposure to market risk is directly related to derivatives, debt and equity linked instruments related to our financing activities.

Our assets and liabilities are denominated in U.S. dollars. Consequently, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

The primary quantifiable market risk associated with our financial instruments is sensitivity to changes in interest rates. Interest rate risk represents the potential loss from adverse changes in market interest rates. We use an interest rate sensitivity simulation to assess our interest rate risk exposure. For purposes of presenting the possible earnings effect of a hypothetical, adverse change in interest rates over the 12-month period from our reporting date, we assume that all interest rate sensitive financial instruments will be impacted by a hypothetical, immediate 100 basis point increase in interest rates as of the beginning of the period. The sensitivity is based upon the hypothetical assumption that all relevant types of interest rates that affect our results would increase instantaneously, simultaneously and to the same degree. We do not believe that our cash and equivalents have significant risk of default or illiquidity.

The sensitivity analyses of the interest rate sensitive financial instruments are hypothetical and should be used with caution. Changes in fair value based on a 1% or 2% variation in an estimate generally cannot be extrapolated because the relationship of the change in the estimate to the change in fair value may not be linear. Also, the effect of a variation in a particular estimate on the fair value of financial instruments is calculated independent of changes in any other estimate; in practice, changes in one factor may result in changes in another factor, which might magnify or counteract the sensitivities. In addition, the sensitivity analyses do not consider any action that we may take to mitigate the impact of any adverse changes in the key estimates.

Based on our analysis, for the years ended December 31, 2017, December 31, 2018 and for the interim period through March 31, 2019, we determined the effect of a 100+1- basis point change in interest rates on the value of our financial instruments and the resultant effect on our net loss to be immaterial.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of September 30, 2018, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No change in internal control over financial reporting occurred during the most recent quarter with respect to our operations, which materially affected, or is reasonable likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Investing in our Common Stock, Series A Preferred Stock or any other type of equity or debt securities (together our "Securities") involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K including the consolidated financial statements and the related notes, as well as the risks, uncertainties and other information set forth in the reports and other materials filed or furnished by our partners and affiliates Checkpoint, Mustang, and Avenue with the SEC, before deciding to invest in our Securities. If any of the following risks or the risks included in the public filings of Checkpoint, Mustang or Avenue were to materialize, our business, financial condition, results of operations, and future growth prospects could be materially and adversely affected. In that event, the market price of our Securities could decline, and you could lose part of or all of your investment in our Securities. In addition, you should be aware that the below stated risks should be read as being applicable to our partners and affiliates such that, if any of the negative outcomes associated with any such risk is experienced by one of our partners or affiliates, the value of Fortress' holdings in such partner or affiliate (if any) may decline.

Risks Related to our Growth Strategy

If we acquire, enter into joint ventures with or obtain a controlling interest in companies in the future, it could adversely affect our operating results and the value of our Securities, thereby diluting stockholder value, disrupting our business and/or diminishing the value of our holdings in our partner companies.

As part of our growth strategy, we might acquire, enter into joint ventures with, or obtain significant ownership stakes in other companies. Acquisitions of, joint ventures with and investments in other companies involve numerous risks, including, but not necessarily limited to:

- risk of entering new markets in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- successfully negotiating a proposed acquisition or investment timely and at a price or on terms and conditions favorable to us;
- the impact of regulatory reviews on a proposed acquisition or investment;
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisitions or investment;
- with respect to an acquisition, difficulties in integrating operations, technologies, services and personnel; and
- potential inability to maintain relationships with customers of the companies we may acquire or invest in.

If we fail to properly evaluate potential acquisitions, joint ventures or investments, we might not achieve the anticipated benefits of any such transaction, we might incur higher costs than anticipated, and management resources and attention might be diverted from other necessary or valuable activities.

If we or certain of our partner companies cannot innovate and develop products and services and/or commercialize biopharmaceutical products or grow our and their respective businesses, we may not be able to generate revenue.

Our growth strategy also depends on our ability to generate revenue. If we cannot innovate and develop products and services or commercialize future biopharmaceutical products or grow their respective businesses, we may not be able to generate revenue growth as anticipated.

We may not be able to generate returns for our investors if certain of our partners or affiliates, several of which have limited or no operating history, no commercialized revenue generating products, and are not yet profitable, cannot obtain additional third-party financing.

As part of our growth strategy, we have made and will likely continue to make substantial financial and operational commitments in our affiliated partners, which at the time of investment often have limited or no operating history, no commercialized revenue generating products, and require additional third-party financing to fund product and services development or acquisitions. Our business depends in large part on the ability of one or more of our partner companies to innovate, in-license, acquire or invest in successful biopharmaceutical products, develop financial services and/or acquire companies in increasingly competitive and highly regulated markets. If certain of our partner companies do not successfully obtain additional third-party financing to commercialize products, successfully acquire companies, as applicable, the value of our businesses and our ownership stakes in our partner companies may be materially adversely affected.

If we cannot continue to fund our research and development programs, we may be required to reduce product development, which will adversely impact our growth strategy.

Our research and development ("R&D") programs will require substantial additional capital to conduct research, preclinical testing and clinical trials, establish pilot scale and commercial scale manufacturing processes and facilities, and establish and develop quality control, regulatory, marketing, sales, and administrative capabilities to support these programs. We expect to fund our R&D activities from a combination of cash generated from royalties and milestones from our partners in various past, ongoing, and future collaborations, and through additional equity or debt financings from third parties. These financings could depress the stock prices of our Securities. If additional funds are required to support our operations and such funds cannot be obtained on favorable terms, we may not be able to develop products, which will adversely impact our growth strategy.

Collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate substantial reliance upon strategic collaborations for marketing and commercializing our existing product candidates and we may rely even more on strategic collaborations for R&D of other product candidates. We may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited.

If we enter into R&D collaborations during the early phases of drug development, success will, in part, depend on the performance of research collaborators. We may not directly control the amount or timing of resources devoted by research collaborators to activities related to product candidates. Research collaborators may not commit sufficient resources to our R&D programs. If any research collaborator fails to commit sufficient resources, the preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to collaborators or to observe other obligations in agreements with them, the collaborators may have the right to terminate or stop performance of those agreements.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property positions. In addition, there has been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues that might follow are likely to be lower than if we directly marketed and sold products. Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on, and such collaborations could be more attractive than the one with us for any future product candidate.

Management of our relationships with collaborators will require:

- significant time and effort from our management team;

- coordination of our marketing and R&D programs with the respective marketing and R&D priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

As we continue to execute our growth strategy, we may be subject to further government regulation which would adversely affect our operations.

If we engage in business combinations and other transactions that result in holding passive investment interests in a number of entities, we may become subject to regulation under the Investment Company Act of 1940, as amended (the "Investment Company Act"). If we do become subject to the Investment Company Act, we would be required to register as an investment company and could be expected to incur significant registration and compliance costs in the future.

We may not be able to manage our anticipated growth, which may in turn adversely impact our business.

We will need to continue to expend capital on improving our infrastructure to address our anticipated growth. Acquisitions of companies or products could place a strain on our management, and administrative, operational and financial systems. In addition, we may need to hire, train, and manage more employees, focusing on their integration with us and corporate culture. Integration and management issues associated with increased acquisitions may require a disproportionate amount of our management's time and attention and distract our management from other activities related to running our business.

We may not be able to hire or retain key officers or employees needed to implement our business strategy and develop products and businesses.

Our success depends on the continued contributions of our executive officers, financial, scientific, and technical personnel and consultants, and on our ability to attract additional personnel as we continue to implement growth strategies and acquire and invest in companies with varied businesses. During our operating history, many essential responsibilities have been assigned to a relatively small number of individuals. However, as we continue to implement our growth strategy, the demands on our key employees will expand, and we will need to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel, or our inability to attract additional personnel to fill critical positions, could adversely affect our business.

We currently depend heavily upon the efforts and abilities of our management team and the management teams of our partners. The loss or unavailability of the services of any of these individuals could have a material adverse effect on our business, prospects, financial condition and results. In addition, we have not obtained, do not own, and are not the beneficiary of key-person life insurance for any of our key personnel. We only maintain a limited amount of directors' and officers' liability insurance coverage. There can be no assurance that this coverage will be sufficient to cover the costs of the events that may occur, in which case, there could be a substantial impact on our ability to continue operations.

Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third-party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with current good manufacturing practices ("CGMPs"), comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, comply with internal procedures, policies or agreements to which such employees, consultants or partners are subject, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee, consultant, or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as civil and criminal liability. 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such 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 and results of operations, including the imposition of significant fines or other civil and/or criminal sanctions.

We receive a large amount of proprietary information from potential or existing licensors of intellectual property and potential acquisition target companies, all pursuant to confidentiality agreements. The confidentiality and proprietary invention assignment agreements that we have in place with each of our employees and consultants prohibit the unauthorized disclosure of such information, but such employees or consultants may nonetheless disclose such information through negligence or willful misconduct. Any such unauthorized disclosures could subject us to monetary damages and/or injunctive or equitable relief. The notes, analyses and memoranda that we have generated based off such information are also valuable to our businesses, and the unauthorized disclosure or misappropriation of such materials by our employees and consultants could significantly harm our strategic initiatives - especially if such disclosures are made to our competitor companies.

Certain of our officers and directors serve in similar roles at our partners, affiliates, related parties and/or other entities with which we transact business or in which we hold significant minority ownership positions; ongoing and future relationships and transactions between these parties could result in conflicts of interest.

We share directors and/or officers with certain of our partners, affiliates, related parties and/or other entities with which we transact business or in which we hold significant minority ownership positions, and such arrangements could create conflicts of interest in the future, including with respect to the allocation of corporate opportunities. While we believe that we have put in place policies and procedures to identify and mitigate such conflicts, and that any existing agreements that may give rise to such conflicts and any such policies or procedures were negotiated at arm's length in conformity with fiduciary duties, such conflicts of interest may nonetheless arise. The existence and consequences of such potential conflicts could expose us to lost profits, claims by our investors and creditors, and harm to our results of operations.

Risks Related to Our Biopharmaceutical Business and Industry

We are an early-stage company with limited operating history on which stockholders can base an investment decision, and we rely heavily on third parties for the development and manufacturing of their products and product candidates.

We are primarily an early-stage biopharmaceutical company and certain of our partners and affiliates, on whose successes we largely rely, are also early-stage biopharmaceutical companies with limited operating histories. To date, we have engaged primarily in acquisition, evaluative and R&D activities and have not generated any revenues from product sales (except through Journey Medical Corporation). We have incurred significant net losses since our inception. As of March 31, 2019, we had an accumulated deficit of approximately $394.9 million. We may need to rely on third parties for activities critical to the product candidate development process, including but not necessarily limited to:

- identifying and evaluating product candidates;
- negotiating, drafting and entering into licensing and other arrangements with product development partners; and
- continuing to undertake pre-clinical development and designing and executing clinical trials.

We have also not demonstrated the ability to perform the functions necessary for the successful commercialization of any of our pre-commercial product candidates, should any of them be approved for marketing. If we were to have any such product candidates approved, the successful commercialization of such products would require us to perform or contract with third parties for performance of a variety of critical functions, including, but not necessarily limited to:

- advising and participating in regulatory approval processes;
- formulating and manufacturing products for clinical development programs and commercial sale; and
- conducting sales and marketing activities.

Our operations have been limited to acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of, product candidates, both at the Fortress level and via our partner companies. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to develop and commercialize potential product candidates, as well as for you to assess the advisability of investing in our Securities. Each of these requirements will require substantial time, effort and financial resources.

If we are unable to establish or maintain sales and marketing capabilities or fail to enter into agreements with third parties to market, distribute and sell products that may be successfully developed, we may not be able to effectively market and sell products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates (except for that which exists through Journey Medical Corporation), and we must build and maintain such infrastructures or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or certain of our partners, or the establishment of a contract sales force to market any products for which we may receive marketing approval, is expensive and time-consuming and could delay any such product launch or compromise the successful commercialization of such products. If we are unable to establish and maintain sales and marketing capabilities or any other non-technical capabilities necessary to commercialize any products that may be successfully developed, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third parties on commercially reasonable terms, or at all.

If any of our product candidates that are successfully developed do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates generate from sales will be limited.

Even if our product candidates receive regulatory approval, which may not occur, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved products would depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indication;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- changes in regulatory requirements by government authorities for our product candidates;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and in turn we may not become or remain profitable.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

We intend to seek approval to market our future products in both the United States and in countries and territories outside the United States. If we obtain approval in one or more foreign countries, we will be subject to rules and regulations in those countries relating to such products. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which pharmaceuticals they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of 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
- experimental or investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Additionally, while we may seek approval of our products in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community.

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. Since 2003, there have been a number of other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "ACA," was enacted in 2010 and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;

- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the United States House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate in 2017 to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, 2018, Texas federal district court judge Reed O'Connor issued a ruling declaring that the ACA in it is entirety is unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome through the appeals process may have a significant impact on our business.

Most recently, the Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applies to biosimilars beginning in 2019.

The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services ("HHS") finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program. HHS also has signaled its intent to pursue reimbursement policy changes for Medicare Part B drugs as a whole that likely would reduce hospital and physician reimbursement for these drugs.

HHS has made numerous other proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. These proposals include giving Medicare Advantage and Part D plans flexibility in the availability of drugs in "protected classes," more transparency in the cost of drugs, including the beneficiary's financial liability, and less costly alternatives and permitting the use of step therapy as a means of prior authorization. HHS has also proposed requiring pharmaceutical manufacturers disclose the prices of certain drugs in direct-to-consumer television advertisements.

HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits and less generous coverage. The Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the US and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program, which requires manufacturers of certain 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 Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to "covered recipients," which include physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals) and applicable manufacturers. Applicable group purchasing organizations also are required to report annually to CMS the ownership and investment interests held by the physicians and their immediate family members. The SUPPORT for Patients and Communities Act added to the definition of covered recipient practitioners including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse-midwives effective in 2022. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign 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 and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may 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. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our businesses. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our businesses.

Failure to be included in formularies developed by managed care organizations and coverage by other organizations may negatively impact the utilization of our products, which could harm our market shares and could have a material adverse effect on our business and financial condition.

Managed care organizations and other third-party payors try to negotiate the pricing of medical services and products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies can be based on the prices and therapeutic benefits of the available products. Due to their lower costs, generic products are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our products. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, this could have a material adverse effect on our business and financial condition.

Most of our product candidates are at early stages of development and may not be successfully developed or commercialized.

Most of our existing product candidates remain in the early stages of development and will require substantial further capital expenditures, development, testing and regulatory clearances/approvals prior to commercialization. The development and regulatory approval processes take several years, and it is not likely that our product candidates, even if successfully developed and approved by the FDA, would be commercially available for several years. Of the large number of drugs in development, only a small percentage successfully completes the FDA regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to fund development programs, we cannot assure you that any of our product candidates will be successfully developed or commercialized, which could result in the failure of our business and a loss of your investment in our Company.

Because we in-license the intellectual property needed to develop and commercialize products and product candidates from third parties, any dispute with the licensors or the non-performance of such license agreements may adversely affect our ability to develop and commercialize the applicable product candidates.

The patents, patent applications and other intellectual property rights underpinning all of our existing product candidates were in-licensed from third parties. Under the terms of such license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach. The licenses require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments depends on the ability to generate cash in the future. These license agreements also generally require the use of diligent and reasonable efforts to develop and commercialize product candidates.

If there is any conflict, dispute, disagreement or issue of non-performance between us or one of our partners, on the one hand, and the respective licensing partner, on the other hand, regarding the rights or obligations under the license agreements, including any conflict, dispute or disagreement arising from a failure to satisfy payment obligations under such agreements, the ability to develop and commercialize the affected product candidate may be adversely affected.

The types of disputes that may arise between us and the third parties from whom we license intellectual property include, but are not necessarily limited to:

- the scope of rights granted under such license agreements and other interpretation-related issues;
- the extent to which our technologies and processes infringe on intellectual property of the licensor that is not subject to such license agreements;
- the scope and interpretation of the representations and warranties made to us by our licensors, including those pertaining to the licensors' right title and interest in the licensed technology and the licensors' right to grant the licenses contemplated by such agreements;
- the sublicensing of patent and other rights under our license agreements and/or collaborative development relationships, and the rights and obligations associated with such sublicensing, including whether or not a given transaction constitutes a sublicense under such license agreement;
- the diligence and development obligations under license agreements (which may include specific diligence milestones) and what activities or achievements satisfy those diligence obligations;
- whether or not the milestones associated with certain milestone payment obligations have been achieved or satisfied;
- the applicability or scope of indemnification claims or obligations under such license agreements;
- the permissibility and advisability of, and strategy regarding, the pursuit of potential third-party infringers of the intellectual property that is the subject of such license agreements;
- the calculation of royalty, milestone, sublicense revenue and other payment obligations under such license agreements;
- the extent to which rights, if any, are retained by licensors under such license agreements;
- whether or not a material breach has occurred under such license agreements and the extent to which such breach, if deemed to have occurred, is or can be cured within applicable cure periods, if any;
- disputes regarding patent filing and prosecution decisions, as well as payment obligations regarding past and ongoing patent expenses;
- intellectual property rights resulting from the joint creation or use of intellectual property (including improvements made to licensed intellectual property) by our and our partners' licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations or may conflict in such a way that puts us in breach of one or more agreements, which would make us susceptible to lengthy and expensive disputes with one or more of such third-party licensing partners. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreements, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Product candidates that we advance into clinical trials may not receive regulatory approval.

Pharmaceutical development has inherent risks. We will be required to demonstrate through well-controlled clinical trials that product candidates are effective with a favorable benefit-risk profile for use in their target indications before seeking regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful, as product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Also, we may need to conduct additional clinical trials that are not currently anticipated. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. As a result, product candidates that we advance into clinical trials may not receive regulatory approval.

In addition, even if our product candidates were to obtain approval, regulatory authorities may approve any such product candidates or any future product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the commercial prospects for one or more of our current or future product candidates. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of the product.

Any product candidates we advance into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of any product candidate, including our product candidates, is subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market a product candidate until such product candidate's Biologics License Application ("BLA") or New Drug Application ("NDA") is approved by the FDA. The process of obtaining approval is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to significant clinical testing requirements, our ability to obtain marketing approval for product candidates depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations may change, and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in the clinical development of product candidates, regulatory approval is never guaranteed.

The FDA and other regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- our inability to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for an indication;
- the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from that of the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- the FDA may disagree with the interpretation of data from preclinical studies or clinical trials;
- the FDA may not approve the manufacturing processes or facilities or those of third-party manufacturers with which we or our respective collaborators currently contract for clinical supplies and plan to contract for commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering the clinical data insufficient for approval or the product characteristics or benefit-risk profile unfavorable for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, recent events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause regulatory authorities to interrupt, delay or stop clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale. For example, in Phase 1/2 oncology trials, dose limiting toxicity ("DLT") stopping rules are commonly applied.

We have not completed testing for any of our product candidates for the indications for which we intend to seek product approval in humans, and we currently do not know the extent of the adverse events, if any, that will be observed in patients who receive any of our product candidates. If any of our product candidates causes unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such products, or, if such product candidates are approved for marketing, future adverse events could cause us to withdraw such products from the market.

Delays in the commencement of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

The commencement of clinical trials can be delayed for a variety of reasons, including, but not necessarily limited to, delays in:

- obtaining regulatory clearance/approval to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreements on acceptable terms with prospective clinical research organizations ("CROs") and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Institutional Review Board ("IRB") or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; or
- retaining (or replacing) patients who have initiated a clinical trial but who may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, personal issues, or other reasons.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Suspensions or delays in the completion of clinical testing could result in increased costs and delay or prevent our ability to complete development of that product or generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements and on a timely basis. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities, due to a number of factors, including, but not necessarily limited to:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- stopping rules contained in the protocol;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may in turn impact the costs and timing of, and the likelihood of successfully completing, a clinical trial. If we experience delays in the completion of, or if we must suspend or terminate, any clinical trial of any product candidate, our ability to obtain regulatory approval for that product candidate will be delayed, and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

Even if approved, any product candidates that we may develop and market may be later withdrawn from the market or subject to promotional limitations.

We may not be able to obtain the labeling claims necessary or desirable for the promotion of our product candidates if approved. We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory or if adverse events or other safety issues arise after approval, the FDA or a comparable regulatory authority in another jurisdiction may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and/or time consuming to complete. In addition, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of such products if approved.

We currently rely predominantly on third parties to manufacture our preclinical and clinical pharmaceutical supplies and expect to continue to rely heavily on them and other contractors to produce commercial supplies of our products, and our dependence on third-party suppliers could adversely impact our businesses.

We depend heavily on third party manufacturers for product supply. If our contract manufacturers cannot successfully manufacture material that conforms to applicable specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for those products. Our third-party suppliers will be required to maintain compliance with CGMPs and will be subject to inspections by the FDA and comparable agencies and authorities in other jurisdictions to confirm such compliance. In the event that the FDA or such other authorities determine that our third-party suppliers have not complied with CGMPs or comparable regulations, the relevant clinical trials could be terminated or subjected to a clinical hold until such time as we are able to obtain appropriate replacement material and/or applicable compliance, and commercial product could be unfit for sale, or if distributed, could be recalled from the market. Any delay, interruption or other issues that arise in the manufacture, testing, packaging, labeling, storage, or distribution of our products as a result of a failure of the facilities or operations of our third-party suppliers to comply with regulatory requirements or pass any regulatory agency inspection could significantly impair our abilities to develop and commercialize our products and product candidates.

We also rely on third-party manufacturers to purchase from third-party suppliers the materials necessary to produce product candidates for anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture those products. We do not have any control over the process or timing of the acquisition of these raw materials by our third-party manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of raw material components related to an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval.

We do not expect to have the resources or capacity to commercially manufacture our products internally, if approved, and would likely continue to be heavily dependent upon third-party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials, as well as our planned dependence on third party manufacturers for any products that may be approved, may adversely affect our abilities to develop and commercialize products in a timely or cost-effective manner, or at all.

We rely on third parties to conduct clinical trials. If these third parties do not meet agreed-upon deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful, and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We intend to, and do, use CROs to conduct planned clinical trials and will, and do, rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with specified clinical protocols. These CROs, investigators, and other third parties will and do play a significant role in the conduct of our trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of the clinical trial sites terminates for any reason, we may lose follow-up information on patients enrolled in our ongoing clinical trials unless the care of those patients is transferred to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisers or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site, or the FDA’s willingness to accept such data, may be jeopardized.

We rely on clinical and pre-clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of the strategy we implement to mitigate development risk, we seek to develop product candidates with well-studied mechanisms of action, and we intend to utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical and pre-clinical data and other results produced or obtained by third parties, which may ultimately prove to be inaccurate or unreliable. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates, we could make inaccurate assumptions and conclusions about our product candidates, and our research and development efforts could be compromised or called into question during the review of any marketing applications that we submit.

If our competitors develop treatments for any of the target indications for which our product candidates are being developed and those competitor products are approved more quickly, marketed more successfully or demonstrated to be more effective, the commercial opportunity with respect to that product candidate will be reduced or eliminated.

We operate in highly competitive segments of the biopharmaceutical market and face competition from many different sources, including commercial pharmaceutical enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies, as well as new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than we do. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in clinical and pre-clinical research, some in direct competition with us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other biological and pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in establishing clinical trial sites, in patient registration for clinical trials, and in identifying and in-licensing new product candidates.

We may incur substantial product liability or indemnification claims relating to the clinical testing of product candidates.

We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and/or intend to maintain product liability insurance relating to clinical trials, that coverage may not be sufficient to cover potential claims, and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that may be approved for marketing. Additionally, we have entered into various agreements under which we indemnify third parties for certain claims relating to product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

We may use biological materials and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

We, and/or third parties on our behalf, may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations may also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property and 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 penalized with fines in an amount exceeding our respective resources, and clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted in connection with the storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. 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.

Our success depends upon our abilities to obtain and maintain intellectual property rights and take advantage of certain regulatory market exclusivity periods.

Our success depends, in large part, on our ability to obtain patent protection for product candidates and their formulations and uses. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in obtaining patents or what the scope of an issued patent may ultimately be. These risks and uncertainties include, but are not necessarily limited to, the following:

- patent applications may not result in any patents being issued, or the scope of issued patents may not extend to competitive product candidates and their formulations and uses developed or produced by others;
- our competitors, many of which have substantially greater resources than us or our partners, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that may limit or interfere with our abilities to make, use, and sell potential product candidates, file new patent applications, or may affect any pending patent applications that we may have;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

In addition, patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the PTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our US patent positions. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technologies or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Third parties are often responsible for maintaining patent protection for our product candidates, at our and their expense. If that party fails to appropriately prosecute and maintain patent protection for a product candidate, our abilities to develop and commercialize products may be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Such a failure to properly protect intellectual property rights relating to any of our product candidates could have a material adverse effect on our financial condition and results of operations.

In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), was signed into law, and includes a number of significant changes to U.S. patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The USPTO implemented the America Invents Act on March 16, 2013.

We and our licensors also rely on trade secrets and proprietary know-how to protect product candidates. Although we have taken steps to protect our and their trade secrets and unpatented know-how, including entering into confidentiality and non-use agreements with third parties, and proprietary information and invention assignment agreements with employees, consultants and advisers, third parties may still come upon this same or similar information independently. Despite these efforts, any of these parties may also breach the agreements and may unintentionally or willfully disclose our or our licensors' proprietary information, including our trade secrets, and we may not be able to identify such breaches or obtain adequate remedies. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our or our licensor' trade secrets were to be lawfully obtained or independently developed by a competitor, we and our licensors would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our or our licensors' trade secrets were to be disclosed to or independently developed by a competitor, our competitive positions would be harmed.

We also may rely on the regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is generally 12 years from the date of marketing approval (depending on the nature of the specific product), there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period, as initially proposed by President Obama. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect our business.

If we or our licensors are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends on our ability, and the abilities of any of our respective current or future collaborators, to develop, manufacture, market and sell product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our or our licensors' intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we or our licensors are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we/such licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we and our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a US patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the PTO to determine priority of invention in the US. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to, among other things:

- obtain additional licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign products or processes to avoid infringement;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross-licenses to product candidates; and/or
- defend litigation or administrative proceedings which may be costly regardless of outcome, and which could result in a substantial diversion of financial and management resources.

We may be involved in lawsuits to protect or enforce patents or the patents of licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our or our licensors' patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging invalidity of our or our licensors' patents or that we infringe their patents; or provoke those parties to petition the PTO to institute *inter partes* review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensor's is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could likewise put pending patent applications at risk of not issuing. 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.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers.

As is common in the biopharmaceutical industry, we engage the services of consultants to assist in the development of product candidates. Many of these consultants were previously employed at, or may have previously been or are currently providing consulting services to, other pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims related to whether these consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending these claims, litigation could result in substantial costs and be a distraction to management.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with products, when and if any of them is approved.

Any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping, and requirements regarding company presentations and interactions with healthcare professionals. Even if we obtain regulatory approval of a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. We also may be subject to state laws and registration requirements covering the distribution of drug products. Later discovery of previously unknown problems with products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on product manufacturing, distribution or use;
- restrictions on the labeling or marketing of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls;
- fines;
- suspension or withdrawal of marketing or regulatory approvals;
- refusal to permit the import or export of products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

If we or our suppliers, third-party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we or our collaborators may lose marketing approval for products when and if any of them are approved, resulting in decreased revenue from milestones, product sales or royalties.

We rely on information technology, and any internet or internal computer system failures, inadequacies, interruptions or compromises of our systems or the security of confidential information could damage our reputation and harm our business.

Although a significant portion of our business is conducted using traditional methods of contact and communications such as face-to-face meetings, our business is increasingly dependent on critical, complex and interdependent information technology systems, including internet-based systems, to support business processes as well as internal and external communications. We could experience system failures and degradations in the future. We also rely on space and office-sharing arrangements that impose additional burdens on our ability to maintain the security of confidential information. We cannot assure you that we will be able to prevent an extended and/or material system failure or the unintentional disclosure of confidential information if any of the following or similar events occurs:

- human error;
- subsystem, component, or software failure;
- a power or telecommunications failure;
- hacker attacks, cyber-attacks, software viruses, security breaches, unauthorized access or intentional acts of vandalism; or
- terrorist acts or war.

If any of the foregoing events were to occur, our business operations could be disrupted in ways that would require the incurrence of substantial expenditures to remedy. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data and applications, or inappropriate/unauthorized disclosure of confidential or proprietary information (including trade secrets), we could incur liability and our business and financial condition could be harmed.

The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits or we could lose key data which could cause us to curtail or cease operations.

We are vulnerable to damage and/or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our business could be seriously impaired. We have property, liability and business interruption insurance which may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

We cannot predict the likelihood, nature or extent of how government regulation that may arise from future legislation or administrative or executive action taken by the U.S. presidential administration may impact our business and industry. In particular, the U.S. President has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a civilian hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze was to remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget ("OMB") in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance or implement or enforce regulatory requirements in a timely fashion or at all. This hiring freeze was lifted later in 2017. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business or the business of our partners.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business or the business of our partners. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If the timing of FDA's review and approval of new products is delayed, the timing of our or our partners' development process may be delayed which would result in delayed milestone revenues and materially harm our operations of business.

Risks Relating to our Finances, Capital Requirements and Other Financial Matters

We are an early-stage company with a history of operating losses that is expected to continue, and we are unable to predict the extent of future losses, whether we will generate significant or any revenues or whether we will achieve or sustain profitability. We have also historically financed our growth and operations in part through the assumption of debt; should an event of default occur under any applicable loan documents, our business would be materially adversely affected.

We are an early-stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We continue to generate operating losses in all periods including losses from continuing operations of approximately $130.8 million and $97.5 million for the years ended December 31, 2018 and 2017, respectively. At March 31, 2019, we had an accumulated deficit of approximately $394.9 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense in the future, and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates and finance investments in certain of our existing and new partners and affiliates in accordance with our growth strategy. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant or any revenues or if we will ever achieve or sustain profitability.

At March 31, 2019, the total amount of debt outstanding was $82.9 million. If we default on our obligations, the holders of our debt may declare the outstanding amounts immediately payable together with accrued interest. If an event of default occurs, we may not be able to cure it within any applicable cure period, if at all. If the maturity of our indebtedness is accelerated, we may not have sufficient funds available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us, or at all. In addition, current or future debt obligations may limit our ability to finance future operations or satisfy capital needs or to engage in, expand or pursue our business activities. Such restrictive covenants may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

To service our debt securities, which includes series of preferred stock, we will be required to generate a significant amount of cash. Our ability to generate cash depends on a number of factors, some of which are beyond our control, and any failure to meet our debt obligations would have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock and/or debt securities to decline.

Prevailing economic conditions and financial, business and other factors, many of which are beyond our control, may affect our ability to make payments on our debt. If we do not generate sufficient cash flow to satisfy our debt obligations, we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, reducing or delaying capital investments or seeking to raise additional capital. Alternatively, as we have done in the past, we may also elect to refinance certain of our debt, for example, to extend maturities. Our ability to restructure or refinance our debt will depend on the capital markets and our financial condition at such time. If we are unable to access the capital markets, whether because of the condition of those capital markets or our own financial condition or reputation within such capital markets, we may be unable to refinance our debt. In addition, any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. Our inability to generate sufficient cash flow to satisfy our debt obligations or to refinance our obligations on commercially reasonable terms, or at all, could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common stock and/or debt securities to decline.

Repayment of our indebtedness is dependent in part on the generation of cash flow by Journey and its ability to make such cash available to us, by dividend, debt repayment or otherwise. Journey may not be able to, or may not be permitted to, make distributions to enable us to make payments in respect of our indebtedness. Each of our subsidiaries, including Journey, is a distinct legal entity and, under certain circumstances, legal and contractual restrictions may limit our ability to obtain cash from our subsidiaries.

Our ability to continue to reduce our indebtedness will depend upon factors including our future operating performance, our ability to access the capital markets to refinance existing debt and prevailing economic conditions and financial, business and other factors, many of which are beyond our control. We can provide no assurance of the amount by which we will reduce our debt, if at all. In addition, servicing our debt will result in a reduction in the amount of our cash flow available for other purposes, including operating costs and capital expenditures that could improve our competitive position and results of operations.

We have in the past acted, do currently act, and are likely to continue in the future to act as guarantor and/or indemnitor of the obligations, actions or inactions of certain of our subsidiaries and affiliated companies; depending on the terms of such arrangements, we may be contractually obligated to pay substantial amounts to third parties based on the actions or inactions of our subsidiaries and/or affiliates.

We have in the past acted, do currently act, and are likely to continue in the future to act as guarantor of the debt obligations of several of our subsidiaries and/or affiliates, including Aevitas, Cellvation, Cyprium and Tamid. Depending on the terms of such guaranty arrangements, we may be contractually obligated to pay substantial amounts to third parties lenders based on the actions or inactions of such subsidiaries and/or affiliates, which would result in a reduction of the amount of our cash available for other purposes and may have a material adverse effect on the price of our Securities.

We also have in the past acted, do currently act, and are likely to continue in the future to act as indemnitor of potential losses that may be experienced by one or more of our affiliated companies and/or their partners or investors. In particular, under that certain Indemnification Agreement, dated as of November 12, 2018 (the "Indemnification Agreement"), we indemnify InvaGen Pharmaceuticals Inc. ("InvaGen") and its affiliates for any losses they may sustain in connection with inaccuracies that may appear in the representations and warranties that our partner company Avenue made to InvaGen in that certain Stock Purchase and Merger Agreement, dated as of November 12, 2018 (the "Avenue SPMA"). The maximum amount of indemnification we may have to provide under the Indemnification Agreement is $35 million, and such obligation terminates upon the consummation of the Merger Transaction (as defined in the Avenue SPMA). In the event of payment by us of any such indemnification amount, we would be able to recoup such amounts (other than our pro rata share of the indemnification as a shareholder in Avenue) from the Merger Transaction proceeds, but if the Merger Transaction never occurs, we would have no means of recouping such previously-paid indemnification amounts. If we become obligated to pay all or a portion of such indemnification amounts (regardless of whether or not we are partially reimbursed out of the proceeds of the Merger Transaction), our business and the market value of our common stock and/or debt securities may be materially adversely impacted.

We have in the past and are likely in the future to undergo collaborations and/or divestitures with respect to certain of our assets and subsidiaries, some of which may be material and/or transformative, which could adversely affect our business, prospects and opportunities for growth.

We have in the past completed a number of partnerships and/or contingent sales of our assets and subsidiaries, including an equity investment and contingent sale between Avenue and InvaGen and an equity investment and option transaction between Caelum and Alexion Pharmaceuticals, Inc. Each of these transactions has been time-consuming and has diverted management's attention. As a result of these contingent sales (and other similar transactions we may in the future complete), we may experience a reduction in the size or scope of our business, our market share in particular markets, our opportunities with respect to certain markets, products or therapeutic categories or our ability to compete in certain markets and therapeutic categories. For example, in connection with execution of the Avenue SPMA, we signed a Restrictive Covenant Agreement, which prohibits us from, directly or indirectly, engaging in the business of hospital administered pain management anywhere in the world other than Canada, Central America or South America for a period of five years after the earlier of the termination of the Avenue SPMA or consummation of the Merger Transaction (as defined in the Avenue SPMA).

In addition, in connection with any such transaction that involves a (contingent or non-contingent) sale of one of our assets or subsidiaries, we may surrender our ability to realize long-term value from such asset or subsidiary, in the form of foregone royalties, milestone payments, sublicensing revenue or otherwise, in exchange for upfront and/or other payments. In the event, for instance, that a product candidate underpinning any such asset or subsidiary is granted FDA approval for commercialization following the execution of documentation governing the sale by us of such asset or subsidiary, the transferee of such asset or subsidiary may realize tremendous value from commercializing such product, which we would have realized for ourselves had we not executed such sale transaction and been able to achieve applicable approvals independently.

Should we seek to enter into collaborations or divestitures with respect to other assets or subsidiaries, we may be unable to consummate such arrangements on satisfactory or commercially reasonable terms within our anticipated timelines. In addition, our ability to identify, enter into and/or consummate collaborations and/or divestitures may be limited by competition we face from other companies in pursuing similar transactions in the biotechnology and pharmaceutical industries. Any collaboration or divestiture we pursue, whether we are able to complete it or not, may be complex, time consuming and expensive, may divert the management's attention, have a negative impact on our customer relationships, cause us to incur costs associated with maintaining the business of the targeted collaboration or divestiture during the transaction process and also to incur costs of closing and disposing the affected business or transferring the operations of the business to other facilities. In addition, if such transactions are not completed for any reason, the market price of our common stock may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of us generally and a decline in the market price of our common stock.

As a result of these factors, any collaboration or divestiture (whether or not completed) could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares and/or debt securities to decline.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business or the business of our partners.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business or the business of our partners. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If the timing of FDA's review and approval of new products is delayed, the timing of our or our partners' development process may be delayed which would result in delayed milestone revenues and materially harm our operations of business.

The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits or we could lose key data which could cause us to curtail or cease operations.

We are vulnerable to damage and/or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our business could be seriously impaired. We have property, liability and business interruption insurance which may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects.

We may need substantial additional funding and may be unable to raise capital when needed, which may force us to delay, curtail or eliminate one or more of our R&D programs, commercialization efforts or planned acquisitions and potentially change our growth strategy.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2018 and 2017 we incurred R&D expenses of approximately $83.3 million and $48.3 million, respectively. We expect to continue to spend significant amounts on our growth strategy. We believe that our current cash and cash equivalents will enable us to continue to fund operations in the normal course of business for at least the next 12 months. Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance potential cash needs. Our ability to obtain additional funding when needed, changes to our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our planned R&D activities, expenditures, acquisitions and growth strategy, increased expenses or other events may affect our need for additional capital in the future and require us to seek additional funding sooner or on different terms than anticipated. In addition, if we are unable to raise additional capital when needed, we might have to delay, curtail or eliminate one or more of our R&D programs and commercialization efforts and potentially change our growth strategy.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financings may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain financial commitments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing or sublicensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our Securities.

Pursuant to Section 404 of the Sarbanes Oxley Act of 2002 and related rules, our management is required to report on, and our independent registered public accounting firm is required to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to further upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. If material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future could cause us to fail to meet our future reporting obligations and cause the price of our Securities to decline.

Future revenue based on sales of our dermatology products, especially Targadox and Exelderm®, may be lower than expected or lower than in previous periods.

The vast majority of our operating income for the foreseeable future is expected to come from the sale of dermatology products through our partner company Journey Medical Corporation. Any setback that may occur with respect to such products, in particular Targadox and Exelderm®, could significantly impair our operating results and/or reduce our revenue and the market prices of our Securities. Setbacks for such products could include, but are not necessarily limited to problems with shipping, distribution, demand, manufacturing, product safety, marketing, government regulation or reimbursement, licenses and approvals, intellectual property rights, competition with existing or new products, physician or patient acceptance of the products, as well as higher than expected total rebates, returns or rebates. These products also are or may become subject to third party generic competition.

Risks Associated with our Capital Stock

Some of our executives, directors and principal stockholders can control our direction and policies, and their interests may be adverse to the interests of our other stockholders.

At March 31, 2019, Lindsay A. Rosenwald, M.D. our Chairman, President and Chief Executive Officer, beneficially owned 15.3% of our issued and outstanding capital stock, including 98,164 shares of our Series A Stock. At March 31, 2019, Michael S. Weiss, our Executive Vice Chairman, Strategic Development, beneficially owned 14.9% of our issued and outstanding capital stock. By virtue of their holdings and membership on our Board of Directors, Dr. Rosenwald and Mr. Weiss may individually influence our management and our affairs and may make it difficult for us to consummate corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders.

The market price of our Securities may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

The stock prices of our Securities may experience substantial volatility as a result of a number of factors, including, but not necessarily limited to:

- announcements we make regarding our current product candidates, acquisition of potential new product candidates and companies and/or in-licensing through multiple partners/affiliates;
- sales or potential sales of substantial amounts of our Common Stock;
- issuance of debt or other Securities;
- our delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of any of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors and/or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- unstable regional political and economic conditions, such as those caused by the U.S. presidential administration change;
- variations in our anticipated or actual operating results; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market prices of our Securities, regardless of our actual operating performance.

Sales of a substantial number of shares of our Common Stock, or the perception that such sales may occur, may adversely impact the price of our Common Stock.

Almost all of the 66.0 million outstanding shares of our Common Stock, inclusive of outstanding equity awards, as of March 31, 2019 are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), or an effective registration statement. In addition, pursuant to our current shelf registration statement on Form S-3, from time to time we may issue and sell shares of our Common Stock having an aggregate offering price of up to $10.2 million as of March 31, 2019. Any sale of a substantial number of shares of our Common Stock could cause a drop in the trading price of our Common Stock on the Nasdaq Stock Market.

We have never paid and currently do not intend to pay cash dividends in the near future, except for the dividend we pay on shares of our Series A Preferred Stock. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our or their common stock, or made stock dividends, except for the dividend we pay on shares of our Series A Preferred Stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our businesses, and retain our stock positions. In addition, the terms of existing and future debt agreements may preclude us from paying cash of stock dividends. Equally, each of our affiliates and partners is governed by its own board of directors with individual governance and decision-making regimes and mandates to oversee such entities in accordance with their respective fiduciary duties. As a result, we alone cannot determine the acts that could maximize value to you of such affiliates/partners in which we maintain ownership positions, such as declaring cash or stock dividends. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

Provisions in our certificate of incorporation, our bylaws and Delaware law might discourage, delay or prevent a change in control of our Company or changes in our management and, therefore, depress the trading price of our Common Stock or other Securities.

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our Common Stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you would receive a premium for your ownership of our Securities through an acquisition.

Item 2. **Unregistered Sales of Equity Securities and Use of Proceeds**

None.

Item 3. **Defaults Upon Senior Securities**

None.

Item 4. **Mine Safety Disclosures**

None.

Item 5. **Other Information**

None.

Item 6. **Exhibits**

Exhibit Index

Exhibit Number	Exhibit Title
10.1	Development, Option and Stock Purchase Agreement dated January 30, 2019 by and among Fortress Biotech, Inc., Caelum Biosciences, Inc. ("Caelum"), Alexion Therapeutics, Inc., and the Caelum security holders parties thereto.
31.1	Certification of Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chairman, President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

SIGNATURES

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

May 10, 2019 FORTRESS BIOTECH, INC.

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D., Chairman, President and Chief Executive Officer (Principal Executive Officer)

May 10, 2019 By: /s/ Robyn M. Hunter
Robyn M. Hunter Chief Financial Officer (Principal Financial Officer)

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Section 2: EX-10.1 (EXHIBIT 10.1)

Exhibit 10.1

EXECUTION VERSION

DEVELOPMENT, OPTION AND STOCK PURCHASE AGREEMENT

BY AND AMONG

ALEXION PHARMACEUTICALS, INC.,

CAELUM BIOSCIENCES, INC.,

THE SELLERS,

AND FORTRESS BIOTECH, INC., AS THE REPRESENTATIVE

DATED AS OF JANUARY 30, 2019

DEVELOPMENT, OPTION AND STOCK PURCHASE AGREEMENT

This DEVELOPMENT, OPTION AND STOCK PURCHASE AGREEMENT (this "Agreement") is made and entered into as of January 30, 2019, by and among Alexion Pharmaceuticals, Inc., a Delaware Corporation (the "Buyer"), Caelum Biosciences, Inc., a Delaware corporation (the "Company"), the holders of the securities of the Company listed on Exhibit A and signatories hereto (collectively, the "Sellers"), and Fortress Biotech, Inc. ("Fortress"), in its capacity as the Representative.

RECITALS

A. The Buyer desires to purchase from the Company and the Company desires to issue to the Buyer Class B Preferred Shares representing 19.9% of the Fully Diluted Capitalization for $30.0 million and on the terms and subject to the conditions of this Agreement (the "Stock Purchase Investment").

B. The Buyer and the Company desire to collaborate to develop the Company's lead asset, CAEL-101 (mAb 11-1F4), a novel antibody for the treatment of patients with amyloid light chain amyloidosis (the "Product").

C. The Company desires and Buyer is willing to provide funding to the Company in an amount up to $30.0 million (the "Development Funding") for the purpose of developing the Product, as consideration for which the Buyer desires and the Sellers are willing to provide the Buyer the Purchase Option (as defined herein) to consummate the Acquisition (as defined herein) on the terms and subject to the conditions of this Agreement (the Acquisition together with the Development Funding, the Stock Purchase Investment and the other transactions contemplated by this Agreement and the Ancillary Agreements (as defined herein), the "Transactions").

D. Concurrently with the execution and delivery of this Agreement, the Buyer, the Company and the Sellers have entered into that certain stockholders agreement, effective as of the Signing Date (as amended from time to time, the "Stockholders Agreement") and attached as Exhibit B hereto, providing for certain agreements between Buyer, the Company and the Sellers.

E. Concurrently with the execution and delivery of this Agreement, the Buyer, the Company and Fortress have entered into that certain waiver and termination agreement, effective as of the Signing Date (as amended from time to time, the "Waiver Agreement") and attached as Exhibit C hereto, pursuant to which Fortress has agreed to terminate that certain Founders Agreement by and between the Company and Fortress dated January 1, 2017 (the "Founders Agreement") and that certain Management Services Agreement by and between the Company and Fortress dated January 1, 2017 (the "MSA"), and to irrevocably waive certain payments otherwise due to it under the Founders Agreement and the MSA and any and all dividends, payable in cash or equity, under the terms of the Class A Preferred Shares of the Company.

F. Concurrently with the execution and delivery of this Agreement, the Buyer and Fortress have entered into a restrictive covenant agreement, effective as of the Signing Date (as amended from time to time, the "Fortress Restrictive Covenant Agreement"), attached as Exhibit D hereto.

G. The parties hereto desire to make certain representations, warranties, covenants and agreements in connection with the Transactions and also to prescribe various conditions to the Development Funding, the Stock Purchase Investment and the Acquisition.

NOW, THEREFORE, in consideration of the foregoing and the respective representations and warranties, covenants and agreements set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1.
DEFINITIONS

For purposes of this Agreement, including the recitals, the following terms have the following meanings (such meanings to be equally applicable to both the singular and plural forms of the terms defined):

"Accelerated BLA Approval"	The accelerated approval by the FDA of a biologic license application for the Product.
"Acquisition"	Defined in Section 4.1.
"Acquisition Closing"	Defined in Section 4.4.
"Acquisition Closing Purchase Price"	An amount equal to (i) the Baseline Purchase Price minus (ii) the Escrow Amount (iii) minus the Miscellaneous Transaction Expenses.
"Acquisition Shares"	Defined in Section 4.1.
"Adoption Agreement"	Defined in Section 9.7(b)(1).
"Affiliate"	With respect to any specified Person, any other Person that controls, is controlled by or is under common control with such Person (it being understood that a Person will be deemed to "control" another Person, for purposes of this definition, if such Person directly or indirectly (i) has the power to direct or cause the direction of the management and policies of such other Person, whether through the ownership of voting securities of such other Person, through contract or otherwise or (ii) owns more than 50% of the voting securities of such other Person entitled to vote in the election of directors); provided that, for all purposes of this Agreement and the Ancillary Agreements, in no event shall the Company be deemed an Affiliate of the Buyer at any time prior to the Acquisition Closing.
"Agreement"	Defined in the Preamble.

"Ancillary Agreements"	The Stockholders Agreement, Waiver Agreement, Fortress Restrictive Covenant Agreement, the Escrow Agreement (solely with respect to the Acquisition Closing), and any other agreement, certificate, instrument or document contemplated hereby and thereby, including each exhibit hereto and thereto.
"Applicable Closing"	Defined in Section 5.8.
"Baseline Purchase Price"	An amount equal to (i) $150,000,000 plus (ii) only in the event that the Company has received Accelerated BLA Approval prior to Acquisition Closing, the Supplemental Baseline Purchase Price.
"Bankruptcy Code"	Defined in Section 5.14(h).
"Broad Patient Population"	An FDA-approved indication that does not limit usage to the Mayo Stage 3b (a generally accepted patient staging criteria).
"Budget"	Defined in Section 2.1(a).
"Business Day"	Any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by law to be closed in the State of Delaware.
"Buyer"	Defined in the Preamble.
"Buyer Indemnified Party"	Defined in Section 11.1.
"Cap"	Defined in Section 11.4(a).
"Change of Control"	The occurrence of any of the following events: (i) an acquisition of the relevant Person by another Person by means of any transaction or series of related transactions (including any reorganization, merger or consolidation but excluding any merger effected exclusively for the purpose of changing the domicile of the relevant Person), or (ii) a sale of all or substantially all of the assets of such Person, so long as in either case such Person's stockholders of record immediately prior to such transaction will, immediately after such transaction, hold less than fifty percent (50%) of the voting power of the surviving or acquiring Person.
"Class A Preferred Shares"	Any shares of Class A Preferred Stock of the Company with a par value of $0.0001 per share, whether issued or not.
"Class B Preferred Shares"	Any shares of Class B Preferred Stock of the Company with a par value of $0.0001 per share, whether issued or not.

"Clinical Trial"	A clinical study of a pharmaceutical product conducted on human subjects.
"COBRA"	The requirements of Part 6 of Subtitle B of Title I of ERISA and Section 4980B of the Code and any similar state law.
"Code"	The United States Internal Revenue Code of 1986, as amended.
"Columbia"	The Trustees of Columbia University in the City of New York.
"Columbia SPA"	Stock Purchase Agreement between Caelum Biosciences, Inc. and the Trustees of Columbia University in the City of New York dated December 30, 2016.
"Commercially Reasonable Efforts"	The use of such efforts and resources typically used by biopharmaceutical companies similar in size and scope to the Company for the development and commercialization of similar products to the Product at similar development stages.
"Common Shares"	Any shares of Common Stock of the Company with a par value of $0.0001 per share, whether issued or not.
"Company"	Defined in the Preamble.
"Company Assets"	All property, assets, rights, privileges, powers, franchises owned by, and all and every other interest of, the Company, including all Company Intellectual Property.
"Company Board"	The Board of Directors of the Company.
"Company Contract"	Any Contract to which the Company is a party or by which the Company (or any property or asset thereof) is bound.
"Company Employees"	The employees, officers, independent contractors, or directors of the Company.
"Company Employee Plan"	Any Company Plan which covers any current or former Company Employees.
"Company Intellectual Property"	All Owned Intellectual Property and Licensed Intellectual Property.
"Company Plan"	Any Plan or portion thereof (including any Liabilities thereof), covering Company Employees which is sponsored or maintained by the Company or Fortress, or to which the Company or Fortress contributes or is required to contribute, or for which the Company or Fortress has any Liability, including the Company's 2017 Stock Incentive Plan.

"Company's Knowledge" or "Knowledge of the Company" or similar words	The actual knowledge of the Persons listed in Schedule 1.1 after due and reasonable investigation and inquiry; provided that to the extent that any such Person's employment with the Company is terminated prior to the Acquisition Closing, any replacement employee thereof shall be deemed to be listed on Schedule 1.1 for purposes of the applicable representations made at the Acquisition Closing.
"Company Restricted Share"	Defined in Section 4.2.
"Company Securities"	Defined in Section 5.3(c).
"Company Shares"	Defined in Section 4.1.
"Confidential Intellectual Property"	All Know How and any other confidential, proprietary, non-public or sensitive Intellectual Property constituting Company Intellectual Property.
"Confidentiality Agreement"	Defined in Section 12.1.
"Contract"	Any oral or written agreement, arrangement, instrument, contract, undertaking, mortgage, note, indenture, lease, license or other understanding or obligation, including amendments thereto.
"Damages"	Any and all losses, damages, Liabilities, deficiencies, judgments, interest, awards, penalties, fines, costs or expenses of whatever kind, including reasonable attorneys' fees and disbursements, the cost of defending any claim, the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance claim.
"DEA"	U.S. Drug Enforcement Agency or any successor agency thereto.
"Development Funding"	Defined in the Recitals.
"Development Plan"	Defined in Section 2.1(b).
"Direct Claim"	Defined in Section 11.3(d).
"Disclosure Schedule"	Defined in Article 5.
"Disputed Amounts"	Defined in Section 4.6(e).
"Earn-Out Payment"	Defined in Section 4.6(a).

"Encumbrance"	Any mortgage, deed of trust, lien (statutory or other), pledge, charge, security interest, title retention device (including the interest of a seller or lessor under any conditional sale agreement or capital lease, or any financing lease having substantially the same economic effect as any of the foregoing), collateral assignment, adverse claim, priority payment obligation, restriction or other encumbrance of any kind in respect of such asset, whether or not filed, recorded or perfected under applicable Legal Requirements (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset, but other than restrictions under applicable securities laws).
"Environmental Claim"	Defined in Section 5.12(a).
"Environmental Law"	Any Legal Requirement relating to (i) the protection of the environment or natural resources (including air, water vapor, surface water, soil, sediments, groundwater, drinking water supply, wastewater treatment, surface or subsurface land); or (ii) the exposure to, or the use, storage, recycling, treatment, generation, transportation, processing, handling, labeling, recycling, release or disposal of, Hazardous Substances.
"Environmental Permits"	Any permit, approval, license or other authorization required by a Governmental Authority under or issued by a Governmental Authority pursuant to any applicable Environmental Law.
"ERISA"	The Employee Retirement Income Security Act of 1974, as amended, and all laws promulgated pursuant thereto or in connection therewith.
"Escrow Agent"	As defined in Section 4.5(a).
"Escrow Agreement"	As defined in Section 4.5(a).
"Escrow Amount"	An amount equal to ten percent (10%) of the Baseline Purchase Price, to be deposited with the Escrow Agent pursuant to the Escrow Agreement.
"Escrow Fund Release Amount"	Defined in Section 4.5(c).
"Escrow Funds"	The funds from time to time being held by the Escrow Agent pursuant to the terms of the Escrow Agreement.

"FDA"	United States Food and Drug Administration, or any successor agency thereto.
"FDCA"	Defined in Section 5.11.
"Financial Statements"	Defined in Section 5.4(a).
"Fortress"	Defined in the Preamble.
"Fortress Restrictive Covenant Agreement"	Defined in the Recitals.
"Founders Agreement"	Defined in the Recitals.
"Fully Diluted Capitalization"	The aggregate number of all shares of the Company's capital stock (on an as-converted basis) issued and outstanding, assuming exercise, conversion, acceleration or exchange of all options (vested or unvested), RSUs (vested or unvested), Company Restricted Shares (vested or unvested), warrants and other convertible or exchangeable securities (including convertible notes, Class B Preferred Shares or any other shares of convertible preferred stock and any Company Restricted Shares), plus all shares of the Company's capital stock, or derivatives thereof, authorized for issuance, but as yet unissued, under the Company's 2017 Stock Incentive Plan as of the Signing Date.
"Fundamental Claim"	Defined in Section 11.4(c).
"Fundamental Representations"	The representation or warranties contained in Section 5.1 (Organization of the Company; Due Authorization), Section 5.3 (Capital Stock of the Company), Section 5.8 (Taxes), Section 5.14 (Intellectual Property), Section 5.17 (Regulatory Compliance), Section 7.1 (Organization of Seller), Section 7.4 (Title to Stock), and Section 7.6 (Brokers).
"Funding Payment"	Defined in Section 2.2(a).
"GAAP"	United States generally accepted accounting principles in effect from time to time.
"Governmental Authority"	Any foreign, federal, national, state, local, cantonal, municipal, international or multinational government, governmental, regulatory or administrative authority, agency or commission, any court, tribunal, or judicial or arbitral body of competent jurisdiction or any quasi-governmental or private body exercising any regulatory, taxing, importing or other governmental or quasi-governmental authority.

"Governmental Permits"	Any permit, approval, registration, certification, clearance, license or other authorization required by a Governmental Authority under or issued by a Governmental Authority pursuant to any applicable Legal Requirement, with the exception of Environmental Laws.
"Hazardous Substance"	Any waste, material, chemical or substance in any form that is regulated, controlled or defined as hazardous, toxic, or a pollutant under any applicable Environmental Law, including all materials regulated under any applicable Environmental Law as capable of causing harm or injury to human health or the environment, including oils, petroleum, polychlorinated biphenyls, petroleum products and constituents, and asbestos.
"Healthcare Regulatory Authority"	The FDA, the DEA or any other Governmental Authority that is concerned with or regulates the development, approval, labelling, marketing, sale, use, handling and control, safety, efficacy, reliability or manufacturing of drug or biological products or is concerned with or regulates public health care programs.
"Healthcare Regulatory Authorizations"	All approvals, clearances, authorizations, registrations, certifications, licenses and permits granted by any Healthcare Regulatory Authority, including all investigational new drug applications and new drug applications.
"HSR Act"	The U.S. Hart – Scott – Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.
"IND"	An Investigational New Drug application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto.
"Indebtedness"	(i) the principal, accreted value, accrued and unpaid interest, prepayment and redemption premiums or penalties (if any), unpaid fees or expenses and other monetary obligations in respect of (A) indebtedness, whether or not contingent, for borrowed money, (B) obligations evidenced by bonds, debentures, notes or other similar instruments for the payment of which such Person is liable, (C) obligations for the deferred purchase price of property or services, including any earn-out (whether or not contingent), (D) indebtedness created or arising under any conditional sale or other title retention agreement with respect to property acquired by such Person (even if the rights and remedies of the seller or lender under such agreement in the event of default are limited to repossession or sale of such property), (E) all obligations of such Person to purchase, redeem, retire, defease or otherwise acquire for value any capital stock of such Person or any warrants, rights or options to acquire such capital stock, valued, in the case of redeemable preferred stock, at the greater of its voluntary or involuntary liquidation preference plus accrued and unpaid dividends, and (F) all loans to such Person by any of its suppliers or licensors, (ii) all obligations or liabilities of such Person (whether or not contingent) under or in connection with letters of credit or bankers' acceptances or similar items; provided, however, that undrawn amounts shall not be included in this definition of Indebtedness, (iii) any obligations with respect to capital leases, (iv) all obligations of such Person under interest rate, currency swap or other hedging transactions, (v) all obligations under direct or indirect guaranties in respect of, and obligations (contingent or otherwise) to purchase or otherwise acquire, or otherwise to assure a creditor against loss in respect of, Indebtedness or obligations of others of the kinds referred to in clauses (i) through (iv) above and (vi) all obligations of the type referred to in clauses (i) through (v) of other Persons secured by (or for which the holder of such obligations has an existing right, contingent or otherwise, to be secured by) any Encumbrance on any property or asset of such Person (whether or not such obligation is assumed by the Person or any of its subsidiaries).

"Indemnified Party"	Defined in Section 11.3(a).
"Indemnified Person"	Defined in Section 9.8(a).
"Indemnifying Party"	Defined in Section 11.3(a).
"Indemnifying Person"	Defined in Section 9.8(b).
"Independent Accountant"	Defined in Section 4.6(e).
"Initial Delivery"	Defined in Section 2.3(c).

"Intellectual Property"	Any and all rights in, arising out of, or associated with any of the following in any jurisdiction throughout the world: (i) patents, patent applications, patent disclosures and inventions, utility models, utility model applications, petty patents, statutory invention registrations, certificates of invention, designs, industrial designs, design registrations and applications (including any continuations, continuations-in-part, divisionals, provisionals, non-provisionals, reexaminations, restorations, extensions, renewals and reissues) for any of the foregoing, and all other indicia of invention ownership by any Governmental Authority ("Patents"); (ii) copyrights (registered and unregistered), copyright applications, copyrightable subject matter, works of authorship (whether or not copyrightable), design rights, and design right registrations, and any and all renewals of any of the foregoing; (iii) trademarks, service marks, trade dress, business names and trade names, assumed names, symbols, brand names, d/b/a's, fictitious names, certification marks, logos and product names whether registered, unregistered or existing at common law, including the goodwill associated therewith (and all registrations and applications therefor), and any and all renewals of any of the foregoing; (iv) unregistered industrial design rights; (v) domain names (and all registrations and applications therefor) whether or not Trademarks, all associated web addresses, URLs, websites and web pages, and all content and data thereon or relating thereto, whether or not Copyrights; (vi) Know How, (vii) software, data processing, communications, inventory management, website content, programs, program interfaces, object code, source code, other computer systems and all documentation relating to the foregoing; (viii) all other proprietary information and intellectual property in all forms and media, and all goodwill associated therewith, now known or hereafter recognized in any jurisdiction worldwide; (ix) all rights pertaining to the foregoing, including those arising under international treaties and convention rights; (x) copies and tangible embodiments of all of the foregoing (in whatever form or medium); (xi) all rights and powers to assert, defend and recover title to any of the foregoing; and to assert, defend, sue, and recover damages for any past, present and future infringement, misuse, misappropriation, impairment, unauthorized use or other violation of any rights in or to any of the foregoing; and (xii) all proceeds, income, royalties, damages and payments now or hereafter due and payable under or in respect of all of the foregoing.
"Intellectual Property Agreements"	Any licenses, sublicenses, consent to use agreements, settlements, co-existence agreements, covenants not to sue, waivers, releases, or any other Contract relating to Intellectual Property to which the Company is party, beneficiary or otherwise bound, including any Contract providing for the license, practice, use, development, modification, design, invention, production, acquisition, purchase, formulation, creation or assignment of any Intellectual Property, including all IP Assignment Agreements.
"Investment Closing"	Defined in Section 3.2.
"Investment Price"	Defined in Section 3.1.
"Investment Shares"	Defined in Section 3.1.
"IP Assignment Agreements"	Defined in Section 5.14(e).

"JSC"	Defined in Section 2.1(b).
"Key License Agreement"	That certain Exclusive License Agreement, dated as of January 1, 2017, by and between The Trustees of Columbia University in the City of New York and the Company, as amended.
"Know-How"	All trade secrets, confidential or proprietary information, including all inventions (whether patentable or unpatentable and whether or not reduced to practice), know-how, processes, techniques, improvements, discoveries, ideas, developments, product composition data (including pharmacological, non-clinical, pre-clinical and clinical data, analytical and quality control data) and specifications, recipes, packaging specifications, research and development data as well as purchasing and marketing data and procedures, customer lists, Personal Data, databases, technologies, instructions, formulae and information, manufacturing drawings, engineering drawings, manuals, designs, lab journals, notebooks, schematics, blue prints, research and development reports, audit reports, inspection reports, GxP documentation, technical information, and design and engineering specifications, including those related to products under development, including each of the foregoing items as they relate to the development, manufacturing, sale and distribution of the goods produced, distributed, marketed or sold by the applicable Person.
"Leased Real Property"	Any parcel of real property leased or subleased and any other rights to use or occupy any land, buildings, structures, improvements, fixtures or other interests in real property held by the Company.
"Legal Requirement"	Any foreign, federal, national, state (including cantonal), local, international, multinational or administrative order, law, common law, ordinance, regulation, statute or treaty or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any Governmental Authority.
"Liabilities"	Any and all debts, liabilities and obligations, whether accrued or fixed, direct or indirect, asserted or unasserted, absolute or contingent, known or unknown, liquidated or not, matured or unmatured or determined or determinable, including those arising under any Legal Requirement, Proceeding or any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Authority and those arising under any Contract.

"Licensed Intellectual Property"	All Intellectual Property licensed or otherwise made available to the Company by any Person.
"Majority Holders"	Defined in Section 12.17(b).
"Material Adverse Effect"	Any event, circumstance, occurrence, state of facts or matters, action, omission, condition, development, change in or result or effect on (each, an "Event") the Company or any of the Sellers that, individually or in the aggregate, is or could become materially adverse to (a) the assets, liabilities, capitalization, results of operations or the condition (financial or otherwise) of the Company, its business or prospects, taken as a whole or (b) the ability of the Company or any of the Sellers to perform and carry out any of their obligations under this Agreement or any of the Ancillary Agreements, and to consummate on a timely basis the Stock Purchase Investment, the Acquisition or any of the other transactions contemplated by this Agreement or any of the Ancillary Agreements; provided, however, that, in the case of clause (a), the following Events shall not be taken into account in determining the occurrence of a "Material Adverse Effect": (i) those caused by, arising out of or attributable to the general political or economic environment or affecting the global securities markets generally; (ii) those that generally affect the industries in which the Company operates (including legal and regulatory changes applicable to the Company after the Signing Date); or (iii) those caused by, arising out of or attributable to acts of terrorism or warfare between two or more countries in which the Company operates (whether or not declared); provided, that any such Event which disproportionately affects the Company relative to other participants in the industries in which the Company operates shall not be excluded from determining the occurrence of a "Material Adverse Effect".
"Material Contract"	Defined in Section 5.5(a).
"Maximum Premium"	Defined in Section 9.8(c).
"Medical Product"	Defined in Section 5.17(e).
"Merger"	Defined in Section 8.1.
"Miscellaneous Transaction Expenses"	The aggregate amount of any and all payments paid or payable to any broker, finder or investment banker in connection with the transactions contemplated by this Agreement and the Ancillary Agreements (including reasonable attorneys' fees and disbursements incurred in connection with a dispute over such matters), except for any such amounts disclosed on Schedule 5.18.

"Milestone Event"	Defined in Section 4.6(a).
"Most Recent Balance Sheet"	Defined in Section 5.4(a).
"Most Recent Balance Sheet Date"	Defined in Section 5.4(a).
"MSA"	Defined in the Recitals.
"Net Sales"	For a particular period of time, the sum of (i) net sales reported by the Buyer (or its Affiliates) for sales of the Product to Third Parties, calculated in a manner consistent with the Buyer's calculations of net sales across its product portfolio generally and as such net sales are reported in externally published audited financial statements for the Product for that period (excluding sales to any sublicensee or Affiliate) (provided that if for any reason the Buyer does not have externally published audited financial statements for the Product, then net sales for any period that would not be covered by an externally published audited financial statement shall be calculated in accordance with GAAP, provided that such amount reflects the gross invoice price at which the Product was sold or otherwise disposed of by Buyer and its Affiliates (excluding sales by any sublicensee) to Third Parties in that period reduced by gross-to-net deductions, the fair-market-value amounts reasonably attributable to other components (other than the Product) of any combination product or bundled product but only if such other components are therapeutically active compounds that are sold separately, and amounts from a prior period which are not collected and are written off by the Buyer or its Affiliates (including bad debts), if not previously deducted from such invoiced amount, taken in accordance with GAAP and (ii) net sales reported by each sublicensee (excluding amounts received by distributors for sales of the Product sold to such distributor, if the sale amounts for such sales to such distributor are otherwise included by this definition of Net Sales) for sales of the Product to Third Parties as determined in accordance with GAAP. The calculations described in clauses (i) and (ii) above shall exclude hedging gains or losses. In the case of sales of the Product for consideration other than cash, such as barter or counter trade, Net Sales shall be calculated with respect to the fair market value of the consideration received. For the avoidance of doubt, the supply of Product for compassionate use, commercial samples, or for administration to patients enrolled in Clinical Trials or to Third Parties as samples for evaluation purposes, in each case free of charge, shall not be included in Net Sales.

"Net Sales Statement"	Defined in Section 4.6(c).
"Notice of Objection"	Defined in Section 4.6(c).
"Option"	Defined in Section 4.2.
"Option Period"	Defined in Section 2.3(a).
"Owned Intellectual Property"	All Intellectual Property that is owned or purported to be owned, in whole or in part, by the Company.
"Payoff Letters"	Defined in Section 9.11.
"Patheon"	Defined in Section 2.2(a)(1).
"Person"	Individuals or entities, including any corporation, limited liability company, joint venture, trust, body corporate (wherever located), unincorporated association, partnership or other entity.
"Personal Data"	Any information (including a Person's name, physical address, telephone number, e-mail address, photograph, social security number, taxpayer identification number, medical and health information, family members, demographic data and any other data and information) which, whether alone or in combination with other information, identifies or is associated with an identified natural Person.
"Phase II Clinical Trial"	A Clinical Trial of the Product for amyloid light chain amyloidosis that is intended to satisfy the requirements of 21 C.F.R. § 312.21(b), as amended from time to time.
"Pivotal Clinical Trial"	A pivotal Clinical Trial with a defined dose or a set of defined doses that is designed to ascertain efficacy and safety of the Product for the purpose of supporting the preparation and submission of a biologic license application.
"Plan"	Any employee benefit plan, scheme, program, agreement, arrangement, commitment, or understanding of any kind (written or unwritten), including any bonus, incentive, stock, stock option, phantom stock, equity-based compensation, deferred compensation, change in control, vacation, sick leave, retention, severance, salary continuation, defined benefit or defined contribution retirement, pension, savings, profit sharing, supplemental retirement, medical, dental, vision, life insurance, accident, disability, long-term care, retiree medical or other welfare or fringe benefit plan, scheme, or program (together with any trust, escrow or other agreement related thereto), and including any "employee benefit plan" as defined in Section 3(3) of ERISA.

"POC Data Delivery Date"	Defined in Section 2.3(c).
"Pre-Closing Period"	The period from the Signing Date until the later of the expiration of the Purchase Option pursuant to Section 2.3 and the Acquisition Closing (to the extent that the Buyer exercises its Purchase Option pursuant to Section 2.3).
"Product"	Defined in the Recitals.
"Privacy Agreements"	Any data and privacy related policies (e.g., privacy policies, acceptable use policies, terms of service, etc.) and other Contracts in effect between the Company and any natural person or other Persons that are applicable to or otherwise implicate the collection, protection, storage, processing, transfer, administration, review, monitoring, use or disclosure of Personal Data in connection with the Company or its business.
"Privacy Laws"	All Legal Requirements concerning or otherwise applicable to the collection, protection, storage, processing, transfer, administration, review, monitoring, use or disclosure of Personal Data.
"Proceeding"	Any action (at law or in equity), suit, claim, review, audit, inquiry or legal or administrative proceeding or arbitration or other alternative dispute resolution proceeding or investigation (whether civil, criminal or administrative).
"Product"	As defined in the Recitals.
"Property Taxes"	Defined in Section 9.10(d).
"Pro Rata Share"	With respect to any payment made for the benefit of the Sellers pursuant to this Agreement, each Seller's share of such payment as determined by multiplying the amount of such payment by the quotient of (i) the number of Company Shares held by such Seller immediately before the Acquisition Closing (after giving effect to the transactions contemplated by Section 4.2) divided by (ii) the total number of Company Shares issued and outstanding at that time and held by all Sellers (after giving effect to the transactions contemplated by Section 4.2, and for clarity, excluding any such shares held by the Buyer at such time).
"Purchase Option"	Defined in Section 2.3(a).

"Qualified Third Party Offer"	An unsolicited term sheet or letter of intent executed by a Third Party and delivered to the Company for the purchase of the securities of the Company that is approved by the Company Board and that (a) addresses all material terms customarily addressed in term sheets or letters of intent for similar transactions, (b) contains no material conditions or contingencies, other than completion of confirmatory due diligence and negotiation of definitive agreements, (c) the consideration to be paid by such Third Party for all the securities of the Company includes (i) an upfront purchase price at least forty percent (40%) greater than the Baseline Purchase Price (including the Supplemental Baseline Purchase Price, as applicable) with respect to all securities of the Company other than those held by the Buyer and (ii) aggregate potential consideration at least forty percent (40%) greater than Six Hundred Twenty-Four Million Dollars ($624,000,000), in each case after reasonably discounting for any contingent payments and other terms of such term sheet or letter of intent, as compared to the terms hereof and (d) the Third Party would reasonably be expected to have the resources and ability to consummate the transaction within a reasonable and customary period.
"Registered Owned Intellectual Property"	All Owned Intellectual Property issued by, registered, recorded or filed with, renewed by or the subject of a pending application before any Governmental Authority, Internet domain name registrar or other authority.
"Related Party Contract"	Any Contract between the Company (or by which the Company (or any property or asset thereof) is bound), on the one hand, and any one or more of the Company's Affiliates, directors, officers or any Person that owns, of record and/or beneficially, any security in the Company (or any immediate family member of any such director, officer or Person), on the other hand.
"Representative"	Defined in Section 12.17(a).
"Representatives"	Defined in Section 9.3.
"Restrictive Contract"	Any Company Contract that (a) restrains, limits or impedes the Company's (or will, after the Investment Closing or the Acquisition Closing, restrain, limit or impede the Buyer's or any of its Affiliates', including the Company's or any of its other subsidiaries') ability to compete with any business or Person, or conduct any business or line of business at any time, in any manner or at any place in the world, or the expansion thereof to other geographical areas or lines of business (including through the grant of rights of exclusivity by the Company to any Person), (b) contains a standstill or similar agreement pursuant to which the Company or any of its Affiliates has agreed (or is subject to any agreement) not to acquire assets or securities of a third party, (c) contains any "nonsolicitation", "no hire" or similar provision which restricts the Company or any of its Affiliates in soliciting, hiring, engaging, retaining or employing the current or former employees of any third party, or (d) contains any most favored nation, favored customer or similar provision.

"RSU"	Defined in Section 4.2.
"Sales Milestone"	Defined in Section 4.6(c).
"SEC"	The United States Securities and Exchange Commission.
"Securities Act"	The U.S. Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
"Seller Indemnified Party"	Defined in Section 11.2.
"Sellers"	Defined in the Preamble.
"Signing Date"	January 30, 2019, being the date of the execution and delivery of this Agreement by the parties hereto.
"Stockholders Agreement"	Defined in the Recitals.
"Stock Purchase Investment"	Defined in the Recitals.
"Straddle Period"	Defined in Section 9.10(d).
"Subsidiary"	With respect to any Person, any corporation, partnership, joint venture or other legal entity of which such Person (either alone or together with any other subsidiary) owns, directly or indirectly, more than fifty percent (50%) of the capital stock (or equivalent), the holders of which are generally entitled to vote for the election of the board of directors or other governing body of such corporation, partnership, joint venture or other legal entity.
"Successful POC"	Defined in Section 2.3(d).
"Supplemental Baseline Purchase Price"	An amount equal to $50,000,000.

"Tax" or "Taxes"	All taxes, duties, levies or imposts imposed by any Governmental Authority, including on or with respect to any income (including capital gains), capital, gross receipts, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental (including taxes under Code §59A), customs duties, capital stock, franchise, profits, production, withholding, social security (or similar), employment, unemployment, disability, national insurance, workers' compensation, governmental pension plan premium, property (including real property and personal property), escheat or unclaimed property, sales, use, transfer, registration or value-added taxes, stamp, customs, duties, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, whether computed on a separate or consolidated, unitary or combined basis or in any other manner, including any interest, penalty, surcharge, fine or addition thereto.
"Tax Claim"	Defined in Section 11.3(c).
"Tax Returns"	Any and all filings, returns, reports, forms, declarations, estimates, information returns or other documents filed or required to be filed with any Governmental Authority with respect to Taxes (including any documents, statements or schedules attached thereto), and including any amendments thereof.
"Third Party"	With respect to any specified Person, any other Person who is not an Affiliate of such specified Person.
"Third Party Claim"	Defined in Section 11.3(a).
"Threshold"	Defined in Section 11.4(a).
"Transactions"	Defined in the Recitals.
"Transfer Taxes"	Defined in Section 9.10(a).
"Termination Date"	Defined in Section 10.6(a)(2).
"USPTO"	Defined in Section 5.14(l).
"Voting Company Debt"	Defined in Section 5.3(c).
"Warrant"	Defined in Section 4.2.
"Waiver Agreement"	Defined in the Recitals.

ARTICLE 2.
DEVELOPMENT PLAN AND OPTION TO PURCHASE

Section 2.1 Company Development and Efforts; Joint Steering Committee.

(a) The Company hereby agrees to use Commercially Reasonable Efforts, in accordance with the Development Plan (as defined below) described in Section 2.1(b) below and the Budget attached as Exhibit E hereto (the "Budget"), to develop the Product through a successful completion of a Phase II Clinical Trial.

(b) The Company and the Buyer will establish a Joint Steering Committee ("JSC"), comprised of an equal number of representatives from each of the Company and the Buyer, which shall manage and oversee all activities contemplated by and taken pursuant to the Development Plan and may at its discretion establish additional subcommittees in connection therewith, including a "Joint Manufacturing Committee" and/or a "Joint Clinical/Regulatory Committee". The JSC will be established within thirty (30) days following the Signing Date. The JSC, once established, shall immediately begin work to finalize the Development Plan for the Product in keeping with the general outline attached as Exhibit F hereto (the "Development Plan"), with the goal of completing the Development Plan within ninety (90) calendar days of the Signing Date. Once approved by the JSC, the Development Plan can only be amended by the written approval of the JSC. All members of the JSC or any of its subcommittees shall be multidisciplinary employees or consultants of the relevant party or any of its Affiliates with appropriate seniority, experience, and delegated authority to make decisions of the JSC or subcommittee, as applicable, within the scope of the JSC's or subcommittee's responsibilities, and all such members shall be subject to written confidentiality obligations commensurate in scope to the provisions of the Confidentiality Agreement. Either party may replace one or more of its respective representatives to the JSC at any time upon prior written notice to the other party. Decisions of the JSC shall be made by unanimous consensus in all decisions, with one vote for the Company (determined by a majority of the Company's JSC representatives present in person or by proxy at such meeting) and one vote for the Buyer (determined by a majority of the Buyer's JSC representatives present in person or by proxy at such meeting). In the event of a disagreement between the members of the JSC with regard to any aspect of the Development Plan or otherwise within the scope of the JSC, the Company shall have the right to make the final decision (determined by a majority of the Company's JSC representatives present in person or by proxy at such meeting); provided, however, that the unanimous consent of the JSC shall be required in connection with (i) the selection of CRO and CMO (DS and DP) Company vendors, (ii) the approval of specifications for any active pharmaceutical ingredient and drug product specifications, (iii) the commencement of any analytical or manufacturing process, (iv) the selection of any principal investigators for Clinical Trials, (v) the amendment of the JSC charter, (vi) any material changes to the Development Plan or (vii) any material change (i.e., greater than twenty-five percent (25%)) to the Budget.

(c) The JSC will meet at least quarterly in person or by audio or video teleconference. Each of the Company and the Buyer will be responsible for all of the expenses of its representatives participating in the JSC meetings. A representative from each of the Company and the Buyer will be necessary for a quorum at any such meeting. Notwithstanding anything herein or in the Development Plan to the contrary, a representative from the Buyer's Global Regulatory Affairs team shall be invited to be present at all meetings of the Company with any Healthcare Regulatory Authorities.

(d) Subject to the final sentence of this Section 2.1(d), in the event that the Company determines in good faith that continued development of the Product in accordance with Section 2.1(a) is no longer commercially reasonable, the Company shall notify the Buyer in writing as promptly as possible, and in no event later than the date that is six (6) months prior to the Company's anticipated termination of development of the Product. The Company and the Buyer agree that, to the extent that the Company has determined that the development of the Product pursuant to Section 2.1(a) is no longer commercially reasonable, they shall each engage in good faith discussions as to the potential for continued development of the Product otherwise, including the potential form, substance and mechanism for such development. Notwithstanding anything in the foregoing to the contrary, the Company shall not terminate the development of the Product, or provide the Buyer written notice of its intent to do so, prior to the beginning of the Option Period pursuant to Section 2.3(a).

Section 2.2 Development Funding.

(a) As funding for the development of the Product pursuant to Section 2.1 and in partial consideration for the Purchase Option described in Section 2.3, the Buyer shall make (or cause to be made), the following payments (each, a "Funding Payment"), in each case within 30 days after the achievement of the events described below as conditions precedent for each such payment:

(1) A one-time payment of Five Million Dollars ($5,000,000) upon the demonstrated equivalence of the clinical supply of the Product from Patheon Biologics LLC ("Patheon") under Patheon's newly-adopted processes to the Product previously used in phase I clinical studies and toxicology studies, provided that the related IND has been appropriately updated without objection from the FDA (and that the Product sufficiently demonstrates the proper identification, quality, purity and strength commensurate with the phase of clinical development);

(2) A one-time payment of Ten Million Dollars ($10,000,000) upon the dosing of the first patient in a Phase II Clinical Trial; and

(3) A one-time payment of Fifteen Million Dollars ($15,000,000) upon the enrollment of fifty percent (50%) of the total number of patients to be enrolled in a Phase II Clinical Trial pursuant to the applicable clinical trial protocol.

(b) For clarity, the maximum aggregate amount of Funding Payments payable under this Section 2.2 is Thirty Million Dollars ($30,000,000).

Section 2.3 Option to Purchase.

(a) In consideration of the Company's right to the Funding Payments provided for herein, and the other agreements and obligations of the parties contained herein, beginning on that date that is twelve (12) months after the Signing Date and ending on the date that is three (3) months after the POC Data Delivery Date (the "Option Period"), the Sellers hereby grant the Buyer (or an Affiliate of the Buyer, in which case all references to the Buyer with respect to the Purchase Option and/or the Acquisition shall be deemed to refer to such Affiliate) an irrevocable and exclusive option (the "Purchase Option"), but not the obligation, exercisable in the Buyer's sole discretion, to acquire all of the Acquisition Shares on the terms and conditions set forth herein.

(b) The Buyer may exercise the Purchase Option (in its sole discretion) at any time during the Option Period by delivery of a written notice to the Representative stating the Buyer's intent to so exercise the Purchase Option. Each Seller and the Company commit to do all such things as may be necessary or useful to effect the Purchase Option (in whole or in part) pursuant to the terms hereof.

(c) For purposes of this Agreement, "POC Data Delivery Date" shall mean the the date of delivery by the Company to the Buyer of all data held by the Company reasonably pertaining to a Successful POC (the "Initial Delivery"); provided that if, within thirty (30) days of the Initial Delivery, the Buyer delivers to the Company any reasonable requests for additional information with respect to the Successful POC and the data delivered in connection therewith, the "POC Data Delivery Date" shall be extended to the date on which the Company has responded in writing to all such reasonable requests by the Buyer (and any reasonable follow-up requests to such responses, provided that the Buyer has delivered such follow-up requests to the Company within fifteen (15) days of such responses). The Company agrees to respond to each such request for additional information, and any follow-up to a request for additional information, as soon as possible and in any event in no more than fifteen (15) days after such request. In no event shall the POC Data Delivery Date be more than ninety (90) days from the Initial Delivery Date.

(d) For purposes of this Agreement, a "Successful POC" shall mean a completed Phase II Clinical Trial that demonstrates a statistically significant improvement in cardiac function (determined by echocardiographic evaluation) and concordant improvement in relevant biomarkers (e.g., NT-proBNP) and/or a statistically significant survival benefit or other primary endpoint as unanimously determined by the JSC which may stem from discussions with the FDA.

(e) Notwithstanding anything in the foregoing to the contrary, the Option Period shall terminate on (1) the date that is six (6) months after the closing of any Change of Control of the Buyer or (2) provided that the Company and the Sellers are and have always been in compliance with Section 9.3, the date that is three (3) months after the notice by the Company to the Buyer of receipt by the Company of a Qualified Third Party Offer, provided that, with respect to this clause (2), the Purchase Option shall be fully restored for the benefit of the Buyer for the duration of its term as otherwise provided in this Section 2.3 in the event that the transactions contemplated by the Qualified Third Party Offer are not consummated (on terms that continue to satisfy the requirements set forth in the definition of "Qualified Third Party Offer" herein) within sixty (60) days after such termination.

ARTICLE 3.
STOCK PURCHASE INVESTMENT

Section 3.1 Sale and Purchase of Investment Shares. Subject to and in accordance with the terms and conditions of this Agreement, the Company shall issue, sell, transfer and deliver to the Buyer, free and clear of any Encumbrances, and the Buyer shall purchase and acquire from the Company, for $30.0 million (the "Investment Price"), 4,141,606 Class B Preferred Shares, which shall equal 19.9% of the Fully Diluted Capitalization as of the Signing Date (after giving effect to such issuance) (the "Investment Shares"), payable as provided in Section 3.3.

Section 3.2 **Investment Closing**. The consummation of the purchase and sale of the Investment Shares (the "Investment Closing") shall take place remotely via the exchange of documents, signatures and payments, at 10:00 a.m. Eastern Time, on the Signing Date, or such other time and place as is mutually agreed by the Company and the Buyer.

Section 3.3 **Investment Closing Deliverables**. At the Investment Closing:

(a) Each of the Company and the Sellers shall deliver to the Buyer a fully-executed copy of each Ancillary Agreement that by its terms is to be executed and delivered at the Investment Closing and the Company shall deliver to the Buyer evidence in form and substance reasonably satisfactory to the Buyer that the Investment Shares have been issued to the Buyer and the Buyer is the beneficial and record owner of the Investment Shares;

(b) The Buyer shall deliver to the Company payment, by wire transfer, to a bank account previously designated in writing by the Company, of immediately available funds in an amount equal to the Investment Price;

(c) The Company shall deliver to the Buyer a certificate duly signed by the secretary of the Company certifying as to: (A) the full force and effect of resolutions of its board of directors attached thereto as an exhibit evidencing the authority of the Company to execute and deliver this Agreement and the Ancillary Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby; (B) the full force and effect of the certificate of incorporation and bylaws of the Company attached thereto as exhibits; and (C) the incumbency and signature of the officers of the Company with authority to execute this Agreement and the Ancillary Agreements to which the Company is a party;

(d) The Company shall deliver to the Buyer an opinion, dated as of the Investment Closing, from Alston & Bird LLP, counsel for the Company, in substantially the form attached as Exhibit G hereto.

(e) The Company shall deliver to the Buyer a certificate evidencing the good standing of the Company in its jurisdiction of incorporation as of a recent date;

(f) The Company shall deliver to the Buyer certificates evidencing the qualification of the Company to do business as a foreign corporation as of a recent date in each jurisdiction outside of its jurisdiction of organization where it conducts business; and

(g) The Company shall deliver to the Buyer all other certificates, documents and instruments that are reasonably requested by Buyer.

ARTICLE 4.
THE ACQUISITION

Section 4.1 **Sale and Purchase of Acquisition Shares**. In the event that the Buyer exercises its Purchase Option pursuant to Section 2.3, subject to and in accordance with the terms and conditions of this Agreement, each Seller shall sell, transfer, assign and deliver, and the Buyer will purchase from each Seller (the "Acquisition"), free and clear of any Encumbrances, all right, title and interest in and to all of the Common Shares, Class A Shares and Class B Shares (collectively, the "Company Shares") owned, of record and/or beneficially, by such Seller as of the Acquisition Closing and after giving effect to Section 4.2, as set forth next to the name of such Seller on Exhibit H under the title "Shares Owned" (the "Acquisition Shares").

Section 4.2 **Exercise and Conversion of Company Securities**. Prior to the Acquisition Closing, each Seller that is a holder of an option to acquire Company Shares (each, an "Option"), or any warrant to issue Company Shares (each, a "Warrant") shall deliver to the Company all funds, documents and instruments necessary to effect the exercise of such Options or Warrants, as applicable, into Company Shares on the Acquisition Closing. Each Seller that is a holder of Options or Warrants acknowledges and agrees that, upon the occurrence of the Acquisition Closing, any such Options or Warrants that were not previously exercised by way of payment of the applicable exercise price and the delivery of required documents and instruments shall be cancelled and no longer be exercisable pursuant to their terms and any such Options and Warrants that were not exercised in accordance with their terms shall be forfeited and shall be of no further force or effect. The Representative shall deliver to the Buyer an amended and updated Exhibit H no less than one (1) Business Day prior to the Acquisition Closing reflecting such exercise and conversion of such Options and Warrants into Company Shares. The Company shall take all requisite action so that, immediately prior to the Acquisition Closing, each restricted stock units with respect to the Company Shares (each, an "RSU") and Company Share subject to vesting, repurchase, or other lapse of restrictions (a "Company Restricted Share") that is outstanding under any Company Employee Plan immediately prior to the Acquisition Closing shall, by virtue of the Acquisition Closing and without any action on the part of the holder thereof, vest in full and become free of restrictions. Prior to the Acquisition Closing, the Company, the Company Board, and the compensation committee of the Company Board, as applicable, shall have adopted any resolutions and taken any actions (including obtaining any employee consents) that may be necessary to effectuate the provisions of this Section 4.2.

Section 4.3 **Acquisition Closing Purchase Price**.

(a) At the Acquisition Closing, the Buyer shall pay to the Representative, for the benefit of and distribution to the Sellers in accordance with their Pro Rata Share, an amount equal to the Acquisition Closing Purchase Price by wire transfer of immediately available funds into an account designated in writing by the Representative no later than two (2) Business Days prior to the Acquisition Closing.

(b) At the Acquisition Closing, the Buyer shall pay to the Escrow Agent an amount equal to the Escrow Amount.

Section 4.4 **Acquisition Closing**. The consummation of the purchase and sale of the Acquisition Shares (the "Acquisition Closing") shall take place two (2) Business Days after the conditions set forth in Article 10 are satisfied or waived (to the extent permitted hereunder or by applicable Legal Requirement) (except for such conditions that by their nature will be satisfied at the Acquisition Closing, but subject to the satisfaction or waiver of such conditions at such time), or at such other time as the Buyer and the Representative agree in writing. The Closing shall take place remotely via the exchange of documents, signatures and payments, at 10:00 a.m. Eastern Time (or at such place as the parties may otherwise designate in writing).

Section 4.5 Escrow Amount.

(a) At the Acquisition Closing, the Buyer shall deposit with Citibank N.A. (the "Escrow Agent"), by wire transfer of immediately available funds, an amount equal to the Escrow Amount, such amount plus all accumulated earnings thereon to constitute the Escrow Fund to be governed in accordance with the terms of this Agreement and the escrow agreement in substantially the form attached hereto as Exhibit I (the "Escrow Agreement"), among the Buyer, the Escrow Agent and the Representative.

(b) The Escrow Fund shall be used to satisfy any amounts owed to the Buyer pursuant to this Agreement, if any, and any indemnification amounts owed hereunder. The Buyer and the Representative shall timely provide any joint written instructions contemplated by this Section 4.5 or Article 11 so that distributions can be made by the Escrow Agent within the time period required by this Section 4.5 or Article 11.

(c) The portion of the Escrow Fund that is not used to satisfy any other amounts owing to the Buyer pursuant to this Agreement, including indemnification amounts, or not subject to any claims hereunder (such portion, the "Escrow Fund Release Amount"), shall be released pursuant to joint written instructions to be provided to the Escrow Agent by the Buyer and the Representative on the date that is one (1) Business Day after the date that is two (2) years after the date of the Acquisition Closing; provided, however, that if there are any indemnification claims hereunder that are properly pending on the date that is two (2) years after the date of the Acquisition Closing, such portion of the Escrow Fund corresponding to the amounts subject to such claims shall not be released until the applicable claims are finally resolved and satisfied. Any Escrow Funds released by the Escrow Agent to the benefit of the Sellers shall be released to the Representative, for the benefit of and distribution to the Sellers in accordance with their Pro Rata Share. Upon the final release of all of the Escrow Fund, the Escrow Agreement shall terminate.

(d) The Escrow Fund shall be held as a trust fund and shall not be subject to any Encumbrance, and shall be held and disbursed solely for the purposes and in accordance with the terms of this Agreement and the Escrow Agreement.

Section 4.6 Earn-Out Payments.

(a) Following the Acquisition Closing, upon the achievement of the following events (each a "Milestone Event") with respect to the Product, as further consideration for the Acquisition, the Buyer shall make (or cause to be made) the following payments (each, an "Earn-Out Payment"), in each case within sixty (60) days after the achievement of the applicable Milestone Event described below as conditions precedent for each such payment, in each case subject to the permitted deductions set forth in Section 4.6(d):

(1) (A) in the event that the Sellers did not receive the Supplemental Baseline Purchase Price, a one-time payment of Seventy-Five Million Dollars ($75,000,000) or (B) in the event that the Sellers did receive the Supplemental Baseline Purchase Price, a one-time payment of Fifty Million Dollars ($50,000,000), in either case upon obtaining the approval of a biologic license application by the FDA for the Product for a Broad Patient Population following the completion of a Pivotal Clinical Trial;

(2) a one-time payment of Twenty-Five Million Dollars ($25,000,000) upon the determination at the end of the Buyer's fiscal year that the Net Sales for such fiscal year exceeded Two Hundred Fifty Million Dollars ($250,000,000);

(3) a one-time payment of Fifty Million Dollars ($50,000,000) upon the determination at the end of the Buyer's fiscal year that the Net Sales for such fiscal year exceeded Five Hundred Million Dollars ($500,000,000);

(4) a one-time payment of Seventy-Five Million Dollars ($75,000,000) upon the determination at the end of the Buyer's fiscal year that the Net Sales for such fiscal year exceeded Seven Hundred Fifty Million Dollars ($750,000,000); and

(5) a one-time payment of One Hundred Million Dollars ($100,000,000) upon the determination at the end of the Buyer's fiscal year that the Net Sales for such fiscal year exceeded One Billion Dollars ($1,000,000,000).

For the avoidance of doubt, one or more (or all) of the foregoing sales milestones may be due and payable with respect to a single given calendar year in the event any or all of the applicable Net Sales milestones is satisfied with respect to such single calendar year.

(b) For clarity, the maximum aggregate amount of Earn-Out Payments payable under this Agreement is Three Hundred Twenty-Five Million Dollars ($325,000,000).

(c) Commencing the calendar year following the year in which the first commercial sale of the Product occurs until payment of all of the Earn-Out Payments described in Sections 4.6(a)(2-5) (the Milestone applicable to each such Earn-Out Payment, a "Sales Milestone") (or the Buyer and the Representative otherwise mutually agree), on or prior to the forty-fifth (45^{th}) day following release by the Buyer of its (or its applicable Affiliate's) audited financial statements for each fiscal year during such period, the Buyer shall prepare and deliver to the Representative a statement setting forth the Buyer's determination of Net Sales with respect to the applicable Sales Milestone for such fiscal year (the "Net Sales Statement"). In order to allow the Representative to reasonably verify the proposed determination with respect to the Sales Milestone, the Buyer shall provide copies of any records or other documentation reasonably requested by the Representative that were used by the Buyer in reaching such determination and shall afford the Representative or its designees reasonable access during normal business hours to appropriate personnel of the Buyer (or its Affiliate) to discuss such records or documentation. If the Representative has any objections to the Buyer's determination, then the Representative may object by delivering a written objection notice (a "Notice of Objection") within thirty (30) days of its receipt of the Net Sales Statement, and the Buyer and the Representative shall proceed to resolve such disagreement in accordance with the dispute resolution procedures set forth in Section 4.6(e). If it is determined through such dispute resolution procedures that a Sales Milestone was achieved, the Buyer shall make (or cause to be made) the applicable Earn-Out Payment to the Representative for further distribution to the Sellers in accordance with their Pro Rata Share. Notwithstanding anything in this Agreement to the contrary, subsequent to the Acquisition Closing, the Buyer shall have sole discretion with regard to all matters relating to the operation of the Company and its business and shall have no obligation, or liability as a result of the failure, to achieve any of the Milestones that would give rise to an Earn-Out Payment.

(d) If at the time any Earn-Out Payment becomes earned and payable, any Buyer Indemnified Party shall have in good faith asserted any indemnification claim(s) pursuant to Article 11 of this Agreement prior to the time by which such claims must be made in accordance with Section 10.5 and such claim(s) shall not have been resolved or satisfied, the amount of such claim(s) shall be deducted from the payment of such Earn-Out Payment and held back by the Buyer to secure its right of set-off, until such indemnification claim(s) shall have been resolved or satisfied. Upon the final resolution or satisfaction of such indemnification claim(s), any excess amount that had been deducted from such Earn-Out Payment will be delivered to the Representative, for the benefit of and distribution to the Sellers in accordance with their Pro Rata Share.

(e) Unless the Representative provides a Notice of Objection within thirty (30) days after the receipt of the Net Sales Statement, the determination of Net Sales set forth therein shall be final and binding for all purposes hereunder. Any Notice of Objection shall specify in reasonable detail the basis for the objections set forth therein and shall include the Representative's calculation of any amounts that are disputed by such Notice of Objection (the "Disputed Amounts") to the extent that such amounts may be determined (it being understood that an objection to one or more of the foregoing amounts shall not prevent any other amount from becoming final and binding for all purposes hereunder). If the Representative provides such Notice of Objection to the Buyer within such thirty (30)-day period, the Buyer and the Representative shall, during the thirty (30)-day period following the Representative's delivery of such Notice of Objection to the Buyer, attempt in good faith to resolve any Disputed Amounts. If the Buyer and the Representative are unable to resolve all such Disputed Amounts within such period, the matters remaining in dispute shall be submitted to a nationally recognized public accounting firm mutually agreed upon by the Buyer and the Representative (such accounting firm being referred to herein as the "Independent Accountant"). The Buyer and the Representative shall instruct the Independent Accountant to render its decision as promptly as possible, but no later than sixty (60) days after its selection. The Independent Accountant will consider only those items and amounts that are identified as being items and amounts to which the Representative and the Buyer have been unable to agree. In resolving any disputed item, the Independent Accountant may not assign a value to any item greater than the greatest value for such item claimed by the Representative or the Buyer or less than the smallest value for such item claimed by either of them. The Buyer and the Representative shall each furnish to the Independent Accountant such work papers and other documents and information relating to the Disputed Amounts as the Independent Accountant may request. The resolution of the Disputed Amounts by the Independent Accountant shall be final and binding, and the determination of the Independent Accountant shall constitute an arbitral award that is final, binding and unappealable and upon which a judgment may be entered by a court having jurisdiction thereover. The Buyer and the Representative shall each pay their own costs and expenses incurred in connection with the resolution of the Disputed Amounts; provided, however that the fees and expenses of the Independent Accountant shall be allocated between the Buyer and the Representative in the same proportion that the total amount of the Disputed Amounts submitted to the Independent Accountant that is unsuccessfully disputed by each such party (as finally determined by the Independent Accountant) bears to the total amount of the Disputed Amounts so submitted by each such party (e.g., should the items in dispute total in amount to $1,000 and the Independent Accountant awards $600 in favor of the Buyer's position, 60% of the costs of its review would be borne by the Representative and 40% of the costs would be borne by the Buyer).

(f) Buyer shall not, with regard to the business of the Company, take any action or make any omission which is solely intended to avoid the achievement of the Earn-Out Payments described above.

Section 4.7 Withholding; Tax Documentation. The Buyer shall be entitled to deduct and withhold from payment of any amounts payable pursuant to this Agreement such amounts as may be required to be deducted and withheld with respect to the making of such payment or any other amounts payable pursuant to this Agreement under the Code or any other Tax Legal Requirement. To the extent that amounts are so withheld by the Buyer and remitted to the applicable Governmental Authority, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person to whom such amounts would otherwise have been paid. The Buyer shall be entitled to request and collect any Tax forms, including IRS Form W-9, or the appropriate series of IRS Form W-8, as applicable, or any similar information, from any recipient of any payment pursuant to, or in connection with, this Agreement, and each such recipient hereby covenants to provide such Tax form or information upon request by the Buyer.

ARTICLE 5.
REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except as set forth in the disclosure schedule delivered by the Company prior to, or concurrently with, the execution of this Agreement (the "Disclosure Schedule") the Company hereby represents and warrants to the Buyer as of the Signing Date and as of the date of the Acquisition Closing, as if such representations and warranties were made as of the date of the Acquisition Closing, as follows:

Section 5.1 Organization of the Company; Due Authorization.

(a) The Company (i) is a corporation duly organized, validly existing and in good standing under the laws of Delaware, (ii) is duly licensed and qualified to conduct its business in each jurisdiction where the nature of the properties owned, leased or operated by it and the business transacted by it requires such licensing or qualification, except where any such failures to be so qualified or licensed have not had, or are not reasonably likely to have, a Material Adverse Effect and (iii) holds all necessary corporate power and authority to own, license and operate its assets and properties, to conduct its business, to enter into this Agreement and the Ancillary Agreements, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby, including the Transactions. This Agreement and the consummation of the transactions contemplated hereby, the execution and delivery of this Agreement and the Ancillary Agreements by the Company, the performance by the Company of its obligations hereunder and thereunder and the consummation by the Company of the transactions contemplated hereby and thereby, have been duly authorized by all requisite action on the part of the Company, and no other proceedings on the part of the Company or its stockholders are necessary to authorize the execution and delivery of this Agreement or the consummation by the Company of the transactions contemplated hereby and thereby.

(b) Each of this Agreement and the Ancillary Agreements to which the Company is or will be a party has been or will be, as the case may be, duly executed and delivered by the Company and (assuming due authorization, execution and delivery by the Buyer) constitutes or will constitute a legal, valid and binding obligation of the Company, enforceable against the Company in accordance with their respective terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally and (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(c) The board of directors of the Company has unanimously adopted resolutions, prior to the Signing Date, (i) determining that this Agreement, the Stock Purchase Investment, the Acquisition and the other transactions contemplated by this Agreement and the Ancillary Agreements are advisable and fair to, and in the best interests of, the Company and its stockholders, and (ii) approving this Agreement, the Ancillary Agreements, the Stock Purchase Investment, the Acquisition and the other transactions contemplated by this Agreement and the Ancillary Agreements.

(d) The Company's certificate of incorporation, as amended, and the Company's bylaws, each as provided to the Buyer prior to the Signing Date are in full force and effect, and, other than as contemplated by the terms of this Agreement, no action has been taken or is contemplated to amend such organizational documents.

Section 5.2 No Conflicts, Consents or Approvals. Assuming that any applicable waiting period under the HSR Act has expired or been terminated, neither the execution or delivery by the Company of this Agreement or any of the Ancillary Agreements, or the performance by the Company of its obligations under this Agreement or any of the Ancillary Agreements, or the consummation of the transactions contemplated hereby or thereby will (a) result in any breach of any provision of the Company's certificate of incorporation and by-laws, each as amended from time to time, (b) result in any breach of, require (with or without notice or lapse of time or both) any payment, consent or notice or constitute a default (or give rise to any right of purchase, termination, amendment, acceleration or cancellation) under, any Company Contract or order or judgment to which the Company is a party or by which it or its assets are bound, (c) result in the creation of an Encumbrance or (d) violate any applicable Legal Requirement.

Section 5.3 Capital Stock of the Company.

(a) The Company has an authorized share capital of 2,000,000 Preferred Shares (of which 250,000 shares have been designated Class A Preferred Shares and the remainder are undesignated) and 50,000,000 Common Shares. Attached hereto as Schedule 5.3 is the capitalization of the Company as of the Signing Date, including all Company Securities, as defined below.

(b) As of the Signing Date, 11,184,177 Common Shares and 250,000 Class A Preferred Shares are issued and outstanding, (ii) there were 668,500 Common Shares underlying outstanding Options and RSUs, in each case issued under the Company's 2017 Stock Incentive Plan (of which the Company has provided the Buyer a true, correct and complete copy prior to the Signing Date), (iii) there were no Common Shares underlying outstanding Warrants (of which the Company has provided the Buyer a true, correct and complete copy prior to the Signing Date) and (iv) no other shares of capital stock of, or other equity interests in, the Company were issued, reserved for issuance or outstanding. All of the outstanding shares of capital stock of the Company have been duly authorized and validly issued, are fully paid and nonassessable and were issued in compliance with all applicable Legal Requirements, the Company's organizational documents and any Company Contracts.

(c) Except as set forth on Schedule 5.3, there are no options, warrants, rights, convertible or exchangeable securities, "phantom" stock rights, stock appreciation rights, restricted stock units, restricted stock, stock-based performance units, commitments, contracts, arrangements or undertakings of any kind to which the Company is a party or by which it is bound (i) obligating the Company to issue, deliver or sell or cause to be issued, delivered or sold, additional shares of capital stock of, or other equity interests in, or any security convertible or exercisable for or exchangeable into any capital stock of, or other equity interest in, the Company, or any Voting Company Debt (as defined below), (ii) obligating the Company to issue, grant, extend or enter into any such option, warrant, call, right, security, commitment, contract, arrangement or undertaking or (iii) that give any Person the right to receive any economic benefit or right similar to or derived from the economic benefits and rights accruing to holders of capital stock of, or other equity interests in, the Company (together with the Common Shares and the Class A Preferred Shares and Class B Preferred Shares, the "Company Securities"). Any Warrant, Option or RSU obligating the Company to issue any Company Securities that is outstanding prior to the Acquisition Closing shall be required to comply with Section 4.2 in connection therewith. There are no outstanding contractual obligations of the Company to repurchase, redeem or otherwise acquire any shares of capital stock of the Company. There are no proxies, voting trusts or other agreements or understandings to which the Company is a party or is bound with respect to the voting of or giving consent by the capital stock of, or other equity interests in, the Company. There are no preemptive or similar rights granted by the Company to any holders of any class or series of securities of the Company. There are no outstanding bonds, debentures, notes or other obligations of the Company, the holders of which have the right to vote (or which are convertible into or exchangeable or exercisable for securities having the right to vote) with the Company's stockholders on any matter ("Voting Company Debt").

(d) Upon consummation of the Investment Closing, Buyer will own the Investment Shares free and clear of all Encumbrances and such shares, along with the Acquisition Shares, shall have been duly authorized and validly issued, be fully paid and nonassessable and issued in compliance with all applicable Legal Requirements, the Company's organizational documents and any Company Contracts.

(e) The Company does not have, and has never had, any Subsidiaries or equity interest in any Person. There is no Company Contract currently or prospectively requiring the Company to form or participate in or make any capital contribution to or investment in any Person.

Section 5.4 Financial Statements; Other Liabilities.

(a) The Company has previously provided to the Buyer (i)(A) with respect to the Investment Closing, the audited balance sheets of the Company for the years ended December 31, 2016 and December 31, 2017, and the statements of operations, stockholders' equity (deficit) and cash flows for the period from October 26, 2016 (the Company's inception) through December 31, 2016 and the twelve months ended December 31, 2017 and (B) with respect to the Acquisition Closing, the audited balance sheets of the Company as of December 31 for each year ended between the Signing Date and the date of the Acquisition for which an audit has been completed in the Company's ordinary course of business consistent with past practice, and the statements of operations, stockholders' equity (deficit) and cash flows for the twelve (12)-month period ended as of each such calendar year and (ii)(A) with respect to the Investment Closing, the unaudited balance sheets of the Company as of September 30, 2018 and (B) with respect to the Acquisition Closing, the unaudited balance sheets of the Company as of the last day of the Company's most recently completed fiscal quarter (in each case, as applicable with respect to the Investment Closing or the Acquisition Closing, the "Most Recent Balance Sheet" and such date, the "Most Recent Balance Sheet Date"), and the statements of operations, stockholders' equity (deficit) and cash flows for the fiscal quarter then ended (the items in clauses (i) and (ii), collectively, the "Financial Statements").

(b) The Company maintains books of account and other financial records that are accurate in all material respects. The Financial Statements (i) were prepared in conformity with GAAP consistently applied throughout the periods indicated, and in accordance with the books of account and other financial records of the Company and (ii) present fairly, in conformity with GAAP consistently applied, the financial position and the results of operations, stockholders' equity (deficit) and cash flows of the Company as of the dates thereof, or for the periods covered thereby, as the case may be.

(c) The Company does not have any (i) "off-balance sheet" arrangements or Liabilities or (ii) except as reflected in the Most Recent Balance Sheet, the Company and its Subsidiaries do not have any material liabilities or obligations (whether absolute, accrued, contingent, matured, or otherwise, and whether due or to become due), except for liabilities and obligations (A) incurred in the ordinary course of business consistent with past practice since the Most Recent Balance Sheet Date, (B) which would not be required to be recorded in an audited consolidated balance sheet of the Company (or disclosed in the notes thereto) that is prepared in accordance with GAAP, or (C) which are disclosed in Schedule 5.4(c).

(d) No director or officer of the Company or, to the Company's Knowledge, non-officer employee, external auditor, external accountant or similar authorized representative of the Company, has received or otherwise been made aware of any complaint, allegation or claim, whether written or oral, regarding the accounting or auditing practices, procedures, methodologies or methods of the Company or its internal accounting controls, including any complaint, allegation or claim that the Company has engaged in questionable accounting or auditing practices.

Section 5.5 Agreements.

(a) Schedule 5.5(a) lists, as of the Signing Date, each of the following Company Contracts, including any amendments thereto (each, a "Material Contract"):

(1) any Contract (A) relating to Indebtedness of the Company or the guarantee of Indebtedness of any Person, (B) securing any Indebtedness through any Encumbrance or (C) otherwise creating an Encumbrance;

(2) any Restrictive Contract;

(3) any joint venture, partnership or limited liability company agreements or other similar agreements or arrangements relating to the formation, creation, operation, management or control of, or investment by the Company in, any joint venture, partnership or limited liability company;

(4) any collective bargaining agreement or other Contract to or with any labor union or other employee representative of a group of employees;

(5) any Related Party Contract;

(6) any Contract pursuant to which the Company (A) in any transaction or series of related transactions, has an option, right or obligation to purchase any other business or portion thereof on an ongoing basis (including by purchasing the assets or capital stock of another Person), (B) in any transaction or series of related transactions, purchased any such business or portion thereof and continues to have any ongoing obligations (including obligations under any shareholder agreement), or (C) without limitation of clause (B), has an obligation to make any earn-out payments based on future performance of an acquired business or assets;

(7) any Contract that (A) obligates the Company to make a loan or capital contribution to, or investment in any Person or (B) on a stand-alone basis obligates the Company to provide indemnification or a guarantee that would reasonably be expected to result in payments in excess of $50,000;

(8) any Contract that (A) grants to any Person a right of first refusal, right of first offer, option or similar preferential right to purchase any of the Company's capital stock or assets, (B) obligates the Company to sell to any Person or Persons (or pursuant to which the Company sold to any Person or Persons and continues to have any ongoing obligations) any capital stock or assets, or (C) obligates the Company to sell, assign, or otherwise transfer or dispose of to any Person or Persons (or pursuant to which the Company sold, assigned, or otherwise transferred or disposed of to any Person or Persons and continues to have any ongoing obligations), in any transaction or series of related transactions, any assets, property or business having an aggregate value exceeding (or for consideration, including assumption of Indebtedness, exceeding) $100,000 or otherwise outside of the ordinary course of business consistent with past practice;

(9) all Intellectual Property Agreements, including any Contract that, as its primary purpose, grants to the Company, or by which the Company grants to any Person, any right to use, exploit or practice any Intellectual Property;

(10) Privacy Agreements;

(11) any Contract regarding Leased Real Property;

(12) any Contract that the Company reasonably anticipates requiring aggregate payments to or by the Company in excess of $50,000 individually (or $200,000 in the aggregate for all such Contracts) in any twelve (12)-month period;

(13) any employment or consulting Contract (in each case with respect to which the Company has continuing obligations as of the Signing Date) with any current or former (A) officer of the Company, (B) member of the board of directors of the Company, or (C) employee of the Company;

(14) any Contract with any agent, distributor or sales representative;

(15) any Contract that contains a "change of control" or similar provision that would require any consent, notice or other action in connection with, or that could reasonably be expected to prevent, delay or impair the consummation of, the transactions contemplated by this Agreement or any Ancillary Agreement;

(16) any Contract to which a Governmental Authority is a party;

(17) any Contract that is an insurance policy referred to in Section 5.6;

(18) any Contract which commits the Company to enter into any of the foregoing;

(19) any Contract involving any resolution or settlement of any actual or threatened Proceeding; or

(20) any Contract which is not otherwise described in clauses (1)-(19) above that is material to the Company.

(b) The execution and delivery by the Company of this Agreement or any Ancillary Agreement to which the Company is or will be a party does not and will not, and the performance by the Company of this Agreement or any Ancillary Agreement to which the Company is or will be a party does not and will not, conflict with, result in any breach of, constitute a material default (or event which with the giving of notice or lapse of time would become a default) or loss of benefit under, require any consent, notice or payment (including any right of acceleration of any royalties, fees, profit participations or other payments to any Person) under, or give to others any rights of purchase, termination, amendment, acceleration or cancellation of any Company Contract.

(c) Neither the Company nor, to the Company's Knowledge, any other party to a Company Contract, is in breach of, or default under, any of the Company Contracts. No event has occurred that would result in any violation or breach of, or conflict with, or constitute (with or without notice or lapse of time or both) a default (or give rise to any right of purchase, termination, amendment, acceleration or cancellation) under, result in the loss of any benefit under, or result in the triggering of any payments (including any right of acceleration of any royalties, fees, profit participations or other payments to any Person) pursuant to, any of the terms, conditions or provisions of any Company Contract. Each Company Contract is valid and binding on, and in full force and effect with respect to, the Company and, to the Company's Knowledge, each other party thereto and enforceable in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally and (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies. The Company has not waived any right under any Company Contract or given to or received from any other Person any notice or other communication regarding any actual, alleged, possible or potential breach of, or default (with or without notice or lapse of time or both) under, any Company Contract, and, to the Company's Knowledge, is not otherwise aware of any intention by any counterparty thereto to terminate (other than Company Contracts that are expiring pursuant to their terms), or not renew any Company Contract, or is seeking the renegotiation thereof or substitute performance thereof.

(d) The Company has made available to the Buyer prior to the Signing Date true, correct and complete copies of all Material Contracts (including all amendments and supplements thereto). The Company does not have any oral Material Contracts.

Section 5.6 Insurance. Schedule 5.6 contains a list of all insurance policies maintained with respect to the business of the Company, all of which are in full force and effect in accordance with their terms and shall remain in full force and effect following the transactions contemplated by this Agreement or any Ancillary Agreement. The Company is not in material default with respect to its obligations under any insurance policy maintained by it. The Company has not received written notice of termination, cancellation or non-renewal of any such insurance policies from any of its insurance brokers or carriers. The Company has complied in all material respects with each such insurance policy and all premiums due on such insurance policies have either been paid or, if due and payable prior to the Acquisition Closing, will be paid prior to the Acquisition Closing in accordance with the payment terms of each insurance policy. The Company has not ever been denied insurance or suffered the cancellation of any insurance. There is no material claim pending by the Company under any insurance policy listed on Schedule 5.6 as to which coverage has been questioned, denied or disputed by the underwriters of such policy. The insurance policies listed on Schedule 5.6 are of the type and in the amounts customarily carried by Persons conducting a business similar to the Company and are sufficient for compliance with all applicable Legal Requirements and Contracts to which the Company is a party or by which it or the Company Assets are bound.

Section 5.7 Real Property; Title, Condition and Sufficiency of Assets. The Company does not own, and has never owned, any real property. Schedule 5.7 contains a true, complete and correct list of all Contracts pursuant to which the Company leases any Leased Real Property. The Company enjoys peaceful and undisturbed possession of all Leased Real Property (whether as tenant, subtenant or pursuant to other occupancy arrangements) and has a good and valid leasehold interest therein, in each case free and clear of all Encumbrances. There are no applicable Legal Requirements in effect that would prevent or limit in any material respect the Company from conducting its operations on the Leased Real Property as they are currently conducted. There does not exist any condemnation, eminent domain or taking proceeding that affects any Leased Real Property. The Company has good title to, or a valid leasehold interest in, or, with respect to licensed assets, a valid license to use, the assets and properties (whether tangible or not) used or held for use by it in connection with the conduct of its business, free and clear of all Encumbrances, and such assets and properties are reasonably sufficient and suitable in all material respects for the operation of the business of the Company as currently conducted and currently intended to be conducted. The tangible personal assets and property of the Company are in good working condition and repair in the ordinary course of business, reasonable wear and tear excepted.

Section 5.8 Taxes. For purposes of this Section 5.8, the term "Applicable Closing" means each of the Investment Closing and the Acquisition Closing.

(a) As of the date of the Applicable Closing: (i) all Tax Returns that are required to be filed on or before such date by or on behalf of the Company have been timely filed; (ii) each such Tax Return is true and correct in all material respects; and (iii) all Taxes due and payable by the Company have been, or will be, timely paid (whether or not shown on any Tax Return). As of the date of the Applicable Closing, there are no Encumbrances for Taxes upon any of the assets of the Company.

(b) The Company shall prepare and timely file, or cause to be prepared and timely filed, all Tax Returns of the Company that are filed after the date of the Investment Closing through the date of the Acquisition Closing and such Tax Returns shall be prepared consistent with the past practices of the Company, unless otherwise required by applicable Legal Requirement.

(c) As of the date of the Applicable Closing, there are no outstanding legally enforceable agreements that waive or extend the statute of limitations applicable to any Tax (including with respect to any Tax assessment, deficiency, claim for refund or claim for abatement) or Tax Return of the Company (other than extensions of time to file income Tax Returns that are obtained by the Company in the ordinary course). As of the date of the Applicable Closing, the Company has not requested any extension of time within which to file any Tax Return, which Tax Return has not since been filed.

(d) As of the date of the Applicable Closing, all Taxes that the Company is required by applicable Legal Requirements to withhold or collect, including sales and use, goods and services, harmonized sales, value added and similar Taxes, and amounts required to be withheld for Taxes of employees, have been duly withheld or collected and, to the extent required, have been timely remitted to the proper Governmental Authorities.

(e) The charges, accruals and reserves for Taxes with respect to the Company reflected on the Financial Statements (excluding accruals and reserves for deferred Taxes established to reflect timing differences between book and Tax income) are adequate to cover all Taxes payable by the Company for all periods through the date of such Financial Statements, and such charges, accruals and reserves, as adjusted for the passage of time and ordinary course business operations of the Company through the date of the Applicable Closing are adequate to cover all Taxes payable by the Company for all periods through the date of the Applicable Closing. Since the Most Recent Balance Sheet Date through the date of the Applicable Closing, none of the Company nor any of its Subsidiaries has made, revoked or changed any election in respect of Taxes, adopted or changed any accounting method in respect of Taxes, settled or compromised any audit, suit, proceeding, investigation, claim or other administrative proceeding or court proceeding relating to Taxes or Tax Returns or filed any amended Tax Return.

(f) As of the date of the Investment Closing, the Tax Returns of the Company have been examined by any applicable taxing authorities through the Tax year ending December 31, 2017.

(g) As of the date of the Applicable Closing, all assessments for Taxes payable by the Company with respect to completed and settled audits or examinations or any concluded litigation have been timely paid in full.

(h) As of the date of the Applicable Closing, the Company has not granted to any Person any power of attorney that is currently in force with respect to any Tax matter.

(i) As of the date of the Applicable Closing, no written claim has ever been made by a Governmental Authority in a jurisdiction where the Company has not filed Tax Returns that the Company is or may be subject to taxation by that jurisdiction. Schedule 5.8(i) sets forth, as of the date of the Applicable Closing, each jurisdiction (other than United States federal) in which the Company files or has been required to file any Tax Return or is liable for any Taxes on a "nexus" basis. As of the date of the Applicable Closing, no deficiencies for Taxes against the Company have been claimed, proposed, assessed or threatened in writing by any Governmental Authority, except for deficiencies that have been paid or otherwise resolved. As of the date of the Applicable Closing, there are no pending Proceedings relating to Taxes of the Company. As of the date of the Applicable Closing, no closing agreement pursuant to Section 7121 of the Code (or any similar provision of state, local or foreign Legal Requirement) has been entered into by or with respect to the Company.

(j) As of the date of the Applicable Closing, the Company (i) is not, nor has ever been a member of any consolidated, combined, affiliated or unitary group of corporations for any Tax purposes and (ii) does not have any current or potential Liability for the Taxes of any Person under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local or foreign Legal Requirement), as a transferee or successor, by Contract or otherwise. As of the date of the Applicable Closing, the Company is not a party to any Tax sharing, Tax allocation, Tax indemnity or any similar agreements, arrangements, or practices (including any advance pricing agreement, closing agreement or other similar written agreement relating to Taxes with any Governmental Authority) that remains in effect, and no facts or circumstances exist as a result of which the Company is likely to become a party to or bound by, or incur any Liability under, any such agreement, arrangement or practice.

(k) As of the date of the Applicable Closing, the Company is not subject to any rulings, or requests for rulings, or advance pricing agreements or other agreements relating to any Tax matter with any Governmental Authority.

(l) Within the five years preceding the Applicable Closing, the Company has not, either as a "distributing corporation" or as a "controlled corporation," participated in a transaction intended to satisfy the requirements of Section 355 or Section 361 of the Code, nor has the Company otherwise engaged in a transaction which could constitute part of a "plan" or "series of related transactions" (within the meaning of Section 355(e) of the Code) in conjunction with the transactions contemplated by this Agreement.

(m) As of the date of the Applicable Closing, the Company has not been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the five (5) year-period ending on such date.

(n) As of the date of the Applicable Closing, the Company has never engaged or participated in (i) any "listed transaction" within the meaning of Treasury Regulations Section 1.6011-4(b)(2) or (ii) any transaction that could give rise to (A) a reporting obligation under Section 6111 of the Code or the Treasury Regulations thereunder, (B) a list maintenance obligation under Section 6112 of the Code or the Treasury Regulations thereunder, (C) a disclosure obligation of a "reportable transaction" under Section 6011 of the Code and the Treasury Regulations thereunder, or (D) any similar obligation under any predecessor or successor Tax Legal Requirement or comparable state, local or foreign Tax Legal Requirement.

(o) The Company does not own any interest in an entity, or is a party to any contractual arrangement or joint venture or other arrangement, that is or could be characterized as a partnership for federal income Tax purposes.

(p) The Company is not, nor ever has been, a party to a transaction or Contract that is in conflict with the Tax rules on transfer pricing in any relevant jurisdiction.

(q) The Company has maintained, and made available to the Buyer, any documentation (including any applicable transfer pricing studies) required in connection with any related party transactions in accordance with Sections 482 and 6662 of the Code and the Treasury Regulations promulgated thereunder and any comparable provision of any other Tax Legal Requirements.

(r) The Company has not participated in an international boycott, as defined in Section 999 of the Code.

(s) The Company does not own any interest in any Person that is treated as a "passive foreign investment company" within the meaning of Section 1297(a) of the Code.

(t) The Company has never (i) made an election under Section 1362 of the Code to be treated as an S corporation for federal income tax purposes or (ii) made a similar election under any comparable provision of any Tax Legal Requirement. The Company has never been a "personal holding company" within the meaning of Section 542 of the Code.

(u) The Company is not a party to any gain recognition agreement under Section 367 of the Code. The Company has not incurred (or been allocated) an "overall foreign loss" as defined in Section 904(f)(2) of the Code that has not been previously recaptured in full as provided in Sections 904(f)(1) and/or 904(f)(3) of the Code.

(v) The Company will not be required to include any item of income in, or exclude any Tax credit or item of deduction from, the calculation of its Taxable income or Tax liabilities for any Taxable period (or any portion thereof) ending after the date of the Applicable Closing, including as a result of: (i) any change in, or improper use of, any method of accounting of the Company before the Applicable Closing or as a result of the transactions contemplated by this Agreement; (ii) any deferred intercompany gain or any excess loss account described in Treasury Regulations under Section 1502 of the Code (or any corresponding or similar provision of state, local or foreign Tax Legal Requirement) with respect to the Company; (iii) any "closing agreement" as described in Section 7121 of the Code (or any corresponding or similar provision of state, local or foreign Tax Legal Requirement) executed with respect to the Company on or prior to the date of the Applicable Closing; (iv) any installment sale or other open transaction disposition made by the Company on or prior to the date of the Applicable Closing; (v) any prepaid amount received or deferred revenue accrued by the Company on or prior to the date of the Applicable Closing; or (vi) Section 108(i) of the Code.

(w) As of the date of the Applicable Closing, except as set forth on Schedule 5.8(w), the Company has never undergone an "ownership change" within the meaning of Section 382 of the Code.

(x) The Company has not been, nor will be, required to pay Tax on any untaxed foreign earnings pursuant to Section 965 of the Code.

Section 5.9 Litigation and Other Proceedings; Orders. No Proceeding is or has ever been pending or, to the Company's Knowledge, threatened by, against, or affecting the Company or any of its assets before or by any court, arbitrator, panel or other Governmental Authority, or which seeks to enjoin, restrain, or prohibit the Buyer in respect of the consummation of the transactions contemplated hereby. Neither the Company nor the Company Assets is operating under or subject to any injunction, writ, temporary restraining order, decree or any order of any nature by any Governmental Authority.

Section 5.10 No Material Adverse Effect. Since the Most Recent Balance Sheet Date, (i) there has been no Event that has had, or could reasonably be expected to result in, a Material Adverse Effect, (ii) the Company has conducted its business only in the ordinary course consistent with past practice and (iii) there has been no action taken by the Company that, if taken during the period from the Signing Date through the Acquisition Closing, would have constituted a breach of Section 9.1.

Section 5.11 Licenses and Permits. The Company possesses all material Governmental Permits necessary for the conduct of its business (including all Governmental Permits under the Federal Food, Drug and Cosmetic Act of 1938, as amended (the "FDCA")). All such Governmental Permits are all listed on Schedule 5.11. As of the Signing Date, the Company has not received written notice that the Company is in violation of any term of any Governmental Permit or that any Governmental Authority intends to revoke, limit or rescind any Governmental Permit related to the business of the Company. The business of the Company complies in all material respects with the Governmental Permits. The consummation of the transactions contemplated by this Agreement or any Ancillary Agreement will not result in the non-renewal, limitation, revocation or termination of any such Governmental Permit.

Section 5.12 Environmental Matters.

(a) The business of the Company has been conducted in material compliance with all applicable Environmental Laws. (i) There has been and there is no release or presence of or exposure to Hazardous Substance at, on, under or from any property currently or formerly leased or operated by the Company in violation of any Environmental Law, or that is reasonably anticipated to result in a Proceeding arising under any Environmental Law (each such Proceeding, an "Environmental Claim") or any requirement for investigation or remediation, and (ii) there is no reasonable basis for any such Environmental Claim.

(b) All material Environmental Permits required under all applicable Environmental Laws for the continued operation of the business of the Company have been obtained, are valid and are listed on Schedule 5.12.

(c) The Company (i) does not own or operate, or has ever owned or operated, any real property contaminated with any substance that is subject to any Environmental Law, (ii) is not liable for any off-site disposal or contamination pursuant to any Environmental Law, and (iii) has not received notice of any Environmental Claim.

Section 5.13 Governmental Consents and Approvals.

The execution, delivery and performance by the Company of this Agreement and the Ancillary Agreements and the consummation by the Company of the transactions contemplated hereby and thereby do not and will not require any filing or registration with, notification to, or authorization, permit, license, declaration, order, consent or approval of, or other action by or in respect of, any Governmental Authority other than as may be required by the HSR Act.

Section 5.14 Intellectual Property.

(a) Schedule 5.14(a) sets forth an accurate and complete list of all Owned Intellectual Property, including, (i) a correct, current and complete categorical description of the Know-How included in the Company Intellectual Property that is material to the Company's business or operations as currently conducted and as planned to be conducted, and (ii) for each item listed that is Registered Owned Intellectual Property, the title, application number, registration number, application date, issuance or registration date, country of registration, and other pertinent information. All assignments of the Owned Intellectual Property to the Company have been properly executed, delivered and recorded by the Company with the applicable Governmental Authority and none of the Owned Intellectual Property is subject to any claims of joint ownership. All registrations set forth on Schedule 5.14(a) are valid, enforceable and in force, and all applications set forth on Schedule 5.14(a) are pending and in good standing.

(b) The Company solely and exclusively owns all rights and interest in and has all title to the Owned Intellectual Property free and clear of all Encumbrances, and has a valid and enforceable license to use all Licensed Intellectual Property, free and clear of all Encumbrances. Each item of Company Intellectual Property will be owned or available for use by the Company immediately following any of the transactions contemplated by this Agreement or any Ancillary Agreement and following the Acquisition Closing on identical terms and conditions as it was prior to the Acquisition Closing. The Company Intellectual Property constitutes all Intellectual Property used in connection with or otherwise necessary for the conduct of the business of the Company as conducted and as planned to be conducted, including with respect to the activities contemplated by the Development Plan. The execution and delivery of this Agreement and the consummation and completion of the transactions contemplated by this Agreement will not result in the alteration, loss or impairment of, or payment of any additional amounts with respect to, require the consent of any Third Party in respect of, or otherwise adversely affect any Company Intellectual Property or otherwise alter or impair the ownership of, or right of the Company to use, any of the Company Intellectual Property.

(c) All of the Company Intellectual Property is subsisting and enforceable. To the Company's Knowledge, there are no facts or circumstances that would render (i) any of the Company Intellectual Property invalid or (ii) any Intellectual Property Agreements invalid or unenforceable. The Company has not received a claim that the Company Intellectual Property or Intellectual Property Agreements are invalid or unenforceable or challenging the ownership of any Owned Intellectual Property or right to use any Company Intellectual Property, nor has any such claim been asserted in any pending or, to the Company's Knowledge, threatened litigation or proceeding before any Governmental Authority, and the Company is not aware of any facts or circumstances that could reasonably be expected to give rise to any such claims. None of the Company Intellectual Property is subject to any pending or, to the Company's Knowledge, threatened claims or proceedings for infringement, misappropriation, re-examination, inter-partes review, opposition, cancellation, dilution, revocation or any other violation of any Intellectual Property rights of any Third Party, and the Company is not aware of any facts or circumstances that could reasonably be expected to give rise to any such claims or proceedings. None of the Intellectual Property Agreements are subject to any pending or, to the Company's Knowledge, threatened claims or proceedings for breach, default, or any violation of any rights of any Third Party, and the Company is not aware of any facts or circumstances that could reasonably be expected to give rise to any such claims or proceedings.

(d) All registration, application issuance, renewal, maintenance and other payments that are or have become due with respect to the Company Owned Intellectual Property have been timely paid, all necessary renewal applications have been timely filed and all other steps necessary for maintenance have been taken in a timely manner.

(e) Each Person (including each current and former employee, officer and director of the Company and each current and former independent contractor of the Company) that was or is involved in the invention, conception, creation, formulation, development, design, modification, and/or reduction to practice of any Owned Intellectual Property has executed a valid and binding written agreement expressly assigning to the Company (and requiring the confidentiality of) all right, title and interest in and to, and including all applicable work made for hire provisions related to, all Intellectual Property invented, created, formulated, developed, modified, conceived and/or reduced to practice by such Person (collectively, the "IP Assignment Agreements"). No Person who has been involved in the invention, conception, creation, formulation, development, design, modification, conception and/or reduction to practice of any Owned Intellectual Property: (i) has any right, license, and claim or interest whatsoever in or with respect to any Owned Intellectual Property or (ii) is in material violation of any IP Assignment Agreement. Each Person that was or is involved in the invention, conception, creation, formulation, development, design, modification, conception and/or reduction to practice of any Owned Intellectual Property undertook such actions either (i) as a current or former employee, officer or director of the Company within the scope of their employment or (ii) as a current or former independent contractor of the Company within the scope of their engagement with the Company.

(f) The Company has taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of the Confidential Intellectual Property and to protect the proprietary nature of the Company Intellectual Property. None of the Confidential Intellectual Property has been disclosed to any Person not bound, prior to such disclosure, by a written confidentiality agreement or IP Assignment Agreement protecting the confidentiality thereof, and there has been no actual or alleged violation of such agreements with respect to any Confidential Intellectual Property. No Proceeding relating to an improper use or disclosure, or breach in the security or confidentiality, of any Confidential Intellectual Property has been initiated or threatened against the Company.

(g) (i) Neither the Company Intellectual Property (or any use thereof), nor the conduct of the business of the Company as currently and formerly conducted, (and, to the Company's Knowledge, as planned to be conducted), nor the products, processes and services of the Company as currently and formerly offered (and, to the Company's Knowledge, as planned to be offered), including the Product, violates any license, agreement or Contract, or infringes, misappropriates or otherwise violates any Intellectual Property owned by a Third Party and (ii) no suit, action or claim has been asserted, threatened or is or was pending concerning any claim or position that the Company has infringed, misappropriated or violated or is currently infringing, misappropriating or violating any Intellectual Property of a Third Party or is in breach or default under any Contract or Intellectual Property Agreement.

(h) All rights and licenses granted under or pursuant to all Intellectual Property Agreements are for purposes of Section 365 (n) of the United States Bankruptcy Code (the "Bankruptcy Code") licenses to rights to "intellectual property" as defined under the Bankruptcy Code.

(i) To the Company's Knowledge, no Person (including any current or former employee or consultant of the Company) has infringed, misappropriated or violated or is currently infringing, misappropriating or violating the Company Intellectual Property.

(j) There have been no material breaches of the Company's or its service providers' security procedures, systems, policies or technologies or any material attempted or successful unauthorized incidents of access, use, disclosure, modification, or destruction of information or interference with systems operations in any information system or database of the Company or any storing any Company Intellectual Property or Personal Data, including any such breach or incident that required or requires notice to any Third Party.

(k) The Company has at all times complied with (i) all Privacy Laws worldwide, including, the EU Data Protection Directive (Directive 95/46/EC), the EU General Data Protection Regulation (Regulation (EU) 2016/679) and Health and Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d) and (ii) all Privacy Agreements, and no Person has made any illegal or unauthorized use of any Personal Data constituting Company Intellectual Property. The Privacy Agreements do not require the delivery of any notice to or consent from any Person, or prohibit the unqualified transfer of Personal Data constituting Company Intellectual Property, in connection with the execution, delivery or performance of this Agreement, or the consummation of any of the transactions contemplated hereby and thereby.

(l) The Company is in compliance with the duty of candor obligations owed to the United States Patent & Trademark Office ("USPTO") required by 37 C.F.R. § 1.56 with respect to all Patent applications filed by the Company with the USPTO, and with all similar Legal Requirements with respect to Patent applications filed outside the United States. Further, and in accordance with the Company's duty of candor, the Company has promptly notified the USPTO (and with respect to Patent applications filed outside the United States, the applicable Government Authority) of all information material to the patentability of any claim of any Patent application, continuation or continuation-in-part pending before the USPTO (or with respect to Patent applications filed outside the United States, the applicable Government Authority).

(m) None of the software included in the Company Intellectual Property was developed using, includes, incorporates, links to or otherwise requires the use of any open source, free software, or freeware of any kind. The Company has not used any open source, free software, or freeware of any kind in a manner that does, will, or would reasonably be expected to, require the (i) disclosure or distribution of any software included in the Company Intellectual Property in source code form or object code form; (ii) license or other provision of any such software on a royalty-free basis; or (iii) grant of any patent license, non-assertion covenant, or other rights under any Company Intellectual Property or rights to modify, make derivative works based on, decompile, disassemble, or reverse engineer any portion of such software.

Section 5.15 Employee Plans and Personnel Matters.

(a) Schedule 5.15 lists each Company Employee Plan. Each Company Employee Plan has been maintained, operated and administered in compliance in all material respects with its terms and the applicable Legal Requirements of the relevant jurisdiction (including the requirements for any funding and Tax-favored treatment intended for such plan or applicable to plans of its type). No event, transaction or condition exists or has occurred that is reasonably likely to result in the loss or material limitation of any such Tax-favored treatment.

(b) All required reports and descriptions (including Form 5500 annual reports, summary annual reports and summary plans descriptions) have been timely filed and/or distributed in accordance with the applicable requirement of ERISA and the Code with respect to each Company Employee Plan. The requirements of COBRA have been met in all material respects with respect to each Company Employee Plan that is subject to COBRA.

(c) All material contributions, premiums and benefit payments in respect of the Company Employees (and any spouse, beneficiary or dependent thereof) under or in connection with the Company Employee Plans due prior to the Signing Date and the Acquisition Closing, as applicable, have been timely made.

(d) Each Company Employee Plan that is intended to meet the requirements of a "qualified plan" under Section 401(a) of the Code has received a determination from the Internal Revenue Service that such Company Employee Plan is so qualified, or with respect to a prototype plan can rely on an opinion letter from the Internal Revenue Service to the effect that such Company Employee Plan is so qualified, and the Company is not aware of any facts or circumstances that would reasonably be expected to adversely affect the qualified status of such plan.

(e) To the Company's Knowledge, there have been no acts or omissions by any party with respect to the Company Employee Plans which have given rise to or may give rise to fines, penalties, taxes or related charges under applicable Legal Requirements for which after the Signing Date or the Acquisition Closing, the Company or the Buyer could reasonably be expected to be liable.

(f) There are no actions, suits, claims (other than routine claims for benefits) or investigations pending or, to Company's Knowledge, threatened, involving any Company Employee Plan or the Company Assets for which the Company (after the Signing Date) or the Buyer (after the Acquisition Closing) could reasonably be expected to incur any material Liability and no event, transaction or condition exists or has occurred which could reasonably be expected to give rise to any such actions, suits, claims (other than routine claims for benefits) or investigations. The Company has no material Liability with respect to any Plan other than for contributions, payments or benefits due in the ordinary course of business under the current Company Employee Plans.

(g) With respect to each Company Employee Plan, the Company has made available to the Buyer correct and complete copies of each of the following: (i) where the Company Employee Plan has been reduced to writing, the plan document together with all amendments; (ii) where the Company Employee Plan has not been reduced to writing, a written summary of all material plan terms; (iii) where applicable, copies of any trust agreements or other funding arrangements, insurance policies and contracts, and administration agreements and similar agreements; (iv) copies of any summary plan descriptions, summaries of material modifications, employee handbooks and any other material written communications relating to any Company Employee Plan; (v) in the case of any Company Employee Plan that is intended to be qualified under Section 401(a) of the Code, a copy of the most recent determination, opinion or advisory letter from the Internal Revenue Service; and (vi) in the case of any Company Employee Plan for which a Form 5500 is required to be filed, a copy of the most recently filed Form 5500 (with all applicable attachments).

(h) Other than as required under COBRA, no Company Employee Plan provides health, life insurance or other welfare benefits to retired or other terminated employees, officers, independent contractors, or directors of the Company (or any spouse, beneficiary or dependent thereof), and the Company does not have any obligation to provide any such benefits..

(i) No Company Employee Plan is a "defined benefit plan" within the meaning of Section 3(35) of ERISA, a "multiemployer plan" within the meaning of Section 3(37) or 4001(a)(3) of ERISA, or a "multiple employee plan" within the meaning of Section 413(c) of the Code, and the Company does not have any Liability with respect to any such plan.

(j) Neither the execution of this Agreement or the Ancillary Agreements, nor the consummation of the transactions contemplated by this Agreement or the Ancillary Agreements, will (either alone or in combination with another event): (i) increase the amount of compensation or benefits otherwise payable under any Company Employee Plan; (ii) result in the acceleration of the time of payment, exercisability, funding or vesting of any such benefits; or (iii) result in any payment (whether severance pay or otherwise) becoming due to, or with respect to, any current or former employee, officer, independent contractor, or director of the Company.

(k) No payment or series of payments that would constitute a "parachute payment" (within the meaning of Section 280G of the Code) has been made or will be made by the Company, directly or indirectly, to any current or former employee, officer, independent contractor, or director in connection with the execution of this Agreement or the Ancillary Agreements or as a result of the consummation of the transactions contemplated hereby.

(l) Each Company Employee Plan that is subject to Section 409A of the Code has been administered in compliance with the operational and documentary requirements of Section 409A of the Code and the regulations thereunder, and no amounts under any such arrangement is or has been subject to the interests and additional tax set forth under Section 409A(a)(1)(B) of the Code. The Company does not have any obligation to gross up, indemnify or otherwise reimburse any current or former employee, officer, independent contractor, or director of the Company for any Taxes, interest or penalties incurred in connection with any Company Employee Plan (including without limitation any Taxes, interest or penalties incurred pursuant to Section 409A or 4999 of the Code).

(m) All of the personnel needed to run the business of the Company are employees or consultants of the Company, and no employees of the Company are, or ever have been, covered by a collective bargaining agreement or represented by a union or other labor organization or bargaining agent; and (ii) to the Knowledge of the Company, no union organizing efforts are being, or within the last three years have been, conducted with respect to any employees of the Company.

(n) The Company has properly classified for all purposes (including for Tax purposes and for purposes of determining eligibility to participate in any Plan) all Persons who have performed services for or on behalf of the Company and has properly withheld and paid all applicable Taxes and made all required filings in connection with services provided by such Persons to the Company in accordance with such classifications.

Section 5.16 Compliance with Legal Requirements. The Company is, and has been since its incorporation, in compliance in all material respects with all Legal Requirements applicable to it. The Company has not received written notice from a Governmental Authority of any violations with respect to Legal Requirements applicable to it, or any notice that any facility of the Company is not in material compliance with applicable Legal Requirements or requires any material improvement, modification or alteration in order to lawfully continue any aspect of the operations conducted at the facility. Neither the Company nor any of its respective directors or officers, or to the Company's Knowledge, any of the Company's agents, employees or any other Persons acting on its behalf, has (i) used any corporate or other funds for unlawful contributions, payments, gifts or entertainment, or made any unlawful expenditures relating to political activity to government officials, candidates or members of political parties or organizations, or private counterparties, or established or maintained any unlawful or unrecorded funds or taken any other action in violation of the Foreign Corrupt Practices Act of 1977, as amended, or any other similar applicable Legal Requirement, (ii) paid, accepted, offered, promised, authorized or received any unlawful contributions, payments, expenditures or gifts, or (iii) violated or operated in noncompliance with any export restrictions, anti-boycott regulations, embargo regulations or other applicable domestic or foreign laws and regulations.

Section 5.17 Regulatory and GxP Compliance.

(a) The Company (i) is and has been in compliance with (A) all applicable Legal Requirements relating to or promulgated by the FDA and other Healthcare Regulatory Authorities and (B) all Healthcare Regulatory Authorizations, including all requirements of the FDA and all other Healthcare Regulatory Authorities, in each case that are applicable to the Company, or by which any property, product, filing, clinical trial, submission, registration, declaration, approval, practice or other asset of the Company is bound, governed or affected and (ii) has held all Healthcare Regulatory Authorizations required for the conduct of its businesses.

(b) All reports, documents, claims and notices required or requested to be filed, maintained, or furnished to any Healthcare Regulatory Authority by the Company, have been so filed, maintained or furnished and were complete and correct in all respects on the date filed (or were corrected in or supplemented by a subsequent filing).

(c) (i) All preclinical and clinical studies or tests sponsored by the Company have been conducted in compliance with standard medical and scientific research procedures and applicable Legal Requirements and GxP requirements (including Good Manufacturing Practices, Good Pharmacovigilance Practices, and Good Clinical Practices requirements and Legal Requirements restricting the use and disclosure of individually identifiable health information) and (ii) the Company has not received written notice from (A) the FDA or any other Healthcare Regulatory Authority with respect to any ongoing clinical or pre-clinical studies or tests requiring the termination, suspension or modification of such studies or tests or investigational product or (B) any Person regarding any breach or alleged breach with respect to individually identifiable health information.

(d) The Company has not (i) made an untrue statement of a fact or fraudulent statement to the FDA or any other Healthcare Regulatory Authority, (ii) failed to disclose a fact required to be disclosed to the FDA or any other Healthcare Regulatory Authority, (iii) committed any other act, made any statement or failed to make any statement, that (in any such case) establishes a basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy or (iv) been the subject of any investigation by the FDA pursuant to its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy. Neither the Company nor any officer, employee, agent or clinical investigator of the Company has been suspended or debarred or convicted of any crime or engaged in any conduct that could result in (a) debarment under 21 U.S.C. Section 335a or any other Legal Requirement or (b) exclusion under 42 U.S.C. Section 1320a-7 or any other Legal Requirement.

(e) As to each product subject to the FDCA, or similar Legal Requirements in any non-United States jurisdiction, that is or is intended to be developed, manufactured, tested, distributed or marketed by the Company (a "Medical Product"), each such Medical Product is being developed, manufactured, tested, distributed and/or marketed in all respects in compliance with all applicable requirements under the FDCA and similar Legal Requirements, including those relating to investigational use, pre-market clearance or marketing approval to market a Medical Product, Good Manufacturing Practices, Good Distribution Practices, labeling, advertising, record keeping, filing of reports and security.

(f) The Company has not received any notice or other communication from any Governmental Authority (A) contesting the premarket clearance or approval of, the uses of or the labeling and promotion of any products of the Company or (B) otherwise alleging any violation applicable to any Medical Product of any Legal Requirement. (i) No Medical Product is under consideration by the Company for recall, withdrawal, suspension, seizure or discontinuance, or has been recalled, withdrawn, suspended, seized or discontinued and (ii) no proceedings (whether completed or pending) seeking the recall, withdrawal, suspension, seizure or discontinuance of any Medical Product are pending against the Company or any licensee of any Medical Product.

Section 5.18 Brokers. Except as set forth on Schedule 5.18, no broker, finder or investment banker is entitled to any brokerage, finder's, opinion or other fee or commission in connection with the transactions contemplated by this Agreement and the Ancillary Agreements based upon or arising from arrangements made on behalf of the Company and its Affiliate.

Section 5.19 No Restrictions on the Transactions. Section 203 of the DGCL does not apply to the Company. There are no anti-takeover, "fair price," "moratorium," "control share acquisition" or similar statute or regulation, restriction or provision of the DGCL or the laws of any other jurisdiction, the certificate of incorporation or organizational regulations, or other organizational or constitutive document or governing instruments of the Company that would prevent, impede or delay the consummation of the transactions contemplated by this Agreement and the Ancillary Agreements, including the Stock Purchase Investment and the Acquisition. There is no stockholder rights plan, "poison pill" or similar anti-takeover agreement or plan in effect to which the Company is subject, party or otherwise bound. No further action by the Board of Directors of the Company is necessary to approve the Transactions. As of the date of this Agreement, the Company does not have an open binding offer (other than this Agreement) that would meet the criteria set forth in Section 9.3.

Section 5.20 Investigation.

(a) The Company and the Sellers acknowledge and agree that, except for the representations and warranties contained in this Agreement, the Buyer does not make any other representations or give any other warranties, express or implied.

(b) The Company and the Sellers acknowledge and agree that in entering into this Agreement they have each relied solely on their own respective investigation and the representations and warranties contained In this Agreement.

ARTICLE 6.
REPRESENTATIONS AND WARRANTIES OF THE BUYER

The Buyer hereby represents and warrants to the Company as follows:

Section 6.1 Organization of the Buyer; Due Authorization.

(a) The Buyer (i) is a corporation duly organized, validly existing and in good standing under the laws of Delaware, (ii) is duly licensed and qualified to conduct its business in each jurisdiction where the nature of the properties owned, leased or operated by it and the business transacted by it requires such licensing or qualification, except where any such failures to be so qualified or licensed have not had, or are not reasonably likely to have, a material adverse effect on the ability of the Buyer to consummate the Transactions and (iii) holds all necessary corporate power and authority to own, license and operate its assets and properties, to conduct its business, to enter into this Agreement and the Ancillary Agreements, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby, including the Transactions. This Agreement and the consummation of the transactions contemplated hereby, the execution and delivery of this Agreement and the Ancillary Agreements by the Buyer, the performance by the Buyer of its obligations hereunder and thereunder and the consummation by the Buyer of the transactions contemplated hereby and thereby, have been duly authorized by all requisite action on the part of the Buyer, and no other proceedings on the part of the Buyer are necessary to authorize the execution and delivery of this Agreement or the consummation by the Buyer of the transactions contemplated hereby and thereby.

(b) Each of this Agreement and the Ancillary Agreements to which it is or will be a party has been or will be, as the case may be, duly executed and delivered by the Buyer and (assuming due authorization, execution and delivery by the Company) constitutes or will constitute a legal, valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with their respective terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally and (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(c) The board of directors of the Buyer has unanimously adopted resolutions, prior to entry thereto, approving this Agreement and the transactions contemplated by this Agreement and the Ancillary Agreements.

Section 6.2 **No Conflict.** Assuming that all consents, approvals, authorizations and other actions have been obtained or made and any applicable waiting period under the HSR Act has expired or been terminated, neither the execution or delivery by the Buyer of this Agreement or any of the Ancillary Agreements, or the performance by the Buyer of its obligations under this Agreement or any of the Ancillary Agreements, or the consummation of the transactions contemplated hereby or thereby will (a) result in any breach of any provision of the Buyer's certificate of incorporation and by-laws, each as amended from time to time, (b) result in any breach of, require (with or without notice or lapse of time or both) any consent or notice or constitute a default (or give rise to any right of purchase, termination, amendment, acceleration or cancellation) under, any contract or order or judgment to which the Buyer is a party or by which it or its assets are bound or (c) violate any applicable Legal Requirement.

Section 6.3 **Governmental Consents.** The execution and delivery of this Agreement by the Buyer does not, and the performance of this Agreement and the Ancillary Agreements by the Buyer will not, require any consent, approval, authorization or other order of, action by, filing with or notification to, any Governmental Authority other than compliance with and filings under the HSR Act.

Section 6.4 **Financing of the Transactions.** On the date of the Acquisition Closing, the Buyer will have sufficient immediately available funds to pay, in cash, the Acquisition Closing Purchase Price, and all other amounts payable by the Buyer pursuant to this Agreement and the Ancillary Agreements or otherwise necessary to be paid by the Buyer to consummate the transactions contemplated hereby and thereby.

Section 6.5 **Litigation and Other Proceedings; Orders.** As of the Signing Date, no litigation, regulation, or legislation shall be pending or, to the Buyer's knowledge, overtly threatened by a Third Party which seeks to enjoin, restrain, or prohibit the Buyer in respect of the consummation of the transactions contemplated hereby.

Section 6.6 **Brokers.** No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement and the Ancillary Agreements based upon or arising from arrangements made on behalf of the Buyer and its Affiliates which would be payable by the Company.

Section 6.7 **Investigation.**

(a) In connection with the Buyer's investigation of the Company and the Company Shares, Buyer has received from the Company certain projections, forecasts and other planning and budget information for the Company. The Buyer acknowledges that there are uncertainties inherent in attempting to make such projections, forecasts, plans and budgets, that the Buyer is familiar with such uncertainties, that the Buyer is taking full responsibility for making its own evaluation of the adequacy and accuracy of all estimates, projections, forecasts, plans and budgets so furnished to it, and that Buyer will not assert any claim against the Company and its Affiliates and/or any of its directors, officers, employees or agents, respectively, or hold any such entities and/or Persons liable with respect thereto.

(b) Buyer acknowledges and agrees that, except for the representations and warranties contained in this Agreement, the Company does not make any other representations or give any other warranties, express or implied.

(c) Buyer acknowledges and agrees that in entering into this Agreement it has relied solely on its own investigation and the representations and warranties contained in this Agreement.

ARTICLE 7.
REPRESENTATIONS AND WARRANTIES OF THE SELLERS

Each Seller hereby severally represents and warrants to the Buyer as of the Signing Date and as of the date of the Acquisition Closing, as if such representations and warranties were made as of the date of the Acquisition Closing, as follows:

Section 7.1 Organization of Seller.

(a) If such Seller is an entity, such Seller (i) is duly organized, validly existing and in good standing under the laws of its jurisdiction and organization, (ii) is duly licensed and qualified to conduct its business in each jurisdiction where the nature of the properties owned, leased or operated by it and the business transacted by it requires such licensing or qualification, except where any such failures to be so qualified or licensed have not had, or are not reasonably likely to have, a material adverse effect on the ability of such Seller to consummate the Transactions and (iii) holds all necessary corporate power and authority to own, license and operate its assets and properties, to conduct its business, to enter into this Agreement and the Ancillary Agreements, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby, including the Transactions. This Agreement and the consummation of the transactions contemplated hereby, the execution and delivery of this Agreement and the Ancillary Agreements by such Seller, the performance by such Seller of its obligations hereunder and thereunder and the consummation by such Seller of the transactions contemplated hereby and thereby, have been duly authorized by all requisite action on the part of such Seller, and no other proceedings on the part of such Seller are necessary to authorize the execution and delivery of this Agreement or the consummation by such Seller of the transactions contemplated hereby and thereby.

(b) Each of this Agreement and the Ancillary Agreements to which it is or will be a party has been or will be, as the case may be, duly executed and delivered by such Seller and (assuming due authorization, execution and delivery by the Buyer) constitutes or will constitute a legal, valid and binding obligation of such Seller, enforceable against such Seller in accordance with their respective terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally and (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

Section 7.2 No Conflict. Assuming that all consents, approvals, authorizations and other actions, and any applicable waiting period under the HSR Act has expired or been terminated, neither the execution or delivery by such Seller of this Agreement or any of the Ancillary Agreements, or the performance by such Seller of its obligations under this Agreement or any of the Ancillary Agreements, or the consummation of the transactions contemplated hereby or thereby will (a) if such Seller is an entity, result in any breach of any provision of such Seller's organizational documents, as amended from time to time, (b) result in any breach of, require (with or without notice or lapse of time or both) any consent or notice or constitute a default (or give rise to any right of purchase, termination, amendment, acceleration or cancellation) under, any contract or order or judgment to which such Seller is a party or by which it or its assets are bound or (c) violate any applicable Legal Requirement.

Section 7.3 Governmental Consents. The execution and delivery of this Agreement by such Seller does not, and the performance of this Agreement and the Ancillary Agreements by such Seller will not, require any consent, approval, authorization or other order of, action by, filing with or notification to, any Governmental Authority other than compliance with and filings under the HSR Act.

Section 7.4 Title to Stock. As of the Signing Date, such Seller is the record and beneficial owner of all of the Company Securities shown in Schedule 5.3 to be held by such Seller, and such Seller has good and valid title to such securities free and clear of any and all Encumbrances. As of immediately prior to the Acquisition Closing, such Seller is the record and beneficial owner of all of the Acquisition Shares shown in Exhibit H (as amended pursuant to Section 4.2) and such Seller has the power and authority to sell, transfer, assign and deliver such Acquisition Shares at the Acquisition Closing as provided in this Agreement, and such delivery will convey to the Buyer good and marketable title to all such Acquisition Shares, free and clear of any and all Encumbrances.

Section 7.5 Litigation and Other Proceedings; Orders. No litigation, regulation, or legislation shall be pending or, to such Seller's knowledge, overtly threatened by a Third Party which seeks to enjoin, restrain, or prohibit such Seller in respect of the consummation of the transactions contemplated hereby.

Section 7.6 Brokers. Except as set forth on Schedule 5.18, no broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement and the Ancillary Agreements based upon or arising from arrangements made on behalf of such Seller.

ARTICLE 8.
ADDITIONAL AGREEMENTS

Section 8.1 Completion of the Acquisition as a Merger. If at the Acquisition Closing, the Acquired Shares delivered or to be delivered by the Sellers constitute less than all of the equity interests of the Company, including equity interests of the Company to be issued upon exercise, conversion or exchange of then-outstanding securities of the Company, other than equity interests of the Company beneficially owned by the Buyer or an Affiliate of the Buyer, then, at the Buyer's sole discretion, (a) the Buyer may proceed at its sole discretion with the Acquisition pursuant to the terms of this Agreement, provided, however, that all payments from the Buyer to the Representative for the benefit of and distribution to the Sellers pursuant to this Agreement shall be reduced accordingly to address the equity interests, including equity interests of the Company to be issued upon exercise, conversion or exchange of then-outstanding securities of the Company, that are not tendered at the Closing, or (b) upon written notice from the Buyer to the Representative, the Buyer, the Company and the Representative shall, on behalf of itself and all of the Sellers, amend this Agreement to provide that the acquisition of the Company by the Buyer shall proceed by way of an Agreement and Plan of Merger (the "Merger"), whereby all Options, RSUs and Warrants in respect of Company Shares and all Acquired Shares (including Company Shares issued on the exercise of Options, RSUs or Warrants) are exercised, redeemed or purchased, as the case may be, on the same terms and conditions as this Agreement. For the avoidance of doubt, the amount of the payment of the consideration to be paid by the Buyer for each Acquired Share pursuant to the Merger shall be identical to the amount of the payment of the consideration to be paid by the Buyer pursuant to this Agreement. If this Agreement is amended pursuant to this Section 8.1, each Seller hereby appoints the Representative as its sole and exclusive attorney and proxy, with full power of substitution and resubstitution, to vote and exercise all voting rights (to the full extent that such Seller is entitled to do so) with respect to the shares of capital stock of the Company that are owned of record by such Seller, and any and all other shares or securities issued or issuable in respect thereof, and to execute and deliver all consents, certificates, agreement or other documents, that the Buyer and the Representative shall determine are necessary or desirable to authorize and approve the Merger. Upon each Seller's execution of this Agreement, any and all prior proxies given by such Seller with respect to the voting of any of its shares of capital stock of the Company in connection with the authorization or approval of the Merger are hereby revoked and such Seller agrees not to grant any subsequent proxies with respect to such matters. The proxy granted pursuant to this Section 8.1 is irrevocable, is coupled with an interest, and is granted in consideration of the Buyer entering into this Agreement. Nothing in this Section 8.1 shall be deemed in any way to limit the Buyer's rights otherwise under this Agreement.

Section 8.2 Completion of the Acquisition as an Asset Sale. At the Acquisition Closing, at the Buyer's sole discretion, upon written notice from the Buyer to the Representative, the Buyer, the Company and the Representative shall, on behalf of itself and all of the Sellers, amend this Agreement to provide that the acquisition of the Company by the Buyer shall proceed by way of an Asset Purchase Agreement, whereby the Buyer shall acquire substantially all of the assets and liabilities of the Company on the same terms and conditions as this Agreement. The amount of the payment of the consideration to be paid by the Buyer to the Company for the assets and liabilities thereunder shall equal the aggregate amount of the consideration to be paid by the Buyer to the Sellers pursuant to this Agreement increased to account for any negative corporate-level tax effects of an asset purchase transaction as compared with a stock purchase transaction, such that the Sellers, after the distribution of such aggregate consideration from an asset purchase transaction to them by the Company, receive the same aggregate consideration as is contemplated by this Agreement. Nothing in this Section 8.2 shall be deemed in any way to limit the Buyer's rights otherwise under this Agreement.

ARTICLE 9.
COVENANTS OF THE PARTIES

Section 9.1 Conduct of Business of the Company. The Company shall, during the Pre-Closing Period, except as expressly required by this Agreement or by applicable Legal Requirements or with the prior written consent of the Buyer (in the Buyer's sole discretion), (i) conduct its business in the ordinary course of business consistent with past practice, (ii) fully comply with its covenants and obligations under any Contract to which it is a party and enforce its rights thereunder, (iii) use its reasonable best efforts to preserve intact its business organization, to keep available the services of its current officers and employees, to preserve its present goodwill and satisfactory relationships with Governmental Authorities, suppliers, licensors, and other Persons having business relationships with it and (iv) comply with the Development Plan and the Budget. Without limiting the generality of the foregoing, between the Signing Date and the Acquisition Closing, except as expressly required by this Agreement or by applicable Legal Requirements, the Company shall not, without the prior written consent of the Buyer (in the Buyer's sole discretion):

(a) amend or propose to amend its certificate of incorporation (including any certificate of designations) or by-laws;

(b) establish any Subsidiary or enter into any new line of business or division;

(c) (i) split, combine, or reclassify any Company Securities or issue or authorize the issuance of any other securities in respect of, in lieu of, or in substitution for, any Company Securities, (ii) repurchase, redeem, or otherwise acquire, or offer to repurchase, redeem, or otherwise acquire, directly or indirectly, any Company Securities, or (iii) declare, set aside, or pay any dividend or distribution (whether in cash, stock, property, or otherwise) in respect of, or enter into any contract with respect to the voting of, the Company Securities;

(d) issue, offer, sell, pledge, dispose of, or encumber any Company Securities, other than (i) issue Common Shares upon the exercise of any equity award granted as of the Signing Date under any Company Employee Plan outstanding as of the Signing Date in accordance with its terms or (ii) issue Common Shares prior to the Acquisition Closing upon the exercise of any equity award in accordance with Section 4.2 and Section 9.7(b)(1);

(e) acquire, by merger, consolidation, acquisition of stock or assets, or otherwise, any business or Person or division thereof;

(f) merge or consolidate with any other Person, adopt or effect a plan of complete or partial liquidation, dissolution, restructuring, recapitalization, or other reorganization, or commence or file any petition seeking liquidation, protection or other relief under any U.S. federal, state or foreign bankruptcy, insolvency, receivership or similar Legal Requirement or the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official;

(g) transfer, license, sell, lease, or otherwise dispose of (whether by way of merger, consolidation, sale of stock or assets, or otherwise) or pledge, encumber, or otherwise subject to any Encumbrance, any Company Assets (including any Company Intellectual Property);

(h) incur, assume or otherwise become directly or indirectly liable for, or modify, any Indebtedness other than trade account payables incurred in the ordinary course of business consistent with past practice, or lend any money to any director, officer or employee of the Company;

(i) enter into, renew or extend, amend or modify, or waive any rights under, any material contract in any material respect, or consent to or initiate the termination of any material contract;

(j) institute, settle, waive its rights under or compromise any Proceeding other than any Proceeding brought by the Company against the Buyer arising out of a breach or alleged breach of this Agreement by the Buyer;

(k) enter into any agreement, agreement in principle, letter of intent, memorandum of understanding, or similar Contract with respect to any joint venture, strategic partnership, or alliance;

(l) abandon, allow to lapse, sell, assign, transfer, grant any security interest in, otherwise encumber or dispose of any Company Intellectual Property, or grant any right or license to any Company Intellectual Property;

(m) disclose to another Person, or facilitate the use or transfer by or to another Person, of any Investigational New Drug, NDA, "regulatory documents", "essential documents" or any amendments thereto, any data or information contained in the files submitted to the FDA, or any other information or data, in each case, related to the Product or improvements thereon except in the ordinary course of business; or

(n) agree or commit to do any of the foregoing.

Section 9.2 Access to Information Prior to the Acquisition Closing. During the Pre-Closing Period, the Company will, and will cause its officers, employees, independent public accountants and other representatives, (i) to afford the Buyer, its Affiliates and their representatives reasonable access to the officers, employees, agents, offices, other facilities, properties, data and books and records of the Company, including financial and accounting information and working papers that the Buyer may from time to time reasonably request and (ii) to furnish, as promptly as practicable, to the Buyer, its Affiliates and their representatives such additional information regarding the Company as the Buyer, its Affiliates and their representatives may from time to time reasonably request (including for the avoidance of doubt, reasonable access to information from Patheon regarding the Product); provided, however, that such access will be provided upon reasonable notice, during normal business hours, and in a manner that will not unreasonably interfere with the conduct of the business of the Company. Notwithstanding anything to the contrary in this Agreement, the Company will not be required to disclose any information to the Buyer if such disclosure would (i) invalidate any attorney-client privilege or (ii) contravene any applicable Legal Requirement or fiduciary duty; provided, however, that the Company shall reasonably cooperate in seeking to find a way to allow disclosure of such information to the extent doing so would not reasonably be likely to result in the violation of any such Legal Requirement or fiduciary duty, or reasonably be likely to cause such privilege to be undermined with respect to such information (including the Company using commercially reasonable efforts to obtain any required consent from any third party under any such Contract for the Buyer, its Affiliates and their representatives to access any such information). The Company acknowledges that the Buyer may be subject to obligations under Legal Requirements and that the Buyer may require the Company's support and cooperation to comply with such statutory obligations. The Company hereby agrees to reasonably cooperate with the Buyer and to take all actions necessary, including providing information, to enable the Buyer to comply with such obligations. No investigation pursuant to this Section 9.2 or information provided, made available or delivered pursuant to this Section 9.2 or otherwise, or any knowledge that any Person may have shall affect any representations or warranties or conditions or rights contained in this Agreement or any Ancillary Agreement.

Section 9.3 **No Solicitation.** During the Pre-Closing Period, the Sellers and the Company shall not (and shall cause their respect Affiliates not to), and shall not authorize or permit their respective directors, officers, employees, agents, advisors, legal counsel, investment bankers and other representatives (the foregoing Persons are referred to herein as "Representatives") to, and shall instruct each of its Representatives not to, directly or indirectly, (a) initiate, solicit, encourage or otherwise facilitate any inquiry, proposal, offer or discussion with any party (other than the Buyer) concerning any merger, reorganization, consolidation, recapitalization, business combination, liquidation, dissolution, share exchange, sale of stock, sale of material assets or similar business transaction involving the Company or any division of the Company, (b) other than in the Company's ordinary course of business including to licensors and advisors who are under an obligation of confidentiality, furnish any non-public information concerning the business, properties or assets of the Company or any division of the Company to any party (other than the Buyer), or (c) engage in discussions or negotiations with any party (other than the Buyer) concerning any such transaction. The Sellers and the Company shall (and shall cause their respective Affiliates to) cease immediately and cause to be terminated, and shall not authorize or knowingly permit any of their respective Representatives to continue, and shall instruct each such Representatives to terminate, any and all existing activities, discussions, or negotiations, if any, with any third party conducted prior to the Signing Date with respect to any such transaction and shall use its reasonable best efforts to cause any such third party (and the Affiliates and Representatives of the Sellers, the Company or their respective Affiliates) in possession of non-public information in respect of the Company that was furnished by or on behalf of the Company or any of the Sellers to return or destroy (and confirm destruction of) all such information. Notwithstanding the foregoing, it shall not be a violation of this Section 9.3 for the Company, acting in good faith, to initiate, solicit, encourage or otherwise facilitate any inquiry, proposal, offer or discussion solely to the extent that such inquiry, proposal, offer or discussion is limited to the purchase of any and all securities in the Company held by the Sellers pursuant to Section 9.7(b)(5) as of the Signing Date.

Section 9.4 **Further Action.**

(a) During the Pre-Closing Period, each of the parties to this Agreement, subject to the Buyer's sole discretion as to the exercise of its Purchase Option, will use all commercially reasonable efforts to take, or to cause to be taken, all appropriate action, to do or cause to be done all things necessary, proper or advisable under applicable Legal Requirements, and to execute and deliver such documents and other papers, as may be required to carry out the provisions of this Agreement and the Ancillary Agreements, satisfy the conditions precedent contained herein for the benefit of the other parties hereto and consummate and make effective the transactions contemplated by this Agreement and the Ancillary Agreements, including to use their commercially reasonable efforts to obtain all requisite consents of or waivers from Third Parties.

(b) To the extent that the execution or delivery by the Company of this Agreement or any of the Ancillary Agreements, or the performance by the Company of its obligations under this Agreement or any of the Ancillary Agreements, or the consummation of the Stock Purchase Investment, the Acquisition or any other transaction contemplated hereby or thereby causes or would cause a breach of any Company Contract, permit or right or gives any Person other than the Company the ability to terminate any such Company Contract, permit or right, the Company shall use reasonable commercial efforts to obtain as promptly as practicable the consent of any Third Parties required to prevent or cure such breach or termination.

Section 9.5 Regulatory and Other Authorizations.

(a) Subject to the following sentence with respect to filings under the HSR Act, the Sellers, the Company and the Buyer will (i) use their reasonable best efforts to obtain as promptly as reasonably practicable all authorizations, consents, orders, actions and approvals, and to make all filings with and to give all notices to all Governmental Authorities required to consummate the transactions contemplated by this Agreement, (ii) cooperate fully with the other parties hereto in promptly seeking to obtain all such authorizations, consents, orders, actions and approvals and to make all such filings and give such notices and (iii) provide such other information to any Governmental Authority as such Governmental Authority may reasonably request in connection therewith. Following the exercise of the Buyer's Purchase Option, each party hereto agrees to make as promptly as possible (but in no event later than ten (10) Business Days after such exercise), any required filings under the HSR Act with respect to the Acquisition and to supply as promptly as reasonably practicable to the appropriate Governmental Authorities any information and documentary material that may be reasonably requested in connection with such HSR Act filings. Each of the Company and the Buyer will pay half of any fees associated with any filings under the HSR Act in connection with this Agreement. The Company will pay all other fees or make other payments provided for under Legal Requirements to any Governmental Authority in order to obtain any such authorizations, consents, orders or approvals.

(b) Notwithstanding any provision of this Agreement to the contrary, in no event shall the Buyer or any of its Affiliates be required to agree to divest, abandon, license, hold separate or take similar action with respect to any assets of the Company or the Buyer or any Affiliate thereof.

(c) During the Pre-Closing Period, (1) the Company and the Buyer will each promptly notify the other party of any communication that it or any of its Affiliates receives from any Governmental Authority relating to the matters that are the subject of this Agreement and permit, when practicable, the other party to review in advance any proposed communication by such party to any Governmental Authority, (2) neither the Company nor the Buyer will agree to participate in any meeting with any Governmental Authority in respect of any filings, investigation (including any settlement of the investigation), litigation, or other inquiry until it consults with the other party in advance and, to the extent permitted by such Governmental Authority, gives the other party the opportunity to attend and participate at such meeting, (3) the Company and Buyer will coordinate and cooperate fully with each other in exchanging such information and providing such assistance as the other party may reasonably request in connection with the foregoing and in seeking early termination of any applicable waiting periods, including under the HSR Act and (4) the Company and the Buyer will provide each other with copies of all correspondence, filings or communications between them or any of their representatives, on the one hand, and any Governmental Authority or members of its staff, on the other hand, with respect to this Agreement and the transactions contemplated by this Agreement; provided, however, that materials may be redacted (w) to remove references concerning the valuation of the Company Shares or the business of the Company, (x) as necessary to comply with contractual arrangements, (y) as necessary to address reasonable privilege or confidentiality concerns and (z) as necessary to address competitive or regulatory concerns; however, both parties shall assess on a case-by-case basis in good faith whether the redacted information may be exchanged between outside competition counsel for the purpose of any merger control proceedings.

(d) The Buyer and the Company will, or will cause their respective Affiliates to, notify their respective employees in respect of whom notification is required under applicable Legal Requirements or by contract of the transactions contemplated by this Agreement and the Ancillary Agreements.

Section 9.6 Notifications.

During the Pre-Closing Period or at any time following the written request of another party hereto, each party hereto will promptly notify the other party (provided that notice to or from the Representative shall be deemed notice to or from all Sellers) in writing of any fact, change, condition, circumstance or occurrence or nonoccurrence of any event of which it is aware that will or is reasonably likely to result in any of the conditions for the benefit of another party set forth in Article 10, as applicable, of this Agreement becoming incapable of being satisfied; provided, however, that the delivery of any notice pursuant to this Section 9.6 will not limit or otherwise affect the representations, warranties, covenants or agreements of the parties (or remedies with respect thereto) or the conditions to the obligations of the parties under this Agreement.

Section 9.7 Limitation on Purchases and Sales of Common Shares.

(a) Except as provided in Section 9.7(b), except for the Investment Shares, during the Pre-Closing Period, neither the Company, the Sellers, nor the Buyer shall issue (in the case of the Company), buy, sell or otherwise subject to a security interest, pledge, hypothecation, mortgage or lien, (or enter into any hedging arrangement or derivative transaction with respect to) any Company Shares (or any other securities of the Company), nor shall any of them register, request registration of or take any action to begin the process of registering Company Shares for sale pursuant to a registration statement filed with the SEC.

(b) The restrictions in Section 9.7(a) shall not apply to:

(1) the grant after the Signing Date of equity awards under the Company's 2017 Stock Incentive Plan that are available and unissued as of the Signing Date in the aggregate amount set forth on Schedule 9.7(b); provided that any recipient of such equity award shall be required to become a party to this Agreement by executing and delivering the Adoption Agreement attached to this Agreement as Exhibit J (the "Adoption Agreement"), upon which such Person shall thereafter be deemed a Seller for all purposes under this Agreement (including Section 4.2);

(2) transfers of Company Shares to the Company as forfeitures to satisfy tax withholding and remittance obligations of the applicable equityholder in connection with the vesting or exercise of equity awards granted pursuant to any Company Employee Plan, or pursuant to a net exercise or cashless exercise by the applicable equityholder of outstanding equity awards pursuant to any Company Employee Plan;

(3) transfers of any equity of the Company by any Person (other than the Company) to an Affiliate of such Person; provided that any recipient of such equity shall be required to become a party to this Agreement by executing and delivering the Adoption Agreement, upon which such Person shall thereafter be deemed a Seller for all purposes under this Agreement;

(4) the transfer of any equity of the Company by gift, by will or intestate succession, or pursuant to a court approved divorce settlement; provided that any recipient of such equity shall be required to become a party to this Agreement by executing and delivering the Adoption Agreement, upon which such Person shall thereafter be deemed a Seller for all purposes under this Agreement; and

(5) the sale by Sellers of Common Shares during the 90 day-period beginning on the Signing Date on the same terms and conditions as the Stock Purchase Investment to purchasers who do not conduct business in the biopharmaceutical industry; provided that any recipient of such Common Shares shall be required to become a party to this Agreement by executing and delivering the Adoption Agreement, upon which such Person shall thereafter be deemed a Seller for all purposes under this Agreement; provided further, that the parties hereto acknowledge that any sale by Fortress is subject to the co-sale rights of Columbia set forth in the Columbia SPA.

Section 9.8 Directors' and Officers' Indemnification and Insurance.

(a) The Buyer agrees that all rights to indemnification, advancement of expenses and exculpation by the Company now existing in favor of each Person who is now, or has been at any time prior to the Signing Date or who becomes prior to the Acquisition Closing an officer or director of the Company (each an "Indemnified Person") as provided in the certificate of incorporation (including any certificate of designations) or by-laws of the Company, in each case as in effect on the Signing Date, or pursuant to any other contracts in effect on the Signing Date, shall survive the Acquisition Closing and shall remain in full force and effect in accordance with their terms, and, in the event that any proceeding is pending or asserted or any claim made during such period, until the final disposition of such proceeding or claim.

(b) For six (6) years after the Acquisition Closing, to the fullest extent permitted under applicable law, the Buyer and the Company (the "Indemnifying Persons") shall indemnify, defend, and hold harmless each Indemnified Person against all losses, claims, damages, liabilities, fees, expenses, judgments, and fines arising in whole or in part out of actions or omissions in their capacity as such occurring at or prior to the Acquisition Closing (including in connection with the transactions contemplated by this Agreement), and shall reimburse each Indemnified Person for any legal or other expenses reasonably incurred by such Indemnified Person in connection with investigating or defending any such losses, claims, damages, liabilities, fees, expenses, judgments, and fines as such expenses are incurred, subject to the Company's receipt of an undertaking by such Indemnified Person to repay such legal and other fees and expenses paid in advance if it is ultimately determined in a final and non-appealable judgment of a court of competent jurisdiction that such Indemnified Person is not entitled to be indemnified under applicable Legal Requirements; provided, however, that the Buyer and the Company will not be liable for any settlement effected without the Buyer's prior written consent (which consent shall not be unreasonably withheld, conditioned, or delayed).

(c) The Company shall, and the Buyer shall cause the Company to: (i) maintain in effect for a period of six (6) years after the Acquisition Closing, if available, the current policies of directors' and officers' liability insurance maintained by the Company immediately prior to the Acquisition Closing (provided, that the Company may substitute therefor policies, of at least the same coverage and amounts and containing terms and conditions that are not less advantageous to the directors and officers of the Company when compared to the insurance maintained by the Company as of the Signing Date); or (ii) obtain as of the Acquisition Closing "tail" insurance policies with a claims period of six (6) years from the Acquisition Closing with at least the same coverage and amounts and containing terms and conditions that are not less advantageous to the directors and officers of the Company, in each case with respect to claims arising out of or relating to events which occurred before or at the Acquisition Closing (including in connection with the transactions contemplated by this Agreement); provided, however, that in no event will the Buyer or the Company be required to expend an annual premium for such coverage in excess of 200 percent of the last annual premium paid by the Company for such insurance prior to the Signing Date, which amount is determined in accordance with Schedule 9.8 (the "Maximum Premium"). If such insurance coverage cannot be obtained at an annual premium equal to or less than the Maximum Premium, the Company will obtain, and Buyer will cause the Company to obtain, that amount of directors' and officers' insurance (or "tail" coverage) obtainable for an annual premium equal to the Maximum Premium.

(d) The obligations of the Buyer and the Company under this Section 9.8 shall survive the consummation of the Acquisition and shall not be terminated or modified in such a manner as to adversely affect any Indemnified Person to whom this Section 9.8 applies without the consent of such affected Indemnified Person (it being expressly agreed that the Indemnified Persons to whom this Section 9.8 applies shall be third party beneficiaries of this Section 9.8, each of whom may enforce the provisions of this Section 9.8).

(e) In the event that, after the Buyer, the Company or any of their respective successors or assigns: (i) consolidates with or merges into any other Person and shall not be the continuing or surviving corporation or entity in such consolidation or merger; or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in either such case, proper provision shall be made so that the successors and assigns of the Buyer or the Company, as the case may be, shall assume all of the obligations set forth in this Section 9.8. The agreements and covenants contained herein shall not be deemed to be exclusive of any other rights to which any Indemnified Person is entitled, whether pursuant to applicable Legal Requirements, Contract, or otherwise. Nothing in this Agreement is intended to, shall be construed to or shall release, waive, or impair any rights to directors' and officers' insurance claims under any policy that is or has been in existence with respect to the Company or its officers, directors, and employees, it being understood and agreed that the indemnification provided for in this Section 9.8 is not prior to, or in substitution for, any such claims under any such policies.

Section 9.9 Anti-Dilution. If during the Pre-Closing Period, either the Sellers or the Company take any action (whether or not permitted by this Agreement) that would reduce the Buyer's equity interest in the Company below 19.9% of the Fully Diluted Capitalization as of such time, then the Company shall issue the requisite number of Class B Preferred Shares to the Buyer to increase the Buyer's equity interest in the Company to 19.9% of the Fully Diluted Capitalization.

Section 9.10 Tax Matters.

(a) Transfer Taxes arising from the Acquisition shall be borne by the Sellers. "Transfer Taxes" means all sales, use, real property transfer, real property gains, transfer, stamp, registration, documentary, recording or similar Taxes, together with any interest thereon, penalties, fines, costs, fees or additions to Tax. If the Buyer is required to file any Tax Return related to Transfer Taxes, the Buyer shall file such Tax Return and pay any Transfer Taxes and the applicable Sellers shall reimburse the Buyer for its share of Transfer Taxes within ten (10) days of written request.

(b) At or prior to the Acquisition Closing, the Company shall deliver to the Buyer (or its designee) a certificate(s), duly executed and acknowledged, in form and substance reasonably satisfactory to the Buyer, certifying that transaction is exempt from withholding under Section 1445 of the Code in accordance with Treasury Regulations under Sections 897 and 1445 of the Code, together with evidence reasonably satisfactory to the Buyer that the Company has provided notice, if applicable, to the Internal Revenue Service in accordance with the provisions of Treasury Regulations Section 1.897-2(h)(2). If the Buyer (or its designee) does not receive the certification and evidence of filing of the notice as described above at or prior to the Acquisition Closing, the Buyer shall be permitted to withhold from the payments to be made pursuant to this Agreement any required withholding Tax under Section 1445 of the Code.

(c) During the Pre-Closing Period: (i) the Company shall prepare and timely file, or cause to be prepared and timely filed, all Tax Returns of the Company that are required to be filed prior to or on the date of the Acquisition Closing and such Tax Returns shall be complete and correct in all material respects and shall be prepared in a manner consistent with past practices of the Company and that does not distort taxable income; provided that no such Tax Returns shall be filed with any Governmental Authority without the Buyer's prior written consent; (ii) the Company shall timely pay all Taxes due and payable in respect of such Tax Returns, except for Taxes that are being contested in good faith through appropriate proceedings and for which appropriate reserves have been established on the books of the Company; (iii) the Company shall promptly notify the Buyer of written or, to the knowledge of the Company, unwritten notice of any Tax Proceeding pending against or with respect to the Company and will not settle or compromise any such Tax Proceeding without the Buyer's prior written consent; and (iv) the Company shall not, without the prior written consent of the Buyer, make, revoke or change any Tax election, adopt or change (or request with any Governmental Authority to change) any material aspect of any Tax accounting method or period, file any amended Tax Return, enter into any closing agreement or settlement, settle or compromise any Tax claim or assessment, surrender any right to claim a refund of Taxes, consent to any extension or waiver of the statute of limitations period applicable to any Tax claim or assessment, or take any other action or omit to take any reasonable action, if any such election, adoption, change, amendment, agreement, settlement, surrender, consent or other action or omission could have the effect of increasing the Tax liability of the Buyer or any of its Affiliates (including, after the Closing, the Company) or reducing any net operating loss, net capital loss, investment Tax credit, foreign Tax credit, charitable deduction or any other credit or Tax attribute which could reduce Taxes (including, without limitation, deductions and credits related to alternative minimum Taxes) of the Buyer or any of its Affiliates (including, after the Closing, the Company), without the prior written consent of the Buyer.

(d) All Taxes of the Company relating to any Tax period that begins on or before and ends after the date of the Acquisition Closing (such Tax period, a "Straddle Period") shall be apportioned to, and be the responsibility of, the Sellers as follows: (i) real, personal and intangible property taxes ("Property Taxes") for the portion of the Straddle Period ending on (and including) the date of the Acquisition Closing shall be equal to the amount of such Property Taxes for the entire Straddle Period multiplied by a fraction, the numerator of which is the number of days during the Straddle Period that are in the portion of the Straddle Period ending on (and including) the Closing Date and the denominator of which is the total number of days in the Straddle Period; and (ii) Taxes (other than Property Taxes) for the portion of the Straddle Period shall be computed as if such taxable period ended as of the close of business on the date of the Acquisition Closing, provided that exemptions, allowances, deductions that are calculated on an annual or other periodic basis (including, but not limited to, depreciation and amortization deductions) shall be allocated between the period ending as of the close of business on the date of the Acquisition Closing and the period after the date of the Acquisition Closing in proportion to the number of days in each such period. For purposes of allocating income or loss to a Tax period (or portion thereof, if a Straddle Period) ending on or before the date of the Acquisition Closing, in the case of any Taxes attributable to the ownership of any equity interest in any partnership or other "flow-through" entity, the "flow-through" income or loss attributable to an equity interest in such "flow-through" entity shall be determined as if a taxable period of such partnership or other "flow-through" entity ended as of the close of business on the date of the Acquisition Closing.

(e) Any and all Tax sharing, Tax allocation, Tax indemnity or similar agreements, arrangements, or practices (including any advance pricing agreement, closing agreement or other similar written agreement relating to Taxes with any Governmental Authority) to which the Company is a party or otherwise subject shall be terminated as of the date of the Acquisition Closing and after that date none of the Buyer or any Affiliate of the Buyer, including the Company, shall be bound thereby, have any liability thereunder, or be obligated to make any payment thereunder.

(f) On or before the date of the Acquisition Closing, the Company and the Representative shall provide the Buyer, and any other Person designated by the Buyer, the information described under Treasury Regulations Section 1.6045A-1 with respect to the Company securities being acquired pursuant to the Acquisition, including (i) whether or not a particular security is a "covered security" under the applicable Treasury Regulations and (ii) if a security is a "covered security", each security holder's date of acquisition of, and cost basis in, the applicable security, and any other information that is required, or reasonably requested, by Buyer or its designee to comply with the Buyer or its designee's tax reporting obligations under the Code and Treasury Regulations, including IRS Form 1099-B reporting requirements.

(g) The Buyer, the Sellers and the Representative, as the case may be, shall reasonably cooperate, and shall cause their respective Affiliates, directors, officers, employees, agents, auditors and other representatives to reasonably cooperate, in preparing and filing all Tax Returns and in resolving all disputes and audits with respect to all taxable periods relating to Taxes, including by maintaining and making available to each other all records reasonably necessary in connection with Taxes and making employees available on a mutually convenient basis to provide additional information or explanation of any material provided hereunder or to testify at proceedings relating to such matters. The Representative further agrees that (i) if the Buyer determines that IRS Form 1099-B or IRS Form 1099-INT reporting is required in connection with the transactions contemplated by this Agreement, the Representative shall provide such information and assistance to the Buyer as is required for any such Forms to be properly completed and timely issued, and (ii) the Representative shall not undertake any tax reporting on IRS Form 1099-B or IRS Form 1099-INT with respect to the transactions contemplated by this Agreement without prior consultation and approval of the Buyer, in which case the form and substance of such reports shall be subject to the written approval of the Buyer prior to issuance.

Section 9.11 Payoff Letters. The Company shall obtain, no later than two (2) Business Days prior to the Acquisition Closing, payoff letters (the "Payoff Letters") in form reasonably satisfactory to Buyer from the holders (or the agents for such holders) of any Indebtedness of the Company as of immediately prior to the Acquisition Closing, and all documents related thereto (including any credit agreements, pledge agreements, security agreements, notes and guarantees) and all Encumbrances securing such Indebtedness shall be released or terminated upon the repayment of such Indebtedness in accordance with the terms of such payoff letters. Each Payoff Letter shall set forth the principal amount of the obligation, any prepayment premiums or fees or termination fees with respect thereto, any accrued interest thereon and any expense reimbursement or other amounts due in respect thereof, shall provide wire instructions and shall provide for the release of, or authorize the Company to release, all Encumbrances associated with such Indebtedness and the termination of all other obligations associated therewith upon the payment of such outstanding amounts.

Section 9.12 Additional Investor Rights. If the Company issues securities after the Signing Date that (a) have rights, preferences or privileges that are more favorable than the terms of the Class B Preferred Shares or (b) provide the applicable investors other contractual terms such as registration rights, the Company shall provide substantially equivalent rights to the Buyer with respect to the Class B Preferred Shares, subject to the Buyer's execution of any documents, including, if applicable, investor rights, co-sale, voting, and other agreements, executed by the investors purchasing such securities.

Section 9.13 Patent Application Prosecutions. During the Pre-Closing Period, the Company shall keep the Buyer reasonably informed with regard to the prosecution of any Company Patent applications (including submitting for discussion and comments any preparatory documents in relation thereto) and shall consult with and consider in good faith the Buyer's comments, requests and suggestions with respect to such documents and strategies for prosecuting any such Company Patent applications.

Section 9.14 Key License Agreement. During the Pre-Closing Period, the Company will maintain the Key License Agreement in full force and effect and shall not breach or default on any of the provisions set forth therein. The Company will not amend the Key License Agreement without the advance written consent of the Buyer. The Company will promptly inform the Buyer in the event of any breach or suspected breach of the Key License Agreement by any party.

Section 9.15 Information Rights.

(a) As soon as practicable, but in any event within ninety (90) days after the end of each fiscal year of the Company, the Company shall provide the Buyer (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and (iii) a statement of stockholders' equity as of the end of such year, all such financial statements audited and certified by independent public accountants of nationally recognized standing.

(b) As soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, the Company shall provide the Buyer unaudited statements of income and cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of stockholders' equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments; and (ii) not contain all notes thereto that may be required in accordance with GAAP).

ARTICLE 10.
CONDITIONS PRECEDENT, WAIVER, AND TERMINATION PROVISIONS OF THE ACQUISITION

Section 10.1 Conditions Precedent to Performance of the Parties. The obligations of the parties to consummate the Acquisition are subject to fulfillment, at or prior to the Acquisition Closing, of each of the following conditions:

(a) Exercise of Purchase Option: The Buyer shall have exercised its Purchase Option pursuant to Section 2.3;

(b) Regulatory Requirements: Any applicable waiting period (and any extension thereof) under the HSR Act will have expired or terminated early; and

(c) No Order: No Governmental Authority will have enacted, issued, enforced or entered into any statute, rule, regulation, injunction or other order that is in effect and has the effect of making the Acquisition illegal or otherwise restraining or prohibiting its consummation.

Section 10.2 Conditions Precedent to Performance of the Sellers and the Company. The obligations of the Sellers and the Company to consummate the Acquisition will be subject to the fulfillment or written waiver, at or prior to the Acquisition Closing, of the following conditions:

(a) Agreements and Covenants: The agreements and covenants contained in this Agreement and the Ancillary Agreements to be complied with by the Buyer on or before the Acquisition Closing shall have been complied with in all material respects; and

(b) Accuracy of Representations and Warranties: The representations and warranties of the Buyer contained in Article 6 shall be true and correct in all material respects as of the Acquisition Closing with the same effect as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such date).

Section 10.3 Conditions Precedent to Performance of Buyer. The obligations of the Buyer to consummate the Acquisition will be subject to the fulfillment or written waiver, at or prior to the Acquisition Closing, of the following conditions:

(a) Agreements and Covenants: The agreements and covenants contained in this Agreement and the Ancillary Agreements (other than those to be performed by the Buyer) to be complied with on or before the Acquisition Closing shall have been complied with in all material respects;

(b) Accuracy of Representations and Warranties: (x) the Fundamental Representations shall be true and correct in all respects as of the Signing Date and as of the date of the Acquisition Closing with the same effect as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such date), and (y) all other representations and warranties of the Company and the Sellers contained in this Agreement shall be true and correct (disregarding all qualifications and exceptions contained therein relating to materiality, Material Adverse Effect, or any similar standard or qualification) in all material respects as of the Signing Date and as of the date of the Acquisition Closing with the same effect as if made at and as of such time (except to the extent expressly made as of an earlier date, in which case as of such date);

(c) Material Adverse Effect: Since the Signing Date, no Material Adverse Effect shall have occurred and no event shall have occurred that is reasonably likely to have a Material Adverse Effect;

(d) The Buyer shall have received a certificate dated the date of the Acquisition Closing and signed by the Representative (on behalf of the Sellers) and an authorized officer of the Company, in his or her capacity thereof, certifying that the conditions specified in Sections 10.3(a)-(c) have been satisfied;

(e) The Ancillary Agreements containing rights or obligations surviving the Acquisition Closing shall be in full force and effect;

(f) The Company shall have delivered to the Buyer a resignation from each member of the Company Board and all officers of the Company, unless otherwise specified by the Buyer no later than three (3) Business Days prior to the Acquisition Closing;

(g) The release, in the form attached as Exhibit K hereto, shall have been duly executed by the Sellers and the Company and delivered to the Buyer;

(h) All authorizations, consents or approvals of any and all Governmental Authorities (except as contemplated by Section 10.1(b)) and third parties necessary for the consummation of the transactions contemplated hereby shall have been obtained and be in full force and effect;

(i) The Buyer shall have received the Payoff Letters in accordance with Section 9.11;

(j) The Sellers shall have delivered to the Buyer a certificate dated as of the Acquisition Closing pursuant to Treasury Regulations Section 1.1445-2(b) in form and substance reasonably satisfactory to the Buyer, certifying that none of them are foreign persons within the meaning of Section 1445 of the Code;

(k) The Company shall have delivered to the Buyer a certificate evidencing the good standing of the Company in its jurisdiction of incorporation as of a recent date;

(l) The Company shall have delivered to the Buyer certificates evidencing the qualification of the Company to do business as a foreign corporation as of a recent date in each jurisdiction outside of its jurisdiction of organization where it conducts business; and

(m) The Company and the Sellers shall have delivered to the Buyer all other certificates, documents and instruments that are reasonably requested by the Buyer.

Section 10.4 Waiver; Determination of Satisfaction of Conditions. The Representative may waive all or any of the conditions set forth in Section 10.2 and the Buyer may waive all or any of the conditions set forth in Section 10.3, but neither the Buyer nor the Representative may waive the conditions set forth in Section 10.1.

Section 10.5 Termination of the Acquisition.

(a) The Acquisition may be terminated at any time after the Buyer's exercise of the Purchase Option prior to the Acquisition Closing:

(1) by the Buyer for any reason and in its sole discretion;

(2) by the Representative if the Acquisition Closing has not occurred within six (6) months after the exercise by the Buyer of its Purchase Option (the "Termination Date") because the conditions in Sections 10.1, 10.2 or 10.3 have not been met (provided, that the right to terminate this Agreement pursuant to this Section 10.5(a)(2) shall not be available to the Representative if the Company's or any Seller's breach of this Agreement has materially contributed to the failure of the Acquisition Closing to occur); provided, however, that the Termination Date shall be extended to the date that is twelve (12) months after the exercise by the Buyer of its Purchase Option if on the Termination Date the condition set forth in Section 10.1(b) has not been satisfied but all other conditions to the Acquisition Closing are satisfied or waived (other than those conditions that are by their nature to be satisfied by action taken at the Acquisition Closing);

(3) by either the Representative or the Buyer in the event that any Governmental Authority has enacted, issued, enforced or entered into any statute, rule, regulation, injunction or other order, restraining, enjoining or otherwise prohibiting the Acquisition that has become final and non-appealable; or

(4) by the mutual written consent of the Company and Buyer.

(b) The Acquisition may be terminated at any time prior to the Acquisition Closing by the Buyer for any reason and in its sole discretion after the payment of all Funding Payments contemplated by Section 2.2, or the Buyer's good faith determination, after consultation with the Representative, that no further Funding Payments shall be required to be made pursuant to Section 2.2.

ARTICLE 11.
INDEMNIFICATION

Section 11.1 Indemnification of Buyer Indemnified Parties. From and following the Acquisition Closing and subject to the limitations contained in this Article 11, each of the Buyer, the Company and their respective officers, directors, employees, agents, Affiliates, successors and assigns (each a "Buyer Indemnified Party") shall be indemnified and held harmless by the Sellers, severally and not jointly, based on each Seller's Pro Rata Share, from and against all Damages incurred by the Buyer Indemnified Parties to the extent based upon, arising out of, with respect to or by reason of:

(a) any breach of any representation or warranty of the Sellers or the Company contained in this Agreement or any Ancillary Agreement (provided that such indemnification in respect of a breach of a representation or warranty of a Seller contained in Article 7 may only be recovered against such Seller, including the portion of the Escrow Fund attributable to such Seller), in each case as such representation or warranty would read if all qualifications as to materiality, Material Adverse Effect or other similar qualification were deleted therefrom;

(b) any breach of any covenant of the Sellers or the Company contained in this Agreement or any Ancillary Agreement; or

(c) any (i) Taxes of the Company for all Tax periods ending on or before the date of the Acquisition Closing and for the portion of any Straddle Period ending on the date of the Acquisition Closing as determined pursuant to Section 9.10(d), (ii) any Transfer Taxes, (iii) any Taxes imposed on the Company (or any successor thereto), (A) as a transferee or successor, (B) pursuant to any Contract or other relationship existing at any time prior to the Acquisition Closing, or (C) as a result of the provisions of Treasury Regulation Section 1.1502-6 or the analogous provisions of any state, local or foreign Legal Requirements; (iv) Taxes related to any untaxed foreign earnings pursuant to Section 965 of the Code; (v) Taxes due to any inaccuracy of a representation or warranty in this Agreement related to Taxes; (vi) Taxes attributable to the failure by the Company or any Seller to perform any covenant or agreement in this Agreement relating to Taxes or any inaccuracy in any certificate, instrument or agreement delivered by or on behalf of the Company or any Seller pursuant to this Agreement relating to Taxes; and (vii) withholding Taxes attributable to payments made to any Seller under this Agreement (for which the applicable Seller shall indemnify the Buyer Indemnified Parties).

(d) Any breach of Section 5.18 or Section 7.6.

Section 11.2 Indemnification of Seller Indemnified Parties. From and following the Acquisition Closing and subject to the limitations contained in this Article 11, each of the Sellers and their respective officers, directors, employees, agents, Affiliates, successors and assigns (each a "Seller Indemnified Party") shall be indemnified and held harmless by the Buyer from and against all Damages incurred by the Seller Indemnified Parties to the extent based upon, arising out of, with respect to or by reason of:

(a) any breach of any representation or warranty of the Buyer contained in this Agreement or any Ancillary Agreement, in each case as such representation or warranty would read if all qualifications as to materiality or material adverse effect or other similar qualification were deleted therefrom; or

(b) any breach of any covenant of the Buyer contained in this Agreement or any Ancillary Agreement.

Section 11.3 Indemnification Procedures.

(a) The party making a claim under this Article 11 is referred to as the "Indemnified Party" and the party against whom such claims are asserted under this Article 11 is referred to as the "Indemnifying Party". For purposes of this Article 11, (i) if any Buyer Indemnified Party comprises the Indemnified Party, any references to Indemnifying Party (except provisions relating to an obligation to make payments) shall be deemed to refer to the Representative (on behalf of the Sellers), and (ii) if the Buyer comprises the Indemnifying Party, any references to the Indemnified Party shall be deemed to refer to the Representative. Any payment received by the Representative as the Indemnified Party shall be distributed to the Sellers in accordance with this Agreement. If any Indemnified Party receives written notice of the commencement of any action or proceeding or the assertion of any claim by a third party or the imposition of any penalty or assessment for which a claim for indemnification may be made under this Article 11 (a "Third Party Claim") or otherwise discovers the liability, obligation or facts giving rise to such claim for indemnity, and such Indemnified Party intends to seek indemnity pursuant to this Article 11, such Indemnified Party shall promptly provide the Indemnifying Party with written notice of such Third Party Claim, stating the nature, basis and the amount thereof, to the extent known, along with copies of the relevant documents evidencing such Third Party Claim and the basis for indemnification sought. Failure of the Indemnified Party to give such notice will not prohibit such Indemnified Party from seeking indemnification hereunder, except if and to the extent that the Indemnifying Party is materially prejudiced thereby. The Indemnifying Party shall be entitled to participate in the defense of a Third Party Claim and, to the extent that it wishes, to assume the defense of a Third Party Claim, if, within thirty (30) days from receipt of any such notice of a Third Party Claim, the Indemnifying Party provides written notice to the Indemnified Party that the Indemnifying Party intends to undertake such defense; provided, however, that if the Third Party Claim (x) involves a Governmental Authority, potential criminal liability or is reasonably likely to have a material adverse effect on any other matter beyond the scope or limits of the indemnification obligation of the Indemnifying Party or (y) seeks specific performance or injunctive or other equitable relief, then the Indemnified Party shall be entitled to assume and control the defense of such Third Party Claim by providing written notice to the Indemnifying Party. If the Indemnifying Party has assumed the defense of such Third Party Claim, the Indemnified Party shall have the right to employ separate counsel in any such action and to participate in (but not control) the defense thereof. The fees and disbursements of such counsel shall be at the expense of the Indemnified Party, provided that if in the reasonable opinion of counsel to the Indemnified Party, (A) there are legal defenses available to an Indemnified Party that are different from or additional to those available to the Indemnifying Party; or (B) there exists a conflict of interest between the Indemnifying Party and the Indemnified Party that cannot be waived, the Indemnifying Party shall be liable for the reasonable fees and expenses of counsel to the Indemnified Party in each jurisdiction for which the Indemnified Party reasonably determines counsel is required. If the Indemnifying Party elects not to compromise or defend such Third Party Claim, fails to promptly notify the Indemnified Party in writing of its election to defend as provided in this Agreement, or fails to diligently prosecute the defense of such Third Party Claim, the Indemnified Party may, subject to Section 11.3(b), pay, compromise, defend such Third Party Claim and seek indemnification for any and all Damages based upon, arising from or relating to such Third Party Claim. The Representative and the Buyer shall cooperate with each other in all reasonable respects in connection with the defense of any Third Party Claim, including making available records relating to such Third Party Claim and furnishing, without expense (other than reimbursement of actual out-of-pocket expenses) to the defending party, management employees of the non-defending party as may be reasonably necessary for the preparation of the defense of such Third Party Claim.

(b) Notwithstanding any other provision of this Agreement, the Indemnifying Party shall not enter into settlement of any Third Party Claim without the prior written consent of the Indemnified Party, except as provided in this Section 11.3(b). If a firm offer is made to settle a Third Party Claim without leading to liability or the creation of a financial or other obligation on the part of the Indemnified Party and provides, in customary form, for the unconditional release of each Indemnified Party from all liabilities and obligations in connection with such Third Party Claim and the Indemnifying Party desires to accept and agree to such offer, the Indemnifying Party shall give written notice to that effect to the Indemnified Party. If the Indemnified Party fails to consent to such firm offer within ten (10) days after its receipt of such notice, the Indemnified Party may continue to contest or defend such Third Party Claim and in such event, the maximum liability of the Indemnifying Party as to such Third Party Claim shall not exceed the amount of such settlement offer. If the Indemnified Party fails to consent to such firm offer and also fails to assume defense of such Third Party Claim, the Indemnifying Party may settle the Third Party Claim upon the terms set forth in such firm offer to settle such Third Party Claim. If the Indemnified Party has assumed the defense pursuant to Section 11.3(a), it shall not agree to any settlement without the written consent of the Indemnifying Party (which consent shall not be unreasonably withheld or delayed).

(c) This Section 11.3(c) and not Section 11.3(a) or Section 11.3(b) shall apply with respect to Tax Claims. After the Acquisition Closing, the Buyer Indemnified Party and the Representative shall promptly notify the other party in writing upon receipt (in the case of the Representative, by either the Representative or any Seller) of any written notice of any pending or threatened audit or assessment, suit, proposed adjustment, deficiency, dispute, administrative or judicial proceeding or similar claim relating to Taxes with respect to damages for which a Buyer Indemnified Party may be indemnified under this Agreement (a "Tax Claim"). Failure of the Buyer Indemnified Party to give such notice will not prohibit such Buyer Indemnified Party from seeking indemnification hereunder, except if and to the extent that the Representative, acting on behalf of the Sellers, is materially prejudiced thereby. The Buyer Indemnified Party will control, without affecting its or any other Indemnified Person's rights to indemnification under this Agreement, the defense of all Tax Claims; provided, however, that the Representative and its counsel (at the Representative's sole expense) may participate in (but not control the conduct of) the defense of any such Tax Claim, and provided further that the Buyer Indemnified Party may not settle or compromise any Tax Claim relating to a taxable period that ends on or before the date of the Acquisition Closing or, with respect to any Straddle Period, the portion of such taxable period ending on and including the date of the Acquisition Closing, without the Representative's consent (not to be unreasonably withheld, conditioned or delayed).

(d) Any claim by an Indemnified Party on account of a Damage which does not result from a Third Party Claim or Tax Claim (a "Direct Claim") shall be asserted by the Indemnified Party giving the Indemnifying Party reasonably prompt written notice thereof, but in any event not later than thirty (30) days after the Indemnified Party becomes aware of such Direct Claim. The failure to give such prompt written notice shall not, however, relieve the Indemnifying Party of its indemnification obligations, except and only to the extent that the Indemnifying Party is materially prejudiced thereby. Such notice by the Indemnified Party shall state the nature, basis and the amount of the Direct Claim, to the extent known, along with copies of the relevant documents evidencing such Direct Claim and the basis for indemnification sought. The Indemnifying Party shall have thirty (30) days after its receipt of such notice to respond in writing to such Direct Claim. The Indemnified Party shall allow the Indemnifying Party and its professional advisors to investigate the matter or circumstance alleged to give rise to the Direct Claim, and whether and to what extent any amount is payable in respect of the Direct Claim and the Indemnified Party shall assist the Indemnifying Party's investigation by giving such information and assistance as the Indemnifying Party or any of its professional advisors may reasonably request. If the Indemnifying Party does not so respond within such thirty (30)-day period, the Indemnifying Party shall be deemed to have agreed to such Direct Claim.

Section 11.4 Limitations on Indemnification.

(a) Notwithstanding anything in this Agreement to the contrary (and except as provided in Section 11.4(d)), (i) the Buyer Indemnified Parties shall not be entitled to assert any claim for indemnification under Section 11.1(a) unless and until the aggregate liability for Damages suffered by the Buyer Indemnified Parties thereunder exceeds one-half a percent (0.5%) of the Baseline Purchase Price (the "Threshold"); provided that in the event that the aggregate liability for Damages exceeds the Threshold, the Buyer Indemnified Parties shall be entitled to recover for all such Damages; (ii) the aggregate amount of all Damages for which the Sellers shall be liable for indemnification under Section 11.1(a) shall not exceed ten percent (10%) of the Baseline Purchase Price (the "Cap"); and (iii) the maximum aggregate liability of each Seller under Section 11.1 shall not exceed, except in the case of fraud, in the aggregate the net amount of consideration paid to such Seller hereunder.

(b) Notwithstanding anything in this Agreement to the contrary, (i) the Seller Indemnified Parties shall not be entitled to assert any claim for indemnification under Section 11.2(a) unless and until the aggregate liability for Damages suffered by the Seller Indemnified Parties thereunder exceeds the Threshold; provided, that in the event that the aggregate liability for Damages exceeds the Threshold, the Seller Indemnified Parties shall be entitled to recover for all such Damages; and (ii) the aggregate amount of all Damages for which the Buyer shall be liable for indemnification under Section 11.2(a) shall not exceed the Cap.

(c) Except as provided in Section 11.4(d), amounts payable to the Buyer Indemnified Parties as a result of any claim for indemnification under Section 11.1(a) shall, at the sole discretion of the Buyer, either (x) be set off against any Earn-Out Payments that are otherwise payable after the date of such claim or (y) be paid out of the Escrow Fund to the extent of available funds therein. Except with respect to any claim based on, arising out of, or relating to, any Fundamental Representation ("Fundamental Claim"), recovery from the Escrow Fund and set off against Earn-Out Payments shall be the sole and exclusive remedies of the Buyer Indemnified Parties for any claims for indemnification arising under Section 11.1(a).

(d) Notwithstanding any provision herein to the contrary, the restrictions and limitations set forth in Section 11.4(a)(i), Section 11.4(a)(ii) and Section 11.3(c) shall not be applicable to any claim pursuant to Section 11.1(a) to the extent arising out of a Fundamental Claim. Any amounts payable to Buyer Indemnified Parties under Section 11.1 (other than Section 11.1(a)) shall, at the option of the Buyer (x) be set off against any Earn-Out Payments that are otherwise payable after the date of such claim, (y) be paid out of the Escrow Funds to the extent of available funds therein or (z) be recoverable directly from the Sellers.

(e) The amount of any Damages that any Buyer Indemnified Party is entitled to receive pursuant to this Article 11 shall be reduced by any related recoveries which such Buyer Indemnified Party actually receives under applicable insurance policies or from any other Person alleged to be responsible for any such Damages. If a Buyer Indemnified Party actually receives any amounts under applicable insurance policies, or from any other Person alleged to be responsible for any Damages, subsequent to an indemnification payment being made by the Sellers hereunder or by set-off against an Earn-Out Payment or other payment hereunder, then such Buyer Indemnified Party shall promptly pay to the Representative for distribution to the Sellers (in accordance with their Pro Rata Share) an amount equal to such indemnification payment, up to the amount received by the Buyer Indemnified Party, net of any previously unpaid or unreimbursed expenses incurred by such Buyer Indemnified Party in collecting such amount and the aggregate increase in insurance premiums that are directly and proximately caused by such Damages.

(f) Subject to Section 12.10, each of the parties hereto hereby acknowledges and agrees that, solely to the extent that the Acquisition Closing occurs, its sole and exclusive remedy with respect to any and all claims and Damages relating to or arising from this Agreement or the transactions contemplated hereby (other than claims of, or causes of action arising from, fraud) shall be governed by, and subject to, the terms and provisions set forth in this Article 11.

Section 11.5 Survival of Representations, Warranties and Covenants. Subject to the limitations and other provisions of this Agreement, the representations and warranties contained herein shall survive the Investment Closing and the Acquisition Closing and shall remain in full force and effect until the date that is two (2) years after the date of the Acquisition; provided, that the Fundamental Representations shall survive for the full period of all applicable statutes of limitations (giving effect to any waiver, mitigation or extension thereof) plus sixty (60) days; provided, further, that the representations and warranties and covenants contained in Section 5.18 and Section 7.6 shall survive indefinitely. All other covenants and agreements of the parties contained herein shall survive the Investment Closing and the Acquisition Closing indefinitely or for the period explicitly specified therein. Notwithstanding the foregoing, any claims asserted in good faith with reasonable specificity (to the extent known at such time) and in writing by notice from the Indemnified Party to the Indemnifying Party prior to the expiration date of the applicable survival period, or within sixty (60) days after the applicable survival period in the case of indemnification under Section 11.1(c), shall not thereafter be barred by the expiration of the relevant representation or warranty and such claims shall survive until finally resolved.

Section 11.6 Effect of Investigation. The representations, warranties and covenants of the Indemnifying Party, and the Indemnified Party's right to indemnification with respect thereto, shall not be affected or deemed waived by reason of any investigation made by or on behalf of the Indemnified Party (including by any of its representatives) or by reason of the fact that the Indemnified Party or any of its representatives knew or should have known that any such representation or warranty is, was or might be inaccurate or by reason of the Indemnified Party’s waiver of any condition set forth in Section 10.2 or Section 10.3, as the case may be.

Section 11.7 Tax Treatment of Indemnification Payments. All indemnification payments made under this Agreement shall be treated by the parties as an adjustment to the applicable purchase price for Tax purposes, unless otherwise required by Legal Requirement.

ARTICLE 12.
MISCELLANEOUS

Section 12.1 Entire Agreement. This Agreement and the Ancillary Agreements, together with the Schedules and all other documents referred to herein, constitute the entire agreement between the parties with respect to the subject matter of this Agreement and the Ancillary Agreements and supersede any and all prior agreements, negotiations, correspondence, undertakings, understandings and communications of the parties with respect to the subject matter of this Agreement and the Ancillary Agreements, with the exception of the mutual confidentiality agreement between the Company and the Buyer, dated July 19, 2017 (the “Confidentiality Agreement”), to which Section 12.8 applies. Nothing contained in this Agreement shall be deemed or construed as creating a joint venture or partnership between any of the parties hereto.

Section 12.2 Transaction Costs. Except as otherwise provided herein, the parties to this Agreement will pay their own costs and expenses (including legal, accounting and other fees) relating to this Agreement.

Section 12.3 Modifications. Any amendment or modification to this Agreement, including this undertaking itself, shall only be valid if effected by an instrument or instruments in writing and shall be effective against each of the parties hereto that has signed such instrument or instruments. The parties agree that they jointly negotiated and prepared this Agreement and the Ancillary Agreements and that neither this Agreement nor any Ancillary Agreement will be construed against any party on the grounds that such party prepared or drafted the same.

Section 12.4 Notices.

Notices will be deemed to have been received (a) upon receipt of a registered letter, (b) three (3) Business Days following proper deposit with an internationally recognized express overnight delivery service, or (c) in the case of transmission by email, as of the date so transmitted (or if so transmitted after normal business hours at the place of the recipient, on the Business Day following such transmission):

If to the Company:

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Attn: *
Email: *

With a copy (which shall not constitute notice) to:

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Attn: *
Email: *

If to Buyer:

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Attn: *
Email: *

With a copy (which shall not constitute notice) to:

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Attn: *
Email: *

If to the Representative:

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Attn: *
Email: *

With a copy (which shall not constitute notice) to:

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Attn: *
Email: *

or to such other address as may be hereafter communicated in writing by the parties in a notice given in accordance with this Section 12.4.

Section 12.5 Public Announcements. Except as required by Legal Requirements or by the requirements of any stock exchange on which the securities of a party hereto or any of its Affiliates are listed, no party to this Agreement will make, or cause to be made, any press release or public announcement in respect of this Agreement, the Ancillary Agreements or the transactions contemplated hereby or thereby or otherwise communicate with any news media with respect to the foregoing without prior notification to the other parties, and the parties to this Agreement will consult with each other and cooperate as to the form, timing and contents of any such press release, public announcement or disclosure.

Section 12.6 Severability. Each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Legal Requirements, but if any provision of this Agreement is found to be unenforceable or invalid under applicable Legal Requirements, such provision will be ineffective only to the extent of such unenforceability or invalidity, and the parties will negotiate in good faith to modify this Agreement so that the unenforceable or invalid provision is replaced by such valid and enforceable provision which the parties consider, in good faith, to match as closely as possible the invalid or unenforceable provision and to achieve the same or a similar economic effect and to give effect to the parties' original intent. The remaining provisions of this Agreement will continue to be binding and in full force and effect.

Section 12.7 Assignment. No party hereto may assign, in whole or in part, or delegate all or any part of its rights, interests or obligations under this Agreement without the prior written consent of the other party. Any assignment or delegation made without such consent will be void. Notwithstanding the foregoing, the Buyer shall be entitled to (a) assign its rights under this Agreement to any one of its Affiliates and (b) assign any or all of its rights and obligations under this Agreement (in whole or in part) as collateral security in a financing transaction; provided that no such assignment shall release the Buyer from its obligations under this Agreement.

Section 12.8 Confidentiality Agreement. The terms of the Confidentiality Agreement are hereby incorporated herein by reference and will continue in full force and effect until expiration or termination in accordance with the terms therein.

Section 12.9 Governing Law. This Agreement, any claims or causes of action pursuant to it, and the transactions contemplated hereby will be governed by and construed in accordance with the laws of the State of Delaware, without regard for its principles of conflict of laws.

Section 12.10 Specific Performance. Each party acknowledges and agrees that the other party would be irreparably damaged if the provisions of this Agreement are not performed in accordance with their terms and that any breach of this Agreement and the non-consummation of the transactions contemplated hereby by either party could not be adequately compensated in all cases by monetary damages alone. Accordingly, in addition to any remedy to which such other party may be entitled under Section 12.11, provisional measures and injunctive relief necessary to protect the ability of each party to seek specific performance from the other from the tribunal referred to in Section 12.11 can be sought from any court of competent jurisdiction. Each of the parties hereto (i) agrees that it shall not oppose the granting of any such relief and (ii) hereby irrevocably waives any requirement for the security or posting of any bond in connection with any such relief (it is understood that clause (i) of this sentence is not intended to, and shall not, preclude any party hereto from litigating on the merits the substantive claim to which such remedy relates).

Section 12.11 Submission to Jurisdiction. Each of the parties hereto irrevocably agrees that any Proceeding with respect to this Agreement and the rights and obligations arising hereunder, or for recognition and enforcement of any judgment in respect of this Agreement and the rights and obligations arising hereunder brought by any other party hereto or its successors or assigns, shall be brought and determined exclusively in the Court of Chancery of the State of Delaware, or in the event (but only in the event) that such court does not have subject matter jurisdiction over such action or proceeding, in the federal courts sitting in the State of Delaware. Each of the parties hereto agrees that mailing of process or other papers in connection with any such action or proceeding in the manner provided in Section 12.4 or in such other manner as may be permitted by applicable Legal Requirements, will be valid and sufficient service thereof. Each of the parties hereto hereby irrevocably submits with regard to any such action or proceeding for itself and in respect of its property, generally and unconditionally, to the personal jurisdiction of the aforesaid courts and agrees that it will not bring any action relating to this Agreement or any of the transactions contemplated by this Agreement in any court or tribunal other than the aforesaid courts. Each of the parties hereto hereby irrevocably waives, and agrees not to assert, by way of motion, as a defense, counterclaim, or otherwise, in any action or proceeding with respect to this Agreement and the rights and obligations arising hereunder, or for recognition and enforcement of any judgment in respect of this Agreement and the rights and obligations arising hereunder: (a) any claim that it is not personally subject to the jurisdiction of the above named courts for any reason other than the failure to serve process in accordance with this Section 12.11; (b) any claim that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise); and (c) to the fullest extent permitted by the applicable Legal Requirements, any claim that (i) the suit, action or proceeding in such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper, or (iii) this Agreement, or the subject matter hereof, may not be enforced in or by such courts.

Section 12.12 Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. EACH PARTY TO THIS AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT: (A) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION; (B) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER; (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY; AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 12.12.

Section 12.13 Waiver. Any term or condition of this Agreement may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or condition, and no waiver by any party of any default, misrepresentation, or breach of warranty or covenant hereunder, shall be deemed to extend to any prior or subsequent default, misrepresentation, or breach of warranty, covenant or agreement hereunder or affect in any way any rights arising by virtue of any such prior or subsequent occurrence. No failure or delay of any party in exercising any right or remedy hereunder shall operate as a waiver thereof, and no waiver by any party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.

Section 12.14 Counterparts; Facsimile Signature. This Agreement may be executed in one (1) or more counterparts, by original or facsimile (or other such electronically transmitted) signature, each of which will be deemed an original, but all of which will constitute one and the same instrument.

Section 12.15 Rights Cumulative. All rights and remedies of each of the parties under this Agreement will be cumulative, and the exercise of one or more rights or remedies will not preclude the exercise of any other right or remedy available under this Agreement or applicable Legal Requirements.

Section 12.16 Interpretation. (a) The words "hereof", "herein", and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement; (b) the words "date hereof," when used in this Agreement, shall refer to the date set forth in the Preamble; (c) the terms defined in the singular have a comparable meaning when used in the plural, and vice versa; (d) the terms defined in the present tense have a comparable meaning when used in the past tense, and vice versa; (e) any references herein to a specific Section or Article shall refer, respectively, to Sections or Articles of this Agreement; (f) wherever the word "include", "includes", or "including" is used in this Agreement, it shall be deemed to be followed by the words "without limitation"; (g) references herein to any gender include each other gender; (h) the word "or" shall not be exclusive; (i) the headings herein are for convenience of reference only, do not constitute part of this Agreement and shall not be deemed to limit or otherwise affect any of the provisions hereof; (j) any references herein to any Governmental Authority shall be deemed to also be a reference to any successor Governmental Authority thereto; (k) where a word or phrase is defined herein, each of its other grammatical forms shall have a corresponding meaning; (l) all references to "dollars" or "$" in this Agreement refer to United States dollars, which is the currency used for all purposes in this Agreement; (m) when calculating the period of time before which, within which or following which, any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded, and if the last day of such period is a non-Business Day, the period in question shall end on the next succeeding Business Day; and (n) the parties hereto have participated jointly in the negotiation and drafting of this Agreement and, in the event that an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provision of this Agreement.

Section 12.17 Representative.

(a) By entering into this Agreement, each Seller hereby irrevocably authorizes and appoints Fortress as the "Representative" for all purposes under this Agreement and as such Seller's representative, agent and attorney-in-fact for all purposes in connection with this Agreement and the agreements ancillary hereto, with full authority to act on behalf of, and to bind, each such Person for purposes of this Agreement and the agreements ancillary hereto, and the Representative hereby accepts such appointment; provided, however, that the Representative shall not have authority to amend, waive or otherwise modify the provisions of Section 11.4(a)(iii) hereof or to take any action described in Section 12.18. The Buyer shall be entitled to deal exclusively with the Representative on all such matters and shall be entitled to rely conclusively (without further evidence of any kind whatsoever) on any document executed or purported to be executed on behalf of any Seller by the Representative, and on any other action taken or purported to be taken on behalf of any Seller by the Representative, as being fully binding upon such Seller. Notices or communications to or from the Representative shall constitute notice to or from each of the Sellers. The provisions of this Section 12.17, including the power of attorney granted hereby, are independent and severable, are irrevocable and coupled with an interest and shall not be terminated by any act of any one of the Sellers, or by operation of law, whether by death or other event.

(b) The Representative may resign at any time, and may be removed for any reason or no reason by the vote or written consent of a majority in interest of the Sellers according to each Seller's pro rata share of equity interest in the Company as of the date thereof (the "Majority Holders"); provided, however, in no event shall the Representative resign or be removed without the Majority Holders having first appointed a new Representative who shall assume such duties immediately upon the resignation or removal of the prior Representative. In the event of the death, incapacity, resignation or removal of the Representative, a new Representative shall be appointed by the vote or written consent of the Majority Holders. Notice of such vote or a copy of the written consent appointing such new Representative shall be sent to the Buyer, such appointment to be effective upon the later of the date indicated in such consent or the date such notice is received by the Buyer; provided that until such notice is received, the Buyer shall be conclusively entitled to rely on the decisions and actions of the prior Representative as described in Section 12.17(a) above.

Section 12.18 Columbia. Notwithstanding anything to the contrary in this Agreement or in any document, instrument or agreement to be executed and delivered pursuant hereto, but subject to the last sentence of this Section 12.18: (a) the respective rights and obligations of the parties to the Key License Agreement are not, and will not be, affected by this Agreement or any such document, instrument or agreement, and Columbia is not, and will not be, required to amend, waive or otherwise modify the Key License Agreement; (b) Columbia will not be subject to any non-compete or other restrictive covenant (other than Section 9.3 and Section 9.7 hereof as in effect on the Signing Date); (c) Columbia is not, and will not be, required to act under Sections 2.3(b), 9.4(a) and 9.5 hereof in any capacity other than as a stockholder of the Company, or to incur more than a nominal expense, except as provided in Article 11 hereof; (d) Section 11.4(a)(iii) hereof may not be amended, waived or otherwise modified as to Columbia without Columbia's written consent; (e) this Section 12.18 may not be amended, waived or otherwise modified without the written consent of Columbia; and (f) the Representative does not, and will not, have, the authority (i) to amend, waive or otherwise modify the Key License Agreement or the Columbia SPA on behalf of Columbia, (ii) to subject Columbia to any non-compete or other restrictive covenant (other than Section 9.3 and Section 9.7 hereof, as in effect on the Signing Date), (iii) to require Columbia to act or refrain from acting under Sections 2.3(b), 9.4(a) and 9.5 hereof in any capacity other than as a stockholder of the Company, or to incur more than a nominal expense, except as provided in Article 11 hereof; (iv) to amend, waive or otherwise modify Section 11.4(a)(iii) hereof as to Columbia without Columbia's written consent; or (v) to amend, waive or otherwise modify this Section 12.18. Notwithstanding anything in the foregoing to the contrary, Columbia agrees and acknowledges its obligations to sell, transfer, assign and deliver to the Buyer all Company Shares owned, of record and/or beneficially, by Columbia at the time of the Acquisition Closing in the event that the Buyer exercises its Purchase Option pursuant to Section 2.3.

[Remainder of the page intentionally left blank]

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed as of the date first written above.

THE COMPANY:

CAELUM BIOSCIENCES, INC.

By: /s/ Michael Spector
Name: Michael Spector
Title: CEO

[*Company Signature Page to Development, Option and Stock Purchase Agreement*]

THE BUYER:

ALEXION PHARMACEUTICALS, INC.

By: /s/ Aradhana Sarin
Name: Aradhana Sarin
Title: SVP, Strategy & Business Development

[*Buyer Signature Page to Development, Option and Stock Purchase Agreement*]

THE REPRESENTATIVE:

FORTRESS BIOTECH, INC.

By: /s/ Lindsay Rosenwald
Name: Lindsay A. Rosenwald, M.D.
Title: President & CEO

[*Representative Signature Page to Development, Option and Stock Purchase Agreement*]

SELLER:

By:	/s/ Orin Herskowitz
Name:	Columbia University
By:	Orin Herskowitz
Title:	Exec. Dir., CTV

[*Seller Signature Page to Development, Option and Stock Purchase Agreement*]

SELLER:

By:	/s/ Lindsay Rosenwald
Name:	Fortress Biotech, Inc.
By:	Lindsay A. Rosenwald, M.D.
Title:	President & CEO

[*Seller Signature Page to Development, Option and Stock Purchase Agreement*]

SELLER:

By:	/s/ Michael A. Mullen
Name:	National Holdings Corp.
By:	Michael A. Mullen
Title:	Executive Chairman, NSC

[*Seller Signature Page to Development, Option and Stock Purchase Agreement*]

SELLER:

By: /s/ George Avgerinos
Name: George Avgerinos

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SELLER:

By: /s/ David Barrett
Name: David Barrett

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SELLER:

By: /s/ Samuel Berry
Name: Samuel Berry

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SELLER:

By: /s/ Nikhil Bhambi
Name: Nikhil Bhambi

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SELLER:

By: /s/ Craig Bonn
Name: Craig Bonn

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SELLER:

By: /s/ Paul Brooke
Name: Paul Brooke

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SELLER:

By: /s/ Mary Campos
Name: Mary Campos

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SELLER:

By: /s/ Kenneth Cappell
Name: Kenneth Cappell

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SELLER:

By: /s/ Robert Criscola
Name: Robert Criscola

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SELLER:

By: /s/ Martin Goldman
Name: Martin Goldman

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SELLER:

By: /s/ Dr. Leonid Gorelik
Name: Dr. Leonid Gorelik

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SELLER:

By: /s/ Tim Hillman
Name: Tim Hillman

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SELLER:

By: /s/ Robyn Hunter
Name: Robyn Hunter

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SELLER:

By: /s/ Yune Kunes
Name: Yune Kunes

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SELLER:

By: /s/ Dr. Suzanne Lentzsch
Name: Dr. Suzanne Lentzsch

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SELLER:

By: /s/ Terry Manning
Name: Terry Manning

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SELLER:

By: /s/ Roger Monteforte
Name: Roger Monteforte

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SELLER:

By: /s/ Michael Mullen
Name: Michael Mullen

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SELLER:

By: /s/ Jill Myers
Name: Jill Myers

[*Seller Signature Page to Development, Option and Stock Purchase Agreement*]

SELLER:

By: /s/ William Natbony
Name: William Natbony

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SELLER:

By: /s/ Dr. Jeffrey Paley
Name: Dr. Jeffrey Paley

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SELLER:

By: /s/ Michael Phillips
Name: Michael Phillips

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SELLER:

By: /s/ Joon Rhee
Name: Joon Rhee

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SELLER:

By: /s/ Jonathan Rich
Name: Jonathan Rich

[*Seller Signature Page to Development, Option and Stock Purchase Agreement*]

SELLER:

By: /s/ Lindsay Rosenwald, M.D.
Name: Lindsay Rosenwald, M.D.

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SELLER:

By: /s/ Nova Silver
Name: Nova Silver

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SELLER:

By: /s/ Susan Sobolov
Name: Susan Sobolov

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SELLER:

By: /s/ Dr. Alan Solomon
Name: Dr. Alan Solomon

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SELLER:

By: /s/ Michael Spector
Name: Michael Spector

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SELLER:

By: /s/ Jennifer Talbot
Name: Jennifer Talbot

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SELLER:

By: /s/ Robert Todd
Name: Robert Todd

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SELLER:

By: /s/ Stuart Updegrove
Name: Stuart Updegrove

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SELLER:

By: /s/ Harlan Weisman, M.D.
Name: Harlan Weisman, M.D.

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SELLER:

By: /s/ Michael Weiss
Name: Michael Weiss

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Section 3: EX-31.1 (EXHIBIT 31.1)

Exhibit 31.1

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

I, Lindsay A. Rosenwald, M.D., certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Registrant");

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

(4) The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the Registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth 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 controls over financial reporting.

Dated: May 10, 2019

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

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Section 4: EX-31.2 (EXHIBIT 31.2)

Exhibit 31.2

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

I, Robyn M. Hunter, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Registrant");

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

(4) The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the Registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth 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 controls over financial reporting.

Dated: May 10, 2019

By: /s/ Robyn M. Hunter
Robyn M. Hunter
Chief Financial Officer
(Principal Financial Officer)

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Section 5: EX-32.1 (EXHIBIT 32.1)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Company") for the quarterly period ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lindsay A. Rosenwald, M.D., Chairman, President, and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company, as of, and for, the periods presented in the Report.

Dated: May 10, 2019

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

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Section 6: EX-32.2 (EXHIBIT 32.2)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Fortress Biotech, Inc. (the "Company") for the quarterly period ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robyn M. Hunter, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company, as of, and for, the periods presented in the Report.

Dated: May 10, 2019

By: /s/ Robyn M. Hunter
Robyn M. Hunter
Chief Financial Officer
(Principal Financial Officer)

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