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

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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 September 30, 2018

OR

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

For the transition period from      to

Commission File Number 001-35366

### FORTRESS BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

20-5157386

(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   
Non-accelerated filer

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

As of November 7, 2018, there were 56,679,505 shares of Common Stock of the issuer outstanding.

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**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)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
	(Unaudited)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 95,867	\$ 113,915
Accounts receivable	5,431	7,758
Short-term investments (certificates of deposit)	22,538	36,002
Cash deposits with clearing organizations	336	1,041
Receivables from broker-dealers and clearing organizations	11,884	7,395
Forgivable loans receivable	1,610	1,616
Securities owned, at fair value	6,675	1,985
Inventory	674	171
Other receivables - related party	414	618
Prepaid expenses and other current assets	14,089	12,680
Total current assets	<u>159,518</u>	<u>183,181</u>
Property and equipment, net	14,642	9,513
Restricted cash	17,358	17,387
Long-term investments, at fair value	–	1,390
Intangible assets	13,935	15,223
Goodwill	18,645	18,645
Other assets	821	611
<b>Total assets</b>	<b><u>\$ 224,919</u></b>	<b><u>\$ 245,950</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 37,345	\$ 36,127
Accounts payable and accrued expenses - related party	153	222
Accrued commissions and payroll payable	11,974	10,065
Deferred clearing and marketing credits	629	786
Securities sold, not yet purchased, at fair value	24	151
Warrants issued - National	–	5,597
Interest payable	613	887
Interest payable - related party	94	97
Notes payable, short-term (net of debt discount of \$447 and \$973 at September 30, 2018 and December 31, 2017, respectively)	9,054	8,528
Subsidiary convertible note, short-term, at fair value	10,657	4,700
Deferred revenue	155	–
Derivative warrant liability	–	87
Other current liabilities	77	181
Total current liabilities	<u>70,775</u>	<u>67,428</u>
Notes payable, long-term (net of debt discount of \$445 and \$62 at September 30, 2018 and December 31, 2017, respectively)	64,546	43,222
Subsidiary convertible note, long-term, at fair value	–	10,059
Other long-term liabilities	4,961	4,739
<b>Total liabilities</b>	<b><u>140,282</u></b>	<b><u>125,448</u></b>
<b>Stockholders' equity</b>		
Preferred stock, \$0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 1,000,000 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively; liquidation value of \$25.00 per share	1	1
Common stock, \$0.001 par value, 100,000,000 shares authorized, 56,183,480 and 50,991,285 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	56	51
Common stock issuable, 347,684 and 158,015 shares as of September 30, 2018 and December 31, 2017, respectively	495	500
Additional paid-in-capital	408,615	364,148
Accumulated deficit	<u>(371,394)</u>	<u>(312,127)</u>

Total stockholders' equity attributed to the Company	37,773	52,573
Non-controlling interests	46,864	67,929
Total stockholders' equity	<u>84,637</u>	<u>120,502</u>
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 224,919</u></b>	<b><u>\$ 245,950</u></b>

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 September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Revenue</b>				
<i>Fortress</i>				
Product revenue, net	\$ 5,168	\$ 2,170	\$ 17,366	\$ 8,309
Revenue - from a related party	5	350	525	1,393
Net Fortress revenue	5,173	2,520	17,891	9,702
<i>National</i>				
Commissions	28,397	24,881	85,422	73,380
Net dealer inventory gains	482	1,789	5,601	6,666
Investment banking	19,271	8,942	43,012	26,595
Investment advisory	5,281	3,605	15,811	10,480
Interest and dividends	771	674	2,003	2,065
Transfer fees and clearing services	1,606	1,649	5,680	5,834
Tax preparation and accounting	2,444	2,527	6,835	6,527
Other	268	299	697	1,016
Total National revenue	58,520	44,366	165,061	132,563
Net revenue	63,693	46,886	182,952	142,265
<b>Operating expenses</b>				
<i>Fortress</i>				
Cost of goods sold - product revenue	1,406	505	4,546	1,852
Research and development	16,082	15,890	58,528	34,683
Research and development - licenses acquired	3,706	300	3,804	3,394
General and administrative	12,184	15,104	38,788	36,490
Total Fortress operating expenses	33,378	31,799	105,666	76,419
<i>National</i>				
Commissions, compensation and fees	48,556	39,963	141,462	118,983
Clearing fees	451	470	1,772	1,826
Communications	856	690	2,429	2,094
Occupancy	738	972	2,834	2,916
Licenses and registration	861	391	2,028	1,223
Professional fees	1,076	1,082	3,047	3,336
Interest	26	5	30	13
Underwriting costs	43	-	230	-
Depreciation and amortization	871	507	2,587	1,513
Other administrative expenses	1,726	3,610	5,839	7,315
Total National operating expenses	55,204	47,690	162,258	139,219
Total operating expenses	88,582	79,489	267,924	215,638
Loss from operations	(24,889)	(32,603)	(84,972)	(73,373)
Other income (expenses)				
Interest income	269	204	841	530
Interest expense and financing fee	(2,228)	(3,220)	(6,455)	(5,298)
Change in fair value of derivative liabilities	-	(639)	(7,931)	5,155
Change in fair value of subsidiary convertible note	(84)	(74)	26	(359)
Change in fair value of investments	(565)	270	(1,390)	(241)
Other expenses	(146)	(245)	(258)	(232)
Total other expenses	(2,754)	(3,704)	(15,167)	(445)
<b>Loss before income taxes</b>	<b>(27,643)</b>	<b>(36,307)</b>	<b>(100,139)</b>	<b>(73,818)</b>
Income tax expense	944	-	2,382	-
<b>Net loss</b>	<b>(28,587)</b>	<b>(36,307)</b>	<b>(102,521)</b>	<b>(73,818)</b>
<b>Less: net loss attributable to non-controlling interests</b>	<b>(11,949)</b>	<b>(9,191)</b>	<b>(43,254)</b>	<b>(17,355)</b>
<b>Net loss attributable to common stockholders</b>	<b>\$ (16,638)</b>	<b>\$ (27,116)</b>	<b>\$ (59,267)</b>	<b>\$ (56,463)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.37)</b>	<b>\$ (0.67)</b>	<b>\$ (1.36)</b>	<b>\$ (1.39)</b>

<b>Weighted average common shares outstanding-basic and diluted</b>	<b><u>44,818,186</u></b>	<b><u>40,724,115</u></b>	<b><u>43,578,763</u></b>	<b><u>40,547,364</u></b>
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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 Issuable	Additional Paid-In Capital	Accumulated Deficit	Non-Controlling Interests	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
<b>Balance at December 31, 2017</b>	<b>1,000,000</b>	<b>\$ 1</b>	<b>50,991,285</b>	<b>\$ 51</b>	<b>\$ 500</b>	<b>\$ 364,148</b>	<b>\$ (312,127)</b>	<b>\$ 67,929</b>	<b>\$ 120,502</b>
Stock-based compensation expense	-	-	-	-	-	13,648	-	-	13,648
Issuance of restricted stock	-	-	1,809,421	2	-	(2)	-	-	-
Issuance of common stock under ESPP	-	-	43,707	-	-	128	-	-	128
Issuance of subsidiaries' common shares for license expenses	-	-	-	-	-	229	-	-	229
Issuance of NHLD's common shares for tax withholding	-	-	-	-	-	(82)	-	-	(82)
Subsidiary's public offering, net	-	-	-	-	-	22,668	-	-	22,668
Subsidiary's ATM offering, net	-	-	-	-	-	7,726	-	-	7,726
Exercise of subsidiary's warrants for cash	-	-	-	-	-	186	-	-	186
Issuance of common stock for at-the-market offering	-	-	2,668,756	3	-	6,956	-	-	6,959
At-the-market offering cost	-	-	-	-	-	(240)	-	-	(240)
Contribution of capital for 2017 bonuses	-	-	-	-	-	1,000	-	-	1,000
Common shares issuable 2017 Subordinated Note Financing interest expense	-	-	-	-	495	-	-	-	495
Common shares issued for 2017 Subordinated Note Financing interest expense	-	-	436,281	-	(500)	1,478	-	-	978
Common shares issued for Opus interest expense	-	-	234,030	-	-	574	-	-	574
Preferred A dividends declared and paid	-	-	-	-	-	(1,758)	-	-	(1,758)
Offering cost and financing fee paid to NHLD	-	-	-	-	-	1,297	-	-	1,297
Acquisition of business - NHLD	-	-	-	-	-	(767)	-	-	(767)
Warrant liability reclassification - NHLD	-	-	-	-	-	13,615	-	-	13,615
Non-controlling interest in subsidiaries	-	-	-	-	-	(22,189)	-	22,189	-
Net loss attributable to non-controlling interest	-	-	-	-	-	-	-	(43,254)	(43,254)
Net loss attributable to common stockholders	-	-	-	-	-	-	(59,267)	-	(59,267)
<b>Balance at September 30, 2018</b>	<b>1,000,000</b>	<b>\$ 1</b>	<b>56,183,480</b>	<b>\$ 56</b>	<b>\$ 495</b>	<b>\$ 408,615</b>	<b>\$ (371,394)</b>	<b>\$ 46,864</b>	<b>\$ 84,637</b>

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)

	<b>For the Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash Flows from Operating Activities:</b>		
Net Loss	\$ (102,521)	\$ (73,818)
<b>Reconciliation of net loss to net cash used in operating activities:</b>		
Depreciation expense	1,379	819
Amortization expense of intangible asset	2,100	1,235
Amortization of debt discount	624	1,316
Amortization of product revenue license fee	433	401
Amortization of forgivable loans to registered representatives	474	520
Amortization of deferred clearing credit	(157)	(157)
Stock-based compensation expense	13,658	12,048
Recovery of doubtful accounts	18	(274)
Common shares issuable for 2017 Subordinated Note financing interest expense	495	353
Common shares issued for 2017 Subordinated Note financing interest expense	978	189
Common shares issued for Opus interest expense	574	-
Change in fair value of investments	1,390	241
Change in fair value of derivative liabilities	7,931	(5,155)
Change in fair value of subsidiary convertible note	(26)	359
Loss on write off of investment	-	250
Research and development-licenses acquired, expense	3,804	3,394
Non-cash research and development expense	-	50
Change in fair value of subsidiaries' assets and liabilities	18	1,341
<b>Increase (decrease) in cash and cash equivalents resulting from changes in operating assets and liabilities:</b>		
Accounts receivable	2,327	(3,752)
Receivables from broker-dealers and clearing organizations	(4,489)	(4,925)
Forgivable loans receivable	(468)	(77)
Securities owned, at fair value	(4,690)	762
Inventory	(503)	(115)
Other receivables - related party	204	1,152
Prepaid expenses and other current assets	(562)	(1,426)
Other assets	200	-
Accounts payable and accrued expenses	(980)	4,195
Accounts payable and accrued expense - related party	(19)	84
Securities sold, but not yet purchased, at fair value	(127)	(298)
Deferred Revenue	155	680
Interest payable	(274)	22
Interest payable - related party	(3)	430
Other long-term liabilities	222	(288)
Net cash used in operating activities	<u>(77,835)</u>	<u>(60,444)</u>
<b>Cash Flows from Investing Activities:</b>		
Purchase of research and development licenses	(1,075)	(965)
Purchase of property and equipment	(6,828)	(999)
Purchase of short-term investment (certificates of deposit)	(47,538)	(44,088)
Redemption of short-term investment (certificates of deposit)	61,002	-
Security deposits collected	(344)	-
Security deposits refund	-	42
Acquisition of business - National	(187)	(19)
Acquisition of intangible assets - National	(45)	-
Collection on notes receivable	69	28
Net cash provided by (used in) investing activities	<u>5,054</u>	<u>(46,001)</u>

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)

	<b>For the Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash Flows from Financing Activities:</b>		
Inter-company costs related to the issuance of Series A preferred stock	1,297	–
Payment of Preferred A dividends	(1,758)	–
Proceeds from at-the-market offering	6,959	–
Payment of costs related to at-the-market offering	(240)	–
Proceeds from subsidiaries' offering	23,011	104,034
Payment of costs related to subsidiaries' offering	(343)	(9,389)
Proceeds from subsidiaries' at-the-market offering	7,980	–
Payment of costs related to subsidiaries' at-the-market offering	(234)	–
Proceeds from exercise of subsidiary's warrants	186	–
Proceeds from 2017 Subordinated Note Financing	–	28,355
Payment of debt issuance costs associated with 2017 Subordinated Note Financing	(404)	(1,081)
Payment of debt issuance costs associated with NSC Note	–	(3,608)
Proceeds from exercise of stock options	–	27
Proceeds from issuance of common stock under ESPP	128	42
Repurchase of NHLD common stock for tax withholding	(82)	–
Proceeds from 2018 Venture notes	21,707	–
Payment of debt issuance costs associated with 2018 Venture notes	(132)	–
Proceeds from subsidiaries' Convertible Note	–	9,914
Payment of debt issuance costs associated with subsidiaries' Convertible Note	–	(1,071)
Payment of subsidiaries' Convertible Note	(4,076)	–
Proceeds from Opus Credit Facility	–	2,500
Net cash provided by financing activities	<u>53,999</u>	<u>129,723</u>
Net (decrease) increase in cash and cash equivalents, cash deposits with clearing organizations and restricted cash	(18,782)	23,278
Cash and cash equivalents, cash deposits with clearing organizations and restricted cash at beginning of period	<u>132,343</u>	<u>105,184</u>
<b>Cash and cash equivalents, cash deposits with clearing organizations and restricted cash at end of period</b>	<u><u>\$ 113,561</u></u>	<u><u>\$ 128,462</u></u>
<b>Supplemental disclosure of cash flow information:</b>		
<b>Fortress</b>		
Cash paid for interest	\$ 3,767	\$ 345
Cash paid for interest – related party	\$ 281	\$ –
<b>NHLD</b>		
Cash paid for interest	\$ 13	\$ 11
Cash paid for income taxes	\$ 1,569	\$ 1,004
<b>Supplemental disclosure of non-cash financing and investing activities:</b>		
<b>Fortress</b>		
Issuance of restricted stock	\$ 2	\$ 2
Issuance of warrants by subsidiary in conjunction with NSC debt	\$ –	\$ 750
Issuance of warrants in connection with 2017 Subordinated Note Financing	\$ –	\$ 1,784
Debt discount related to Opus Credit Facility	\$ –	\$ 201
Unpaid debt offering cost	\$ –	\$ 42
Common shares issuable for license acquired	\$ –	\$ 1,682
Conversion of subsidiaries notes payable	\$ –	\$ 314
Common shares issued for 2017 Subordinated Note Financing interest expense	\$ 500	\$ –
Unpaid fixed assets	\$ 125	\$ –
Unpaid subsidiary's ATM offering cost	\$ 20	\$ –
Unpaid intangible assets – Fortress Companies	\$ 1,200	\$ –
<b>NHLD</b>		
Fixed assets (acquired but not paid)	\$ 537	\$ 665
Business acquisition	\$ 187	\$ 19
Reclassification of warrant liability from debt to equity	\$ 13,615	\$ –

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

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**  
Notes to Condensed Consolidated Financial Statements  
(Unaudited)

**1. Organization and Description of Business**

Fortress Biotech, Inc. (“Fortress” or the “Company”) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also referred to as the “Fortress Companies.” Additionally, the Company maintains a controlling interest in National Holdings Corporation, a diversified independent brokerage company (together with its subsidiaries, referred to as “NHLD” or “National”). One of National’s subsidiaries, National Securities Corporation (“NSC”), is an independent broker-dealer offering retail and institutional advisory, investment, insurance and tax planning services. From time to time, NSC provides services to the Company and its affiliates. In addition to its internal development programs, the Company leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. The Company and the Fortress Companies may seek licenses, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs.

As of September 30, 2018, in addition to National, the Company has several consolidated Fortress Companies, some of which contain product licenses, 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”), Tamid Bio, Inc. (“Tamid”) and JG Pharma, Inc., a subsidiary of JMC. The Company also has operational subsidiaries CB Securities Corporation (“CB Securities”), Immune Limited and FBIO Acquisition, Inc. (the acquisition vehicle the Company used to obtain National) and acquisition companies for which the Company is actively seeking product candidate licenses, including Coronado SO Co. (“Coronado SO”), Escala Therapeutics, Inc. (“Escala”), GeneXion Oncology, Inc. (“GeneXion”), Fortress Biotech China, Inc. (“Fortress China”), FBIO Acquisition Corp. IV and FBIO Acquisition Corps. VI - XIV.

*Liquidity and Capital Resources*

Since inception, the Company’s operations have been financed primarily through the sale of equity and debt securities and the 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 develop and seek regulatory approvals for its and its subsidiaries’ 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, grants or other arrangements to develop and seek regulatory approvals for the Company’s and its subsidiaries’ existing and new product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for the Company’s 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. The Company also has the ability, subject to limitations imposed by Rule 144 of the Securities Act of 1933 and other applicable laws and regulations, to raise money from the sale of common stock of the public companies in which it has ownership positions.

**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, Mustang and National. 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 16, 2018, from which the Company derived the balance sheet data at December 31, 2017, as well as National’s Form 10-K and 10-K/A filed with the SEC on December 22, 2017 and January 17, 2018, respectively and their Form 10-Q, filed with the SEC on August 14, 2018, Checkpoint’s Form 10-K filed with the SEC on March 16, 2018, Mustang’s Form 10-K, filed with the SEC on March 29, 2018, and Avenue’s Form 10-K, filed with the SEC on March 1, 2018.

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The Company's unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries: Avenue, Aevitas, Caelum, CB Securities, Cellvation, Coronado SO, Checkpoint, Cyprum, Escala, GeneXion, Helocyte, Immune Limited, JMC, Mustang, NHLD, Tamid, Fortress China, 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 National assets acquired, and liabilities assumed, and revenues and expenses are reported on a one quarter lag. Therefore, the National assets acquired, and liabilities assumed included in these condensed consolidated financial statements as of September 30, 2018 are actually the assets and liabilities as of June 30, 2018 and the revenues and expenses included in these condensed consolidated financial statements for the quarter ending September 30, 2018 are actually the revenues and expenses for the quarter ending June 30, 2018.

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.

#### **Significant Accounting Policies**

There have been no material changes to the Company's significant accounting policies previously disclosed in the Company's Form 10-K filed with the SEC on March 16, 2018, with the exception of revenue recognition.

#### **Recently Adopted Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606) (ASU 2014-09) as modified by ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients.* The impact of adoption on January 1, 2018 is primarily related to National's investment banking expenses of \$0.1 million that were deferred as of September 30, 2017 (National's financials are included in the Company's financials at a three-month lag) under the previously existing accounting guidance, which would have been expensed in prior periods under the new revenue standard. Since the impact was immaterial, the Company elected not to record this amount in retained earnings as of January 1, 2018. The adoption of this standard did not have a material impact on the Company's revenue. Accordingly, the new revenue standard will be applied prospectively in the Company's financial statements from January 1, 2018 forward and reported financial information for historical comparable periods will not be revised and will continue to be reported under the accounting standards in effect during those historical periods. Further, the adoption of ASU 2014-09 did not have a material impact on net Fortress revenue.

The new revenue guidance does not apply to revenue associated with financial instruments, including National's warrants and securities that are accounted for under other U.S. GAAP, and as a result, did not have an impact on the elements of the Company's Condensed Consolidated Statements of Operations most closely associated with financial instruments. The new revenue standard primarily impacts the following of the revenue recognition and presentation accounting policies:

- *Investment Banking Revenues.* Advisory fees from mergers and acquisitions engagements are recognized at the point in time when the related transaction is completed, as the performance obligation is to successfully broker a specific transaction.

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- *Investment Banking Advisory Expenses.* Historically, expenses associated with investment banking advisory assignments were deferred until reimbursed by the client, the related fee revenue is recognized, or the engagement is otherwise concluded. Under the new revenue standard, expenses are deferred only to the extent they are explicitly reimbursable by the client and the related revenue is recognized when all performance obligations are met. All other investment banking advisory related expenses are expensed as incurred.
- *Investment Banking Underwriting and Advisory Expenses.* Expenses have historically been recorded net of client reimbursements and/or netted against revenues. Under the new revenue standard, all investment banking expenses will be recognized within their respective expense category on the consolidated income statement and any expense reimbursements will be recognized as investment banking revenues (i.e., expenses are no longer recorded net of client reimbursements and are not netted against revenues).

The new revenue standard requires enhanced disclosures, which are included in Note 21 to the Company's condensed consolidated financial statements for the three and nine months ended September 30, 2018.

#### *Contract Assets*

Contract assets represent the Company's right to consideration in exchange for goods or services that the Company has transferred to a customer, excluding unconditional rights to consideration that are presented as receivables.

#### *Contract Liabilities*

Contract liabilities represent the Company's obligation to deliver products or provide data to customers in the future for which cash has already been received.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. ASU 2017-09 provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The Company adopted ASU No. 2017-09 as of January 1, 2018. The adoption of this update did not impact the Company's condensed consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments* which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company adopted ASU No. 2016-15 as of January 1, 2018. The adoption of this update did not impact the Company's condensed consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Liabilities*. ASU No. 2016-01 requires several targeted changes including that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) be measured at fair value with changes in fair value recognized in net income. The new guidance also changes certain disclosure requirements and other aspects of current U.S. GAAP. Amendments are to be applied as a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. ASU 2016-01 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The Company adopted ASU No. 2016-01 as of January 1, 2018. The adoption of this update did not impact the Company's condensed consolidated financial statements and related disclosures.

#### **Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* and subsequent amendments to the initial guidance: ASU 2017-13, ASU 2018-10 and ASU 2018-11 (collectively, Topic 842). Topic 842 requires companies to generally recognize on the balance sheet operating and financing lease liabilities and corresponding right-of-use assets. Topic 842 is effective for the Company in our first quarter of fiscal 2019, and earlier adoption is permitted. The Company is currently evaluating the impact of the pending adoption of Topic 842 on its consolidated financial statements. The Company currently expects that most of its operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon our adoption of Topic 842, which will increase the total assets and the total liabilities that the Company will report relative to such amounts prior to adoption.

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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 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 Company is currently assessing the potential impact of adopting ASU 2017-11 on its condensed consolidated financial statements and related disclosures.

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 Dec. 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 is currently evaluating the impact of adopting this standard on its condensed consolidated financial statements and related disclosures but does not expect it to have a material impact.

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 financial statements.

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 was effective on November 5, 2018. The Company is evaluating the impact of this guidance on its condensed consolidated financial statements.

### 3. National Holdings Corporation Acquisition - Intangible Assets

Intangible assets consist of trademark and customer lists acquired in the offer under the purchase method of accounting and are recorded at fair value net of accumulated amortization since the purchase date. Software license is recorded at cost. Amortization is calculated using the straight-line and accelerated methods over the following estimated useful lives:

	<u>Useful life</u>
<b>Trademark</b>	10 years
<b>Customer lists</b>	6 years
<b>Software license</b>	3 years

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The carrying amount related to acquired intangible assets as of September 30, 2018 are as follows (\$ in thousands):

Intangible assets at December 31, 2017	\$ 14,340
Addition	45
Amortization expense	(2,100)
Intangible assets at September 30, 2018	<u>\$ 12,285</u>

The future amortization of these intangible assets is as follows (\$ in thousands):

	Trademark	Customer List	Software License	Total
Three Months Ended December 31, 2018	\$ 76	\$ 630	\$ 4	\$ 710
Year Ended December 31, 2019	300	2,500	15	2,815
Year Ended December 31, 2020	301	2,506	15	2,822
Year Ended December 31, 2021	300	2,500	5	2,805
Year Ended December 31, 2022	300	1,726	–	2,026
Thereafter	1,107	–	–	1,107
Total	<u>\$ 2,384</u>	<u>\$ 9,862</u>	<u>\$ 39</u>	<u>\$ 12,285</u>

The Company reviews its finite-lived intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of a finite-lived intangible asset may not be recoverable. Recoverability of a finite-lived intangible asset is measured by a comparison of its carrying amount to the undiscounted future cash flows expected to be generated by the asset. If the asset is considered to be impaired, the impairment recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no indicators of impairment during the nine months ended September 30, 2018.

#### 4. Broker-Dealers and Clearing Organizations, Other Receivables and Prepaid Expenses and Other Current Liabilities

At June 30, 2018 and September 30, 2017, National's receivables of \$11.9 million and \$7.4 million, respectively, from broker-dealers and clearing organizations represent net amounts due for commissions and fees associated with National's retail brokerage business as well as asset-based fee revenue associated with National's investment advisory business. National also has other receivables at June 30, 2018 and September 30, 2017 of \$5.3 million and \$5.2 million, respectively, which principally represent trailing commissions, tax and accounting fees and investment banking fees, net of an allowance for uncollectable accounts of \$0.6 million, and \$0.5 million, respectively, and are included in prepaid expenses and other current assets on the Company's Condensed Consolidated Balance Sheet.

#### 5. Forgivable Loans Receivable

From time to time, National's operating subsidiaries may make loans, evidenced by promissory notes, primarily to newly recruited independent financial advisors as an incentive for their affiliation. The loans receivable balance is comprised of unsecured non-interest-bearing and interest-bearing loans (weighted average interest rate of 4%). These loans have various schedules for repayment or forgiveness based on production or retention requirements being met and mature at various dates through 2023. Forgiveness of loans amounted to \$0.5 million and \$0.5 million for the nine months ended June 30, 2018 and 2017, respectively, and the related compensation was included in commissions, compensation and fees in the condensed consolidated statements of operations. In the event the advisor's affiliation with the subsidiary terminates, the advisor is required to repay the unamortized balance of any loans payable.

National provides an allowance for doubtful accounts on the notes based on historical collection experience and continually evaluates the receivables for collectability and possible write-offs where a loss is deemed probable. As of June 30, 2018 and September 30, 2017, no allowance for doubtful accounts was required.

There were no unamortized forgivable loans outstanding at June 30, 2018 and September 30, 2017 attributable to registered representatives who ended their affiliation with National's subsidiaries prior to the fulfillment of their obligation.

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**6. Property and Equipment**

Fortress's property and equipment, exclusive of National's property and equipment, consisted of the following (\$ in thousands):

	Estimated Useful Lives (in years)	September 30, 2018	December 31, 2017
Computer equipment	3	\$ 648	\$ 543
Furniture and fixtures	5	1,128	1,009
Machinery and equipment	5	3,128	143
Leasehold improvements	5 - 15	9,236	5,351
Construction in process <sup>(1)</sup>	N/A	33	1,241
Total property and equipment		14,173	8,287
Less: accumulated depreciation		(2,063)	(1,171)
Property and equipment, net		<u>\$ 12,110</u>	<u>\$ 7,116</u>

(1) Relates to the Mustang cell processing facility.

Fortress's depreciation expense for the three months ended September 30, 2018 and 2017, was approximately \$0.4 million and \$0.2 million, respectively, and was recorded in research and development, manufacturing and general and administrative expense in the Condensed Consolidated Statements of Operations. Fortress's depreciation expense for the nine months ended September 30, 2018 and 2017, was approximately \$0.9 million and \$0.5 million, respectively, and was recorded in research and development, manufacturing and general and administrative expense in the Condensed Consolidated Statements of Operations.

National's property and equipment as of June 30, 2018 and September 30, 2017 consisted of the following (\$ in thousands):

	Estimated Useful Lives (in years)	June 30, 2018	September 30, 2017
Equipment	5	\$ 1,854	\$ 1,306
Furniture and fixtures	5	323	284
Leasehold improvements	Lesser of useful life or term	1,041	1,006
Capital Leases (primarily composed of computer equipment)	5	276	276
Total property and equipment		3,494	2,872
Less: accumulated depreciation		(962)	(475)
Property and equipment, net		<u>\$ 2,532</u>	<u>\$ 2,397</u>

National's depreciation expense for the three months ended June 30, 2018 and 2017, was approximately \$0.2 million and \$0.1 million respectively and was recorded in National general and administrative expense in the Condensed Consolidated Statements of Operations. National's depreciation expense for the nine months ended June 30, 2018 and 2017, was approximately \$0.5 million and \$0.3 million, respectively, and was recorded in National general and administrative expense in the Condensed Consolidated Statements of Operations.

**7. 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.

*Origo Acquisition Corporation*

On August 10, 2018, Origo Acquisition Corporation ("Origo") entered into a Termination and Mutual Release between Origo and Hightimes Holding Corp. ("HTH"), HTHC Merger Sub, Inc. ("Merger Sub") and Jose Aldeanueva, pursuant the terms of the Merger Agreement, dated July 24, 2017, as amended, effectively terminating the possibility of a business combination. Additionally, on August 10, 2018 the officers and directors of Origo notified shareholders of their intention to dissolve and liquidate in accordance with the Memorandum and Articles of Association of Origo. In accordance with the liquidation, Origo redeemed all of its outstanding ordinary shares that were included in the units issued in its initial public offering (the "Public Shares"), at a per-share redemption price of approximately \$11.00. The redemption was completed on August 15, 2018.

The Company's investment in Origo was not eligible for the redemption and as such as of September 30, 2018, the Company wrote off its investment in Origo and recorded a decrease in fair-value of investment of \$1.4 million for the nine months ended September 30, 2018. In addition to its investment in Origo, the Company also provided Origo with a working capital note of \$0.3 million, the balance of which was written off in the quarter ended June 30, 2018.



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*Securities Owned*

National

The fair value of National's warrants, representing the cumulative value of warrants received in publicly traded companies that are not related parties, in which NSC as placement agent received warrants as the placement agent. National calculated the fair value of the warrants using a Black Scholes model. A summary of the weighted averages (in aggregate) of significant unobservable inputs (Level 3 inputs) used in measuring National's warrants that are categorized within Level 3 of the fair value hierarchy as of June 30, 2018 is as follows:

	<b>June 30, 2018</b>
Risk-free interest rate	1.93% – 2.73%
Expected dividend yield	–%
Expected term in years	0.14 – 4.83
Remaining volatility	49.7% – 381.0%
Strike price	\$0.01 – \$10.00
	<b>Fair Value of Derivative Warrants</b>
<i>(\$ in thousands)</i>	
Beginning balance at September 30, 2017	\$ 202
Trading revenue gain	392
Ending balance at June 30, 2018	<u>\$ 594</u>

*Warrant Liabilities*

Helocyte

The fair value of Helocyte's warrant liability, which was issued in connection with Helocyte's convertible note (see Note 11), as of September 30, 2018 approximated \$0, as the probability of the conversion of the underlying notes approximated \$0. The table below provides a summary:

	<b>Fair Value of Derivative Warrant Liability</b>
<i>(\$ in thousands)</i>	
Beginning balance at January 1, 2018	\$ 87
Change in fair value of derivative liabilities	(87)
Ending balance at September 30, 2018	<u>\$ –</u>

*Notes at Fair Value*

Helocyte

Helocyte's convertible note is measured at fair value using the Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Helocyte's convertible debt that is categorized within Level 3 of the fair value hierarchy as of September 30, 2018, the fair value approximated cost, as the convertible note approaches maturity, is as follows:

	<b>Helocyte Convertible Note, at Fair value</b>
<i>(\$ in thousands)</i>	
Beginning balance at January 1, 2018	\$ 4,700
Payment of convertible notes	(4,076)
Change in fair value of convertible notes	(291)
Ending balance at September 30, 2018	<u>\$ 333</u>

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Caelum

Caelum's convertible debt, which is guaranteed by the Company, is measured at fair value using the Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Caelum's convertible debt that is categorized within Level 3 of the fair value hierarchy as of September 30, 2018 is as follows:

	<b>September 30, 2018</b>
Risk-free interest rate	2.195% - 2.560%
Expected dividend yield	–%
Expected term in years	0.29 – 0.95
Expected volatility	67.0%

	<b>Caelum Convertible Note, at fair value</b>
<i>(\$ in thousands)</i>	
Beginning balance at January 1, 2018	\$ 10,059
Change in fair value of convertible notes	265
Ending balance at September 30, 2018	<u>\$ 10,324</u>

The following tables classify the fair value hierarchy of Fortress's financial instruments, exclusive of National's financial instruments, measured at fair value as of September 30, 2018 and December 31, 2017:

	<b>Fair Value Measurement as of September 30, 2018</b>			
	Level 1	Level 2	Level 3	Total
<i>(\$ in thousands)</i>				
<b>Liabilities</b>				
Helocyte Convertible Note, at fair value	\$ –	\$ –	\$ 333	\$ 333
Caelum Convertible Note, at fair value	–	–	10,324	10,324
Total	<u>\$ –</u>	<u>\$ –</u>	<u>\$ 10,657</u>	<u>\$ 10,657</u>

	<b>Fair Value Measurement as of December 31, 2017</b>			
	Level 1	Level 2	Level 3	Total
<i>(\$ in thousands)</i>				
<b>Assets</b>				
Long-term investments, at fair value	\$ –	\$ –	\$ 1,390	\$ 1,390
Total	<u>\$ –</u>	<u>\$ –</u>	<u>\$ 1,390</u>	<u>\$ 1,390</u>
<b>Liabilities</b>				
Warrant liabilities	\$ –	\$ –	\$ 87	\$ 87
Caelum Convertible Note, at fair value	–	–	10,059	10,059
Helocyte Convertible Note, at fair value	–	–	4,700	4,700
Total	<u>\$ –</u>	<u>\$ –</u>	<u>\$ 14,846</u>	<u>\$ 14,846</u>

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The following table shows the fair values hierarchy of National's financial instruments measured at fair value on a recurring basis on the Condensed Consolidated Balance Sheets as of June 30, 2018 and September 30, 2017:

	<b>Fair Value Measurement as of June 30, 2018</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets - National</b>				
Securities owned, at fair value				
Corporate stocks	\$ 101	\$ –	\$ –	\$ 101
Municipal bonds	–	530	–	530
Restricted stock	–	1,912	–	1,912
Warrants	–	–	4,132	4,132
<b>Total</b>	<b>\$ 101</b>	<b>\$ 2,442</b>	<b>\$ 4,132</b>	<b>\$ 6,675</b>

<b>Liabilities – National</b>				
Securities sold, but not yet purchased at fair value:				
Corporate stocks	\$ 18	\$ –	\$ –	\$ 18
Corporate debt	–	6	–	6
Contingent consideration	–	–	768	768
<b>Total</b>	<b>\$ 18</b>	<b>\$ 6</b>	<b>\$ 768</b>	<b>\$ 792</b>

	<b>Fair Value Measurement as of September 30, 2017</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets - National</b>				
Securities owned, at fair value				
Corporate stocks	\$ 116	\$ –	\$ –	\$ 116
Municipal bonds	–	1,239	–	1,239
Restricted stock	–	82	–	82
Warrants	–	–	548	548
<b>Total</b>	<b>\$ 116</b>	<b>\$ 1,321</b>	<b>\$ 548</b>	<b>\$ 1,985</b>

<b>Liabilities - National</b>				
Securities sold, but not yet purchased at fair value				
Municipal bonds	\$ –	\$ 151	\$ –	\$ 151
Contingent consideration	–	–	311	311
Warrants issued - National	–	–	5,597	5,597
<b>Total</b>	<b>\$ –</b>	<b>\$ 151</b>	<b>\$ 5,908</b>	<b>\$ 6,059</b>

*Warrants issued - National*

On March 15, 2018, National, together with Computershare Inc., a Delaware corporation (“Computershare”), and its wholly-owned subsidiary, Computershare Trust Company, N.A., a federally chartered trust company (and together with Computershare, the “Warrant Agent”) agreed to amend and restate the terms of the form of warrant agreement dated December 13, 2016 (the “Original Agreement”). The Amended and Restated Warrant Agreement (the “Amended Agreement”) explicitly provides that National shall not be required to pay cash if it cannot issue registered shares of Common Stock upon exercise of a Warrant and as such meeting the criteria for equity classification.

Accordingly, at March 15, 2018, the date of the amendment, the fair value of the warrants issued by National (represents 44% of the warrants issued to non-Fortress shareholders) was \$13.6 million. Such valuation (using level 3 inputs) was determined by use of the Black-Scholes option pricing model using the following assumptions:

	<b>March 15, 2018</b>
Dividend yield	–%
Expected volatility	59.23%
Risk-free interest rate	2.42%
Life (in years)	3.49%

The following table shows the fair value of the warrant liability on the Condensed Consolidated Balance Sheets as of June 30, 2018 and September 30, 2017:

<i>(\$ in thousands)</i>	<b>National's Warrants</b>
Beginning balance at September 30, 2017	\$ 5,597

Change in fair value of derivative liability	8,018
Ending balance at March 15, 2018	<u>13,615</u>
Reclassification of warrant to equity	<u>(13,615)</u>
Ending balance at June 30, 2018	<u>\$ —</u>

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National listed the warrants on the Nasdaq Capital Market under the symbol “NHLDW” in February 2017.

The table below provides a roll-forward of the changes in fair value of Level 3 financial instruments for the nine months ended September 30, 2018:

(\$ in thousands)	Investment in Origo	Helocyte Convertible Note, at fair value	Caelum Convertible Note, at fair value	Warrants issued and issuable	Warrant liabilities	Total
Balance at December 31, 2017	\$ 1,390	\$ 4,700	\$ 10,059	\$ 5,597	\$ 87	\$ 21,833
Payment of convertible note	–	(4,076)	–	–	–	(4,076)
Reclassification of warrant liability from debt to equity	–	–	–	(13,615)	–	(13,615)
Change in fair value of investments	(1,390)	–	–	–	–	(1,390)
Change in fair value of convertible notes	–	(291)	265	–	–	(26)
Change in fair value of derivative liabilities	–	–	–	8,018	(87)	7,931
Balance at September 30, 2018	\$ –	\$ 333	\$ 10,324	\$ –	\$ –	\$ 10,657

For the nine months ended September 30, 2018, no transfers occurred between Level 1, Level 2 and Level 3 instruments.

## 8. 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 the Company and its’ subsidiaries require substantial completion of research and development, regulatory and marketing approval efforts in order to reach technological feasibility. As such, for the three and nine months ended September 30, 2018 and 2017, 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:

(\$ in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Fortress	\$ –	\$ –	\$ –	\$ 300
Fortress Companies:				
Checkpoint	1,000	–	1,000	400
Helocyte	1,500	–	1,521	–
Mustang	1,000	300	1,075	2,375
Cellvation	–	–	1	–
Caelum	201	–	201	219
Cyprium	–	–	–	100
Aevitas	5	–	6	–
Total	\$ 3,706	\$ 300	\$ 3,804	\$ 3,394

### Checkpoint

The table below provides a summary of Checkpoint’s expense related to its licenses, for the three and nine months ended September 30, 2018 and 2017 by license as recorded in the Condensed Consolidated Statements of Operations:

(\$ in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Dana Farber License CK-301	\$ 1,000	\$ –	\$ 1,000	\$ –
Jubilant Biosys License CK-103	–	–	–	400
Total Licenses Acquired Expense	\$ 1,000	\$ –	\$ 1,000	\$ 400

For the three and nine months ended September 30, 2018, Checkpoint recorded a \$1.0 million milestone in connection with their license agreement with Dana-Farber, in connection with the achievement of dosing the 12<sup>th</sup> patient in the Phase 1 trial for CK-301.

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See Note 21 for revenue recognized in connection with the Jubilant license under a sublicense agreement with TGTX, a related party.

*Helocyte*

In connection with Helocyte’s amended and restated license agreement for Triplex with COH, during the fourth quarter of 2018 Helocyte expects to achieve a development milestone. The milestone relates to completion of the Phase 2 clinical trial which Helocyte deems to be probable, due to the completion of the follow-up period for the last patient dosed in the trial. For the three and nine months ended September 30, 2018 and 2017, respectively, Helocyte recorded expense of \$1.5 million and nil, and \$1.5 million and nil, respectively, in connection with this license.

*Mustang*

On August 2, 2018, Mustang entered into an exclusive worldwide license agreement with St. Jude Children’s Research Hospital (“St. Jude”) for the development of a first-in-class ex vivo lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (“X-SCID”), 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 X-SCID. Mustang paid an upfront fee of \$1.0 million in August 2018 under the license in addition to an annual maintenance fee of \$0.1 million (beginning in 2019). St. Jude is also eligible to receive milestone payments totaling up to \$13.5 million, upon and subject to the achievement of five development and commercialization milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. Mustang is obligated to pay to St. Jude a percentage of certain revenues received in connection with a sublicense that is in the mid-teens, regardless of when such sublicense is executed.

The table below provides a summary of Mustang’s expense related to its licenses, for the three and nine months ended September 30, 2018 and 2017 by license as recorded in the Condensed Consolidated Statements of Operations:

(\$ in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
City of Hope (COH) IL-13 License	\$ –	\$ –	\$ –	\$ 250
COH IV/ICV License	–	–	–	125
COH HER2 License	–	–	–	600
COH CS-1 License	–	–	–	600
COH License for PSCA	–	–	–	300
UCLA License for PSCA	–	–	–	200
Fred Hutch CD20	–	300	–	300
X-SCID License – St. Jude’s	1,000	–	1,000	–
Manufacturing License	–	–	75	–
Total licenses acquired expense	<u>\$ 1,000</u>	<u>\$ 300</u>	<u>\$ 1,075</u>	<u>\$ 2,375</u>

*Caelum*

For the three and nine months ended September 30, 2018 and 2017, respectively, Caelum recorded expense of approximately \$0.2 and nil, and \$0.2 and \$0.2 million in connection with its license for CAEL-101 from Columbia University.

*Cyprium*

For the three and nine months ended September 30, 2018 and 2017, respectively, Cyprium recorded no expense in 2018 and nil and \$0.1 million in 2017, in connection with its license for CUTX-101 (copper histidine injection) from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (“NICHD”).

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**9. Sponsored Research and Clinical Trial Agreements**

*Aevitas*

On January 25, 2018, Aevitas entered into a Sponsored Research Agreement 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. The total amount to be funded by Aevitas under the UMass SRA is \$0.8 million. Pursuant to the terms of the UMass SRA, Aevitas paid \$0.8 million which was due upon execution. For the three and nine months ended September 30, 2018, Aevitas recorded expense of approximately \$0.2 million and \$0.6 million in connection with the UMass SRA. The expense was recorded in research and development expenses in the Company’s Condensed Consolidated Statements of Operations. No expense related to this Agreement was recorded in 2017.

On July 24, 2018, Aevitas entered into a Sponsored Research Agreement 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. The total amount to be funded by Aevitas under the UPenn SRA is \$2.0 million. Pursuant to the terms of the UPenn SRA, Aevitas paid \$0.3 million which was due upon execution. For the three and nine months ended September 30, 2018, Aevitas recorded expense of approximately \$0.3 million and \$0.3 million in connection with the UPenn SRA. The expense was recorded in research and development expenses in the Company’s Condensed Consolidated Statements of Operations. No expense related to this Agreement was recorded in 2017.

*Caelum*

On March 12, 2018, Caelum entered into a Sponsored Research Agreement with Columbia University to conduct preclinical research in connection with CAEL-101. The total cost of the study approximates \$0.1 million. For the three and nine months ended September 30, 2018, Caelum recorded expense of approximately \$27,000 and \$0.1 million, respectively in connection with the agreement. The expense was recorded in research and development expense in the Company’s Condensed Consolidated Statements of Operations.

*Cellvation*

For the three and nine months ended September 30, 2018 and 2017, respectively, Cellvation recorded expense of \$0.1 million and \$0.2 million and \$0.1 million and nil, 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.

*Checkpoint*

In connection with its license agreement with NeuPharma, Inc. (“NeuPharma”), Checkpoint entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities and subsequently entered into an agreement with TGTX, a related party, to assume all costs associated with this Sponsored Research Agreement, including all amounts previously paid by the Company. For the three and nine months ended September 30, 2018 and 2017, approximately nil and approximately \$0.1 million and \$31,000 and \$0.5 million, respectively, was recognized in research and development revenue in connection with the Sponsored Research Agreement in the Company’s Condensed Consolidated Statements of Operations.

*Helocyte*

The table below provides a summary of Helocyte’s expense related to its clinical research arrangements, for the three and nine months ended September 30, 2018 and 2017, by agreement as recorded in the Condensed Consolidated Statements of Operations:

(\$ in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
COH Triplex clinical research and support	\$ —	\$ 1,300	\$ —	\$ 2,335
COH PepVax clinical research and support	—	327	—	561
COH Pentamer clinical research and support	113	12	317	24
Total licenses acquired expense	\$ 113	\$ 1,639	\$ 317	\$ 2,920

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During the first quarter of 2018, Helocyte elected to discontinue the further development of its HLA-restricted, single-antigen PepVax program and as such will cease to incur costs associated with this program.

*Mustang*

The table below provides a summary of Mustang's expense related to its sponsored research and clinical trial agreements, for the three and nine months ended September 30, 2018 and 2017, by license as recorded in the Condensed Consolidated Statements of Operations:

(\$ in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
COH CAR T	\$ 500	\$ 500	\$ 1,500	\$ 1,500
COH - CD123	123	642	387	1,237
COH - IL13R $\alpha$ 2	346	194	849	1,204
City of Hope - Manufacturing	114	-	344	-
Fred Hutch – CD20	255	88	938	88
BIDMC – CRISPR	69	-	69	-
Total	\$ 1,407	\$ 1,424	\$ 4,087	\$ 4,029

*Tamid*

On November 30, 2017, in connection with its three separate license agreements with UNC, Tamid entered into a Sponsored Research Agreement with UNC ("UNC SRA") for certain continued research and development activities related to Nanodysferlin for treatment of Dysferlinopathy, and AAV-HLA-G for corneal transplant rejection. Total amount to be funded by Tamid under the UNC SRA is \$2.3 million over a term of three years. Pursuant to the terms of the UNC SRA, Tamid paid \$0.8 million which was due upon execution. For the three and nine months ended September 30, 2018, Tamid recorded expense of \$0.2 million and \$0.6 million, respectively in connection with the UNC SRA. The expense was recorded in research and development expenses in the Company's Condensed Consolidated Statements of Operations.

**10. Intangibles, net**

*Journey*

On August 31, 2018, Journey entered into an agreement with a third party to acquire the exclusive rights to Exelderm®, an antifungal ointment. As of September 30, 2018, Journey recorded this acquisition as an intangible asset and will recognize expense over the expected life of Exelderm® of 3 years.

For the three months ended September 30, 2018 and 2017, Journey recognized amortization expense of approximately \$0.2 million and \$0.1 million, respectively, which was recorded in costs of goods sold in the Company's Condensed Consolidated Statements of Operations. For the nine months ended September 30, 2018 and 2017, Journey recognized amortization expense of approximately \$0.4 million and \$0.4 million, respectively, which was recorded in costs of goods sold in the Company's Condensed Consolidated Statements of Operations.

	Estimated Useful Lives (in years)	Cost
Ceracade®	3	\$ 300
Luxamend®	3	50
Targadox®	3	1,250
Exelderm®	3	1,200
Total		\$ 2,800

The carrying amount related to acquired intangible assets as of September 30, 2018 are as follows (\$ in thousands):

Intangible assets at December 31, 2017	\$ 883
Addition	1,200
Amortization expense	(433)
Intangible assets at September 30, 2018	\$ 1,650



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## 11. Debt and Interest

### Debt

#### *2018 Venture Notes*

During the period ended March 31, 2018, the Company closed a private placement of promissory notes for an aggregate of \$21.7 million (the “2018 Venture Notes”) through National Securities Corporation (“NSC”), a wholly-owned subsidiary of National and a related party by virtue of the Company’s ownership of National. The Company intends to use the proceeds from the 2018 Venture Notes to acquire and license medical technologies and products through existing or recently formed Company subsidiaries. The Company may also use the proceeds to finance its subsidiaries. The notes mature 36 months from issuance, provided that during the first 24 months the Company may extend the maturity date by six months. No principal amount will be due for the first 24 months (or the first 30 months if the maturity date is extended). Thereafter, the note will be repaid at the rate of 1/12 of the principal amount per month for a period of 12 months. Interest on the note is 8% payable quarterly during the first 24 months (or the first 30 months if the note is extended) and monthly during the last 12 months.

NSC acted as the sole placement agent for the 2018 Venture Notes. The Company paid NSC a fee of \$1.7 million during the three months ended March 31, 2018 in connection with its placement of the 2018 Venture Notes. At September 30, 2018, the fee, which was recorded as debt discount and is being amortized over the life of the 2018 Venture Notes, was eliminated in consolidation.

The 2018 Venture Notes allows the Company to transfer a portion of the proceeds from the 2018 Venture Notes to a Fortress subsidiary upon the completion by such subsidiary of an initial public offering in which it raises sufficient equity capital so that it has cash equal to five times the amount of the portion of the proceeds of the 2018 Venture Notes so transferred (the “SubCo Funding Threshold”). At the time of transfer the Company’s obligation under the NSC Note will be reduced by the amount transferred.

During the nine months ended September 30, 2018, the Company has transferred \$1.8 million to Aevitas, \$1.1 million to Tamid, \$1.0 Million to Cyprium and \$1.2 million to Cellvation. Notwithstanding such transfers, the Company continues to hold such debt balances as liabilities on its own balance sheet on a consolidated basis, until such time as the SubCo Funding Threshold is met with respect to a particular subsidiary.

In connection with this transfer NSC will receive warrants to purchase each such subsidiary’s stock equal to 25% of that subsidiary’s proceeds of the 2018 Venture Notes divided by the lowest price at which the subsidiary sells its equity in its first third party equity financing. The warrants issued will have a term of 10 years and an exercise price equal to the par value of the Fortress subsidiary’s common stock. The value of the warrants, if any, is eliminated in consolidation. As of September 30, 2018, the warrants were contingently issuable as neither an initial public offering nor a third-party financing had occurred.

#### *Opus Credit Facility Agreement Maturity Date Extension*

On March 12, 2018, the Company and Opus Point Healthcare Innovation Healthcare Fund (“OPHIF”) amended and restated the Opus Credit Facility (the “A&R Opus Credit Facility”). The A&R Opus Credit Facility extended 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.

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Total debt consists of the following as of September 30, 2018 and December 31, 2017:

<i>(\$ in thousands)</i>	<b>September 30, 2018</b>	<b>December 31, 2017</b>	<b>Interest Rate</b>	<b>Maturity</b>
IDB Note	\$ 14,929	\$ 14,929	2.25%	August - 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 Notes	6,517	-	8.00%	February - 2021
2018 Venture Notes	15,190	-	8.00%	March - 2021
Opus Credit Facility <sup>1</sup>	9,500	9,500	12.00%	September - 2019
Helocyte Convertible Note, at fair value <sup>2</sup>	-	1,000	8.00%	December - 2017
Helocyte Convertible Note, at fair value <sup>1, 2</sup>	300	2,194	8.00%	September - 2018
Helocyte Convertible Note, at fair value <sup>2</sup>	-	1,062	8.00%	April - 2018
Helocyte Convertible Note, at fair value <sup>1,2</sup>	23	444	8.00%	November - 2018
Helocyte Convertible Note, at fair value <sup>1</sup>	10	-	8.00%	October - 2018
Caelum Convertible Note, at fair value <sup>1</sup>	1,044	1,017	8.00%	January - 2019
Caelum Convertible Note, at fair value <sup>1</sup>	7,082	6,900	8.00%	February - 2019
Caelum Convertible Note, at fair value <sup>1</sup>	2,198	2,142	8.00%	March - 2019
Total notes payable	85,149	67,544		
Less: Discount on notes payable	892	1,035		
Total notes payable	<u>\$ 84,257</u>	<u>\$ 66,509</u>		

(1) Classified as short-term on the Company's Condensed Consolidated Balance Sheet as of September 30, 2018.

(2) Classified as short-term on the Company's Condensed Consolidated Balance Sheet as of December 31, 2017.

### 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:

<i>(\$ in thousands)</i>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
<b>IDB Note</b>				
Interest	\$ 85	\$ 85	\$ 254	\$ 254
Total IDB Note	<u>85</u>	<u>85</u>	<u>254</u>	<u>254</u>
<b>NSC Debt</b>				
Interest	-	(8)	-	147
Amortization of fees	-	127	-	200
Total NSC Debt	<u>-</u>	<u>119</u>	<u>-</u>	<u>347</u>
<b>2017 Subordinated Note Financing</b>				
Interest	1,060	755	3,157	1,161
Amortization of fees	28	208	79	383
Total 2017 Subordinated Note Financing	<u>1,088</u>	<u>963</u>	<u>3,236</u>	<u>1,544</u>
<b>Opus Credit Facility</b>				
Interest	288	287	853	798
Amortization of fees	105	282	525	733
Total Opus Note	<u>393</u>	<u>569</u>	<u>1,378</u>	<u>1,531</u>
<b>2018 Venture Notes</b>				
Interest	438	-	923	-
Amortization of fees	10	-	20	-
Total 2018 Venture Notes	<u>448</u>	<u>-</u>	<u>943</u>	<u>-</u>

<b>LOC Fees</b>				
Interest	7	7	23	22
<b>Total LOC</b>	<u>7</u>	<u>7</u>	<u>23</u>	<u>22</u>
<b>Helocyte Convertible Note</b>				
Interest	6	64	93	175
Financing fee	-	-	-	1
<b>Total Helocyte Convertible Note</b>	<u>6</u>	<u>64</u>	<u>93</u>	<u>176</u>
<b>Avenue Convertible Note</b>				
Interest	-	-	-	5
Financing fee	-	-	-	3
<b>Total Avenue Convertible Note</b>	<u>-</u>	<u>-</u>	<u>-</u>	<u>8</u>
<b>Caelum Convertible Note</b>				
Interest	198	68	589	68
Financing fee	-	1,317	-	1,317
<b>Total Caelum Convertible Note</b>	<u>198</u>	<u>1,385</u>	<u>589</u>	<u>1,385</u>
<b>Falk CSR</b>				
Interest	-	26	(64)	26
<b>Total Falk CSR</b>	<u>-</u>	<u>26</u>	<u>(64)</u>	<u>26</u>
<b>Other</b>				
Interest	3	2	3	5
<b>Total D&amp;O Insurance</b>	<u>3</u>	<u>2</u>	<u>3</u>	<u>5</u>
<b>Total Interest Expense and Financing Fee</b>	<u>\$ 2,228</u>	<u>\$ 3,220</u>	<u>\$ 6,455</u>	<u>\$ 5,298</u>

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**12. Accrued Expenses and Other Long-Term Liabilities**

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

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
<b>Accrued Expenses:</b>		
Professional fees	\$ 1,471	\$ 1,625
Salaries, bonuses and related benefits	4,349	5,279
Accrued expenses - related party	50	95
Research and development	3,036	1,873
Milestones related to license agreement	2,500	800
Manufacturing	1,411	1,188
Clinical supplies	2,619	85
License maintenance fees	454	100
Dr. Falk Pharma milestone (See Note 16)	1,300	3,059
Accrued royalties payable	1,045	1,411
Deferred coupon funding	1,490	1,087
Other	644	1,030
<b>Total accrued expenses</b>	<b>\$ 20,369</b>	<b>\$ 17,632</b>
<b>Other long-term liabilities:</b>		
Deferred rent and long-term lease abandonment charge	4,961	4,739
<b>Total other long-term liabilities</b>	<b>\$ 4,961</b>	<b>\$ 4,739</b>

National's accounts payable and other accrued expenses as of June 30, 2018 and September 31, 2017, consisted of the following:

	<b>June 30, 2018</b>	<b>September 30, 2017</b>
Legal	\$ 1,018	\$ 877
Audit	258	176
Telecommunications	207	205
Data Services	547	464
Regulatory	372	540
Settlements	487	2,403
Deferred rent	679	497
Other	3,135	3,242
<b>Total</b>	<b>\$ 6,703</b>	<b>\$ 8,404</b>

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**13. Non-Controlling Interests**

Non-controlling interests in consolidated entities, as recorded on the Condensed Consolidated Balance Sheets are as follows:

	<b>As of September 30, 2018</b>			
	<b>NCI Equity Share</b>	<b>Net gain/(loss) attributable to non-controlling interests</b>	<b>Non-controlling interests in consolidated entities</b>	<b>Non-controlling ownership</b>
Aevitas	\$ (456)	\$ (397)	\$ (853)	37.0%
Avenue <sup>2</sup>	13,043	(11,232)	1,811	64.8%
Caelum	(2,387)	(1,841)	(4,228)	37.0%
Cellvation	(447)	(137)	(584)	21.7%
Checkpoint <sup>1</sup>	30,837	(15,601)	15,236	69.2%
Coronado SO	(290)	-	(290)	13.0%
Cyprium	(197)	(68)	(265)	10.8%
Helocyte	(3,285)	(464)	(3,749)	19.8%
JMC	(456)	197	(259)	6.3%
Mustang <sup>2</sup>	38,147	(11,174)	26,973	60.0%
National Holdings	15,805	(2,345)	13,460	43.7%
Tamid	(196)	(192)	(388)	24.0%
<b>Total</b>	<b>\$ 90,118</b>	<b>\$ (43,254)</b>	<b>\$ 46,864</b>	

	<b>As of December 31, 2017</b>			
	<b>NCI Equity Share</b>	<b>Net gain/(loss) attributable to non-controlling interests</b>	<b>Non-controlling interests in consolidated entities</b>	<b>Non-controlling ownership</b>
Aevitas	\$ (126)	\$ (168)	\$ (294)	35.4%
Avenue <sup>2</sup>	17,454	(4,646)	12,808	66.1%
Caelum	(815)	(1,262)	(2,077)	34.7%
Cellvation	(259)	(96)	(355)	21.5%
Checkpoint <sup>1</sup>	21,635	(12,314)	9,321	62.0%
Coronado SO	(236)	(54)	(290)	13.0%
Cyprium	(143)	(15)	(158)	11.1%
Helocyte	(1,907)	(1,193)	(3,100)	20.0%
JMC	(469)	7	(462)	6.3%
Mustang <sup>2</sup>	48,740	(11,911)	36,829	61.6%
National Holdings	17,021	(1,216)	15,805	43.4%
Tamid	(6)	(92)	(98)	24.0%
<b>Total</b>	<b>\$ 100,889</b>	<b>\$ (32,960)</b>	<b>\$ 67,929</b>	

(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.

(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.

**14. Net Loss per Common Share**

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net 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 net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average common stock outstanding used to calculate both basic and diluted net loss per share is the same.

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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 nine months ended September 30, 2018 and 2017:

	<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>
Warrants to purchase Common Stock	890,892	678,072
Opus warrants to purchase Common Stock	1,880,000	206,593
Options to purchase Common Stock	1,085,502	1,095,905
Convertible Preferred Stock	1,000,000	-
Unvested Restricted Stock	11,014,596	9,848,505
Unvested Restricted Stock Units	1,796,134	1,234,555
<b>Total</b>	<u>17,667,124</u>	<u>13,063,630</u>

### 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 and nine months ended September 30, 2018 and 2017:

<i>(\$ in thousands)</i>	<u>For the Three Months Ended September 30,</u>		<u>For the Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Employee Awards	\$ 1,012	\$ 1,104	\$ 3,075	\$ 3,528
Executive awards of Fortress Companies' stock	446	546	1,408	1,642
Non-employee awards	24	24	70	60
Fortress Companies:				
Avenue	371	246	1,043	269
Checkpoint	1,128	910	2,336	4,271
Mustang	922	834	3,888	1,231
Caelum	152	427	92	427
Other	51	93	141	308
National	929	129	1,605	312
<b>Total stock-based compensation</b>	<u>\$ 5,035</u>	<u>\$ 4,313</u>	<u>\$ 13,658</u>	<u>\$ 12,048</u>

For the three months ended September 30, 2018 and 2017, approximately \$1.8 million and \$1.6 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 \$3.2 million and \$2.7 million, respectively, was included in general and administrative expenses in connection with grants made to employees, members of the board of directors and consultants.

For the nine months ended September 30, 2018 and 2017, approximately \$4.9 million and \$4.8 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 \$8.7 million and \$7.2 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 Companies:

	<u>Number of Shares</u>	<u>Weighted average exercise price</u>	<u>Total weighted average intrinsic value</u>	<u>Weighted average remaining contractual life (years)</u>
Options vested and expected to vest at December 31, 2017	1,110,501	\$ 3.78	\$ 1,351,080	3.95
Exercised	-	-	-	-
Options vested and expected to vest at September 30, 2018	1,110,501	\$ 3.78	\$ 87,132	3.21
Options vested and exercisable	<u>1,085,501</u>	<u>\$ 3.75</u>	<u>\$ 87,132</u>	<u>3.18</u>

As of September 30, 2018, Fortress had no unrecognized stock-based compensation expense related to options.

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**Restricted Stock and Restricted Stock Units**

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

	Number of Shares	Weighted average grant price
Unvested balance at December 31, 2017	11,874,034	\$ 2.63
Restricted stock granted	1,392,856	3.99
Restricted stock vested	(213,333)	2.76
Restricted stock units granted	430,000	4.03
Restricted stock units forfeited	(426,978)	4.05
Restricted stock units vested	(516,732)	3.56
Unvested balance at September 30, 2018	<u>12,539,847</u>	<u>\$ 2.74</u>

As of September 30, 2018, and 2017, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately \$9.8 million and \$1.7 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 3.6 years and 2.0 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, 2017	2,774,189	\$ 3.30	\$ 2,204,530	4.47
Forfeited	(20,000)	5.72	-	-
Outstanding as of September 30, 2018	<u>2,754,189</u>	<u>\$ 3.28</u>	<u>\$ 13,800</u>	<u>3.75</u>
Exercisable as of September 30, 2018	<u>849,189</u>	<u>\$ 3.92</u>	<u>\$ 13,800</u>	<u>3.39</u>

**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 September 30, 2018, 289,359 shares have been purchased and 710,641 shares are available for future sale under the Company's ESPP. Share-based compensation expense recorded was approximately \$52,000 and \$52,000, respectively, for the three months ended September 30, 2018 and 2017, and was approximately \$0.1 million and \$0.1 million, respectively, for the nine months ended September 30, 2018 and 2017.

**Capital Raises**

*Fortress*

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 nine month period ended September 30, 2018, the Company issued 2,668,756 shares of common stock at an average price of \$2.61 per share for gross proceeds of \$7.0 million. In connection with these sales, the Company paid aggregate fees of approximately \$0.2 million.

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**Fortress Companies**

*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 and nine months ended September 30, 2018, Checkpoint sold a total of 1,841,774 shares of its common stock under the Checkpoint ATM for aggregate total gross proceeds of approximately \$8.0 million at an average selling price of \$4.33 per share, resulting in net proceeds of approximately \$7.7 million after deducting commissions and other transactions costs.

Checkpoint Public Offering of Common Stock

On March 12, 2018, Checkpoint closed an underwritten public offering in which it sold 5,290,000 shares of its common stock at a price of \$4.35 per share for gross proceeds of approximately \$23.0 million. Total net proceeds from this offering were approximately \$20.8 million, net of underwriting discounts and estimated offering expenses of approximately \$2.2 million. The shares were sold under the Checkpoint S-3.

Approximately \$69.0 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 - Fortress**

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.

Dr. Falk Pharma, GmbH v. Fortress Biotech, Inc. (Frankfurt am Main Regional Court, Ref. No. 3-06 0 28/16). Dr. Falk Pharma, GmbH ("Dr. Falk Pharma") and Fortress were among the parties to that certain Collaboration Agreement dated March 20, 2012, whereby they agreed to collaborate to develop a product for treatment of Crohn's disease. A dispute arose between Dr. Falk Pharma and Fortress with respect to their relative rights and obligations under the Collaboration Agreement; specifically, Dr. Falk Pharma contended that it had fulfilled its contractual obligations to Fortress and is entitled to the final milestone payment due under the Collaboration Agreement - EUR 2.5 million. Fortress contended that no such payment is due because a condition of the EUR 2.5 million payment was the delivery of a Clinical Study Report that addressed the primary and secondary objectives of a Phase II trial, and Fortress contended that Dr. Falk Pharma failed to deliver such a Clinical Study Report. Dr. Falk Pharma filed a lawsuit against Fortress in the above-referenced Court in Frankfurt, Germany to recover the EUR 2.5 million plus interest and attorneys' fees, and Fortress filed an answer to the complaint, denying that it had any liability to Dr. Falk Pharma. On July 27, 2017, Fortress received a judgment from the court in Frankfurt awarding the full amount (EUR 2.5 million) plus interest to Dr. Falk Pharma. Fortress appealed the decision to the Higher Regional Court of Frankfurt on August 28, 2017, and the initial response of Dr. Falk Pharma to the appeal was filed on February 16, 2018. At an appellate hearing in the Higher Regional Court on June 12, 2018, the court issued an oral ruling upholding the lower court's judgment and indicating that an impending written, enforceable judgment would do the same. On July 12, 2018, the Higher Regional Court approved and recorded terms of settlement between Fortress and Dr. Falk Pharma pursuant to which Fortress will pay \$3.3 million to Dr. Falk Pharma over the course of a year, and approximately \$37,000 to the court in mandated administrative fees. In accordance with the settlement, the Company paid Dr. Falk Pharma \$2.0 million and the court mandated administrative fees of \$39,500 during the three months ended September 30, 2018.



**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**  
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**Litigation and Regulatory Matters - National**

National is a defendant or respondent in various pending and threatened arbitrations, administrative proceedings and lawsuits seeking compensatory damages. Several cases have no stated alleged damages. Claim amounts are infrequently indicative of the actual amounts National will be liable for, if any. Further, National has a history of collecting amounts awarded in these types of matters from its brokers that are still affiliated, as well as from those that are no longer affiliated. Many of these claimants also seek, in addition to compensatory damages, punitive or treble damages, and all seek interest, costs and fees. These matters arise in the normal course of business. National intends to vigorously defend itself in these actions, and the ultimate outcome of these matters cannot be determined at this time.

Liabilities for potential losses from complaints, legal actions, government investigations and proceedings are established where National believes that it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. In making these decisions, management bases its judgments on its knowledge of the situations, consultations with legal counsel and its historical experience in resolving similar matters. In many lawsuits, arbitrations and regulatory proceedings, it is not possible to determine whether a liability has been incurred or to estimate the amount of that liability until the matter is close to resolution. However, accruals are reviewed regularly and are adjusted to reflect National's estimates of the impact of developments, rulings, advice of counsel and any other information pertinent to a particular matter. Because of the inherent difficulty in predicting the ultimate outcome of legal and regulatory actions, management cannot predict with certainty the eventual loss or range of loss related to such matters. At June 30, 2018 and September 30, 2017, National accrued approximately \$0.5 million and \$2.4 million, respectively. These amounts are included in accounts payable and accrued expenses in the condensed consolidated statements of financial condition. Amounts charged to operations for settlements and potential losses during the three months ended June 30, 2018 and 2017 were \$(0.1) million and \$2.3 million, respectively, and during the nine months ended June 30, 2018 and 2017, National charged \$0.6 million and \$3.3 million, respectively, to operations, which is included in other administrative expenses. National has included in "Professional fees" litigation and FINRA related expenses of \$0.4 million and \$0.4 million for the three months ended June 30, 2018 and 2017, respectively, and \$0.7 million and \$1.2 million for the nine months ended June 30, 2018 and 2017, respectively.

**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 13.2% of the Company's issued and outstanding Common Stock as of September 30, 2018. The Company's Executive Vice Chairman, Strategic Development owns approximately 15.3% of the Company's issued and outstanding Common Stock at September 30, 2018.

For their service in 2017, the Company's CEO and Executive Vice Chairman received bonuses of \$500,000 each, paid in cash during the quarter ended June 30, 2018. The bonus recipients waived their right to a cash bonus from the Company. The Company treated this transaction as a capital contribution, which is reflected on the Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2018.

*National Holdings Corporation*

The Company maintains a controlling interest in National Holdings Corporation, a diversified independent brokerage company. One of National's subsidiaries, National Securities Corporation, is an independent broker-dealer offering retail and institutional advisory, investment, insurance and tax planning services. From time to time, NSC provides services to the Company and its affiliates.

*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 September 30, 2018 and 2017, the Company invoiced TGTX \$0.2 million and \$0.2 million, respectively. For the nine months ended September 30, 2018 and 2017, the Company invoiced TGTX \$1.2 million and \$0.8 million, respectively. At September 30, 2018, the amount receivable from TGTX related to this arrangement approximated \$0.1 million.

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*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 September 30, 2018, the Company had paid \$1.8 million in rent under the Desk Space Agreements, and invoiced OPPM and TGTX approximately \$162,000 and \$0.7 million, respectively, for their prorated share of the rent base. In addition, for the nine months ended September 30, 2018, the Company had incurred approximately \$96,000 in connection with the build out of the space and recorded a receivable of \$43,000 due from TGTX and \$10,000 due from OPPM. At September 30, 2018, the amount due from TGTX approximated a credit of \$48,000 and the amount due from OPPM approximated \$162,000.

*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 (see Note 11). For the nine months ended September 30, 2018 and 2017, the Company paid \$0.3 million and \$0.8 million, respectively. The Q2 interest payment due May 31, 2018 was paid in 86,289 shares of Company stock. The Q3 interest payment due August 31, 2018 was paid in 147,741 shares of Company stock.

*Checkpoint Public Offering of Common Stock*

NSC, a subsidiary of National (of which the Company owns 56.3%), served as the sole book running manager in connection with Checkpoint's 2018 equity offering, which closed on March 12, 2018. As the Sole Book Running Manager, NSC received a fee of approximately \$1.8 million, or 8% on the gross proceeds raised of \$23.0 million. The fees were eliminated in consolidation.

*Mustang Option on Collaboration Agreement with TGTX*

On February 2, 2018, Mustang entered into an Option Agreement the ("TGTX Mustang Option") with TG Therapeutics, Inc. ("TGTX"), a related party, whereby TGTX was granted the option to enter into a global collaboration on the joint development and commercialization of product candidates pertaining to Mustang's CD20 license agreement with the Fred Hutchinson Cancer Research Center. In consideration of the TGTX Mustang Option, TGTX is required to pay an option fee of \$50,000, which was recorded by Mustang as Collaboration Revenue Related Party in the Condensed Consolidated Statement of Operations. The TGTX Option expired on August 1, 2018 without action. Mr. Weiss, the Company's Executive Vice Chairman, Strategic Development, serves as the Chief Executive Officer of TGTX.

*2018 Venture Notes*

For the nine-month period ended September 30, 2018, the Company raised approximately \$21.7 million in promissory notes. National Securities Corporation ("NSC"), a wholly-owned subsidiary of National, and a related party as a result of the Company's ownership of National, acted as the sole placement agent for the 2018 Venture Notes. The Company paid NSC a fee of \$1.7 million during the nine months ended September 30, 2018, in connection with the 2018 Venture Notes. At September 30, 2018, the fee, which was recorded as debt discount on the Company's Condensed Consolidated Balance Sheet and will be amortized over the life of the 2018 Venture Notes, was eliminated in consolidation.

*Founders Agreement*

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, 2017, filed with the SEC on March 16, 2018. 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.

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Fortress Company	Effective Date <sup>(1)</sup>	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	2.5%	Common Stock
Mustang	March 13, 2015	2.5%	Common Stock
Checkpoint	March 17, 2015	0.0% <sup>(2)</sup>	Common Stock
Cellvation	October 31, 2016	2.5%	Common Stock
Caelum	January 1, 2017	2.5%	Common Stock
Cyprium	March 13, 2017	2.5%	Common Stock
Aevitas	July 28, 2017	2.5%	Common Stock
Tamid	November 30, 2017 <sup>(3)</sup>	2.5%	Common Stock

(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.

(2) 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.

(3) Represents the Trigger Date.

*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, 2017, filed with the SEC on March 16, 2018. 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 Company	Effective Date	Annual MSA Fee (Income)/Expense
Helocyte	March 20, 2015	\$ 500
Avenue	February 17, 2015	500
Mustang	March 13, 2015	500
Checkpoint	March 17, 2015	500
Cellvation	October 31, 2016	500
Caelum	January 1, 2017	500
Cyprium	March 13, 2017	500
Aevitas	July 28, 2017	500
Tamid	November 30, 2017	500
Fortress		(4,500)
<b>Consolidated (Income)/Expense</b>		<b>\$ -</b>

*National*

On June 12, 2018, Michael S. Weiss, the Company's Executive Vice Chairman, Strategic Development, resigned from his position on the National board of directors. As of September 30, 2018, the Company owns approximately 56.3% of National.

Additionally, the Company's Chairman, President and Chief Executive Officer and the Company's Executive Vice Chairman, Strategic Development are both Co-Portfolio Managers and Partners of OPPM, which owns approximately 4.2% of National. In the normal course, National has occasionally provided the Company and the Company's subsidiaries with placement agent services in connection with third party raises. These fees are eliminated in consolidation.

**18. Net Capital Requirements of Broker-Dealer Subsidiaries**

NSC is subject to the SEC's Uniform Net Capital Rule (Rule 15c3-1) (the "Rule"), which, among other things, requires the maintenance of minimum net capital. At June 30, 2018, National Securities had net capital of \$11.3 million which was \$10.3 million in excess of its required net capital of \$1.0 million. National Securities is exempt from the provisions of the SEC's Rule 15c3-3 since it is an introducing broker-dealer that clears all transactions on a fully disclosed basis and promptly transmits all customer funds and securities to clearing brokers.

Advances, dividend payments and other equity withdrawals from the Company's broker-dealer subsidiaries are restricted by the regulations of the SEC, and other regulatory agencies. These regulatory restrictions may limit the amounts that a subsidiary may dividend or advance to the Company.



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**19. Off Balance Sheet Risk and Concentrations of Credit Risk**

National is engaged in trading and providing a broad range of securities brokerage and investment services to a diverse group of retail and institutional clientele, as well as corporate finance and investment banking services to corporations and businesses. Counterparties to National's business activities include broker-dealers and clearing organizations, banks and other financial institutions. National uses clearing brokers to process transactions and maintain customer accounts for National on a fee basis. National permits the clearing firms to extend credit to its clientele secured by cash and securities in the client's account. National's exposure to credit risk associated with the non-performance by its customers and counterparties in fulfilling their contractual obligations can be directly impacted by volatile or illiquid trading markets, which may impair the ability of customers and counterparties to satisfy their obligations to National. National has agreed to indemnify the clearing brokers for losses they incur while extending credit to National's clients. It is National's policy to review, as necessary, the credit standing of its customers and counterparties. Amounts due from customers that are considered uncollectible by the clearing broker are charged back to National by the clearing broker when such amounts become determinable. Upon notification of a charge back, such amounts, in total or in part, are then either (i) collected from the customers, (ii) charged to the broker initiating the transaction and/or (iii) charged to operations, based on the particular facts and circumstances.

National maintains cash in bank deposits, which, at times, may exceed federally insured limits. National has not experienced and does not expect to experience losses on such accounts.

A short sale involves the sale of a security that is not owned in the expectation of purchasing the same security (or a security exchangeable) at a later date at a lower price. A short sale involves the risk of a theoretically unlimited increase in the market price of the security that would result in a theoretically unlimited loss.

**20. Segment Information**

The Company operates in three operating and reportable segments, Dermatology Product Sales, Pharmaceutical and Biotechnology Product Development and National. The accounting policies of the Company's segments are the same as those described in Note 2. The following tables summarize, for the periods indicated, operating results by reportable segment:

Cost of goods sold is directly related to product sales only. Revenues derived from co-promote revenue had no cost of goods sold.

<i>(\$ in thousands)</i>	<b>Pharmaceutical and Biotechnology</b>		<b>National</b>	<b>Consolidated</b>
	<b>Dermatology Products Sales</b>	<b>Product Development</b>		
<b>Three Months Ended September 30, 2018</b>				
Net Revenue	\$ 5,168	\$ 5	\$ 58,520	\$ 63,693
Direct cost of goods	(1,406)	-	-	(1,406)
Sales and marketing costs	(2,754)	-	-	(2,754)
Research and development	-	(19,788)	-	(19,788)
General and administrative	(505)	(8,925)	-	(9,430)
National expenses	-	-	(55,204)	(55,204)
Segment income (loss) from operations	<u>\$ 503</u>	<u>\$ (28,708)</u>	<u>\$ 3,316</u>	<u>\$ (24,889)</u>
Segment assets	<u>\$ 10,765</u>	<u>\$ 157,781</u>	<u>\$ 56,373</u>	<u>\$ 224,919</u>

<i>(\$ in thousands)</i>	<b>Pharmaceutical and Biotechnology</b>		<b>National</b>	<b>Consolidated</b>
	<b>Dermatology Products Sales</b>	<b>Product Development</b>		
<b>Three Months Ended September 30, 2017</b>				
Net Revenue	\$ 2,170	\$ 350	\$ 44,366	\$ 46,886
Direct cost of goods	(505)	-	-	(505)
Sales and marketing costs	(2,786)	-	-	(2,786)
Research and development	-	(16,190)	-	(16,190)
General and administrative	(349)	(11,969)	-	(12,318)
National Expenses	-	-	(47,690)	(47,690)
Segment loss from operations	<u>\$ (1,470)</u>	<u>\$ (27,809)</u>	<u>\$ (3,324)</u>	<u>\$ (32,603)</u>
Segment assets	<u>\$ 7,362</u>	<u>\$ 160,038</u>	<u>\$ 77,691</u>	<u>\$ 245,091</u>

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<i>(\$ in thousands)</i> <b>Nine Months Ended September 30, 2018</b>	<b>Pharmaceutical and Biotechnology</b>			
	<b>Dermatology Products Sales</b>	<b>Product Development</b>	<b>National</b>	<b>Consolidated</b>
Net Revenue	\$ 17,366	525	\$ 165,061	\$ 182,952
Direct cost of goods	(4,546)	–	–	(4,546)
Sales and marketing costs	(8,443)	–	–	(8,443)
Research and development	–	(62,332)	–	(62,332)
General and administrative	(1,270)	(29,075)	–	(30,345)
National expenses	–	–	(162,258)	(162,258)
Segment income (loss) from operations	\$ 3,107	\$ (90,882)	\$ 2,803	\$ (84,972)
Segment assets	\$ 10,765	\$ 157,781	\$ 56,373	\$ 224,919

<i>(\$ in thousands)</i> <b>Nine Months Ended September 30, 2017</b>	<b>Pharmaceutical and Biotechnology</b>			
	<b>Dermatology Products Sales</b>	<b>Product Development</b>	<b>National</b>	<b>Consolidated</b>
Net Revenue	\$ 8,309	\$ 1,393	\$ 132,563	\$ 142,265
Direct cost of goods	(1,852)	–	–	(1,852)
Sales and marketing costs	(7,663)	–	–	(7,663)
Research and development	–	(38,077)	–	(38,077)
General and administrative	(961)	(27,866)	–	(28,827)
National Expenses	–	–	(139,219)	(139,219)
Segment loss from operations	\$ (2,167)	\$ (64,550)	\$ (6,656)	\$ (73,373)
Segment assets	\$ 7,362	\$ 160,038	\$ 77,691	\$ 245,091

**21. Revenues from Contracts and Significant Customers**

*Fortress*

On January 1, 2018, the Company adopted Topic 606 applying the modified retrospective method to all contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 were presented under Topic 606, while prior period amounts were not adjusted and reported under the accounting standards in effect for the prior periods.

Impact to Journey Medical Product Sales

Topic 606 does not generally change the practice under which the Company recognizes product revenue from sales of Targadox®, Luxamend® and Ceracade®. The Company's performance obligation to deliver products is satisfied at the point in time that the goods are delivered to the customer, which is when the customer obtains title to and has the risks and rewards of ownership of the products.

The Company's contracts include variable consideration in the form of refunds for rights of return, price protection, and consideration payable to the customer. As such, for the three months ended September 30, 2018 and 2017, the Company recorded a return reserve of \$0.5 million and \$0.3 million, respectively. The Company estimates variable consideration using a percentage of sales approach. Under this method, the transaction price is constrained for the potential future returns and consideration payable to the customer because it is not probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

Because the Company's agreements for sales of product to its distributors can be cancelled early, prior to the termination date, they are deemed to have an expected duration of one year or less, and as such, the Company has elected the practical expedient in ASC 606-10-50-14(a) to not disclose information about its remaining performance obligations.

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*Checkpoint*

Impact to Checkpoint's Collaboration and License Agreement Revenues

*Collaboration Agreement with TGTX related to Dana-Farber License*

In connection with Checkpoint's license agreement with Dana-Farber, Checkpoint entered into a collaboration agreement with TGTX, a related party, to develop and commercialize the anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies, while the Company retains the right to develop and commercialize these antibodies in the field of solid tumors. Michael Weiss, Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also the Executive Chairman, President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the collaboration agreement, TGTX paid Checkpoint \$0.5 million, representing an upfront licensing fee, and the Checkpoint is eligible to receive substantive potential milestone payments up to an aggregate of approximately \$21.5 million for each product upon TGTX's successful achievement of certain clinical development, regulatory and first commercial sale milestones. This is comprised of up to approximately \$7.0 million upon TGTX's successful completion of clinical development milestones, and up to approximately \$14.5 million upon first commercial sales in specified territories. In addition, Checkpoint is eligible to receive up to an aggregate of \$60.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered high single digit percentage of net sales. Following the second anniversary of the effective date of the agreement, Checkpoint receives an annual license maintenance fee, which is creditable against milestone payments or royalties due to Checkpoint. For the three months ended September 30, 2018 and 2017, the Company recognized approximately nil and \$46,000, respectively, in revenue from Checkpoint's collaboration agreement with TGTX in the Condensed Consolidated Statements of Operations. For the nine months ended September 30, 2018 and 2017, the Company recognized approximately \$44,000 and \$84,000, respectively, in revenue from Checkpoint's collaboration agreement with TGTX in the Condensed Consolidated Statements of Operations.

*Sublicense Agreement with TGTX related to Jubilant License*

In connection with Checkpoint's license agreement with Jubilant, Checkpoint entered into a sublicense agreement with TGTX, a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while the Company retains the right to develop and commercialize these compounds in the field of solid tumors. Michael Weiss, Chairman of the Board of Directors of Checkpoint and Fortress' Executive Vice Chairman, Strategic Development, is also the Executive Chairman, President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the Sublicense Agreement, TGTX paid Checkpoint \$1.0 million, representing an upfront licensing fee, and Checkpoint is eligible to receive substantive potential milestone payments up to an aggregate of approximately \$87.2 million upon TGTX's successful achievement of clinical development and regulatory milestones. This is comprised of up to approximately \$25.5 million upon TGTX's successful completion of three clinical development milestones for two licensed products, and up to approximately \$61.7 million upon the achievement of five regulatory approvals and first commercial sales in specified territories for two licensed products. In addition, Checkpoint is eligible to receive potential milestone payments up to an aggregate of \$89.0 million upon TGTX's successful achievement of certain sales milestones based on aggregate net sales by TGTX, for two licensed products, in addition to royalty payments based on a mid-single digit percentage of net sales by TGTX. TGTX also pays Checkpoint 50% of IND enabling costs and patent expenses. For the three months ended September 30, 2018 and 2017, Checkpoint recognized approximately \$5,000 and \$0.2 million, respectively, in revenue related to the sublicense agreement in the condensed consolidated statements of operations. For the nine months ended September 30, 2018 and 2017, Checkpoint recognized approximately \$0.4 million and \$0.8 million, respectively, in revenue related to the sublicense agreement in the condensed consolidated statements of operations.

*Sponsored Research Collaboration with NeuPharma, Inc. and TGTX*

In connection with Checkpoint's license agreement with NeuPharma, Inc. ("NeuPharma") Checkpoint entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities. Effective January 11, 2016, TGTX agreed to assume all costs associated with this Sponsored Research Agreement and paid Checkpoint for all amounts previously paid. This assumption of costs by TGTX survives any termination or expiration of the option agreement. For the three months ended September 30, 2018 and 2017, Checkpoint recognized approximately nil and \$0.1 million, respectively, in revenue in connection with the Sponsored Research Agreement in the Condensed Statements of Operations. For the nine months ended September 30, 2018 and 2017, the Company recognized approximately \$31,000 and \$0.5 million, respectively, in revenue in connection with the Sponsored Research Agreement in the condensed consolidated statements of operations.

The collaborations described above with TGTX each contain a single material performance obligation under Topic 606, which is the granting of a license that is functional intellectual property. Checkpoint's performance obligation is satisfied at the point in time when the customer has the ability to use and benefit from the right to use the intellectual property.

The milestone payments are based on successful achievement of clinical development, regulatory, and sales milestones. Because these payments are contingent on the occurrence of a future event, they represent variable consideration and are constrained and included in the transaction price only when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The sales based royalty payments are recognized as revenue when the subsequent sales occur. Checkpoint also receives variable consideration for certain research and development and patent maintenance related activities that are dependent upon Checkpoint's actual expenditures under the collaborations and are constrained and included in the transaction price only when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Revenue is recognized approximately when the amounts become due because it relates to an already satisfied performance obligation. For the nine months ended September 30, 2018, Checkpoint did not receive any milestone or royalty payments.





**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**  
Notes to Condensed Consolidated Financial Statements  
(Unaudited)

Disaggregation of Total Revenues

The Company has four marketed products, Targadox®, Exelderm®, Luxamend® and Ceracade®. 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):

	<b>Three months ended September 30, 2018</b>	<b>Nine months ended September 30, 2018</b>
Targadox®	\$ 4,322	\$ 16,183
Other branded revenue	846	1,183
<b>Total product revenues</b>	<b>5,168</b>	<b>17,366</b>
TGTX	5	525
<b>Total Revenue</b>	<b>\$ 5,173</b>	<b>\$ 17,891</b>

Contract Balances and Performance Obligations

The Company recognized collaboration and license agreement revenues of \$5,000 and \$0.5 million during the three and nine months ended September 30, 2018, respectively, that were included in the deferred revenue balance as of January 1, 2018.

Significant Customers

For the three months ended September 30, 2018, one of the Company’s Dermatology Products customers accounted for more than 10.0% of its total gross product revenue in the amount of \$10.9 million. For the three months ended September 30, 2017, two of the Company’s Dermatology Products customers each accounted for more than 10.0% of its total gross revenue in the amount of \$3.0 million and \$1.7 million. The revenue from these customers is captured in the product revenue, net line item within the Condensed Consolidated Statement of Operations.

For the nine months ended September 30, 2018, two of the Company’s Dermatology Products customers each accounted for more than 10.0% of its total gross product revenue in the amount of \$22.5 million and \$7.3 million. For the nine months ended September 30, 2017, two of the Company’s Dermatology Products customers each accounted for more than 10.0% of its total gross revenue in the amount of \$6.7 million and \$6.0 million. The revenue from these customers is captured in the product revenue, net line item within the Condensed Consolidated Statement of Operations.

At September 30, 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 \$9.0 million and \$1.4 million, respectively.

At September 30, 2017, 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 \$1.7 million and \$1.5 million, respectively.

Net Revenue from Pharmaceutical and Biotechnology Product Development represents collaboration revenue from TGTX in connection with Checkpoint and Mustang, which is classified as related party revenue.

*National Revenue Recognition with Customers*

National recognizes revenue from contracts with customers when, or as, National satisfies its performance obligations by transferring the promised goods or services to the customers. A good or service is transferred to a customer when, or as, the customer obtains control of that good or service. A performance obligation may be satisfied over time or at a point in time. Revenue from a performance obligation satisfied over time is recognized by measuring progress in satisfying the performance obligation in a manner that depicts the transfer of the goods or services to the customer. Revenue from a performance obligation satisfied at a point in time is recognized at the point in time that National determines the customer obtains control over the promised good or service. The amount of revenue recognized reflects the consideration National expects to be entitled to in exchange for those promised goods or services (i.e., the “transaction price”). In determining the transaction price, National considers multiple factors, including the effects of variable consideration. Variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. In determining when to include variable consideration in the transaction price, the Company considers the range of possible outcomes, the predictive value of past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of influence, such as market volatility or the judgment and actions of third parties.

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**  
Notes to Condensed Consolidated Financial Statements  
(Unaudited)

The following provides detailed information on the recognition of National's revenues from contracts with customers:

*Commissions and Other Fees.* National earns commission revenue based on the execution of transactions for clients primarily in equity and equity-related products. Trade execution, when provided together, represent a single performance obligation as the services are not separately identifiable in the context of the contract. Commission revenues are recognized at a point in time on trade-date. Commission revenues are generally paid on settlement date and National records a receivable between trade-date and payment on settlement date.

*Investment Banking.* National provides clients with a full range of investment banking services. Investment banking services include underwriting and placement agent services in both the equity and debt, including private equity placements, initial public offerings, follow-on offerings and equity-linked convertible securities transactions and private debt. Underwriting and placement agent revenues are recognized at a point in time on trade-date, as the client obtains the control and benefit of the investment banking offering at that point. Costs associated with investment banking transactions are deferred until the related revenue is recognized or the engagement is otherwise concluded and are recorded on a gross basis within Underwriting costs in the Condensed Consolidated Statements of Operations as National is acting as a principal in the arrangement. Any expenses reimbursed by National's clients are recognized as investment banking revenues.

National's revenues from advisory services primarily consist of fees generated in connection with mergers and acquisition and advisory transactions. Advisory fees from mergers and acquisitions engagements are recognized at a point in time when the related transaction is completed, as the performance obligation is to successfully execute a specific transaction. Fees received prior to the completion of the transaction are deferred within other liabilities on the Condensed Consolidated Balance Sheets. A significant portion of the fees National receives for advisory services are considered variable as they are contingent upon a future event and are excluded from the transaction price until the uncertainty associated with the variable consideration is subsequently resolved, which is expected to occur upon achievement of the specified milestone. Payment for advisory services is generally due promptly upon completion of a specified milestone or, for retainer fees, periodically over the course of the engagement. National recognizes a receivable between the date of completion of the milestone and payment by the customer. Expenses associated with investment banking advisory engagements are deferred only to the extent they are explicitly reimbursable by the client and the related revenue is recognized at a point in time. All other investment banking advisory related costs are expensed as incurred. All investment banking advisory expenses are recognized within their respective expense category on the Condensed Consolidated Statements of Operations and any expenses reimbursed by the clients are recognized as Investment banking revenues.

*Asset Management Fees.* National receives management and performance fees in connection with investment advisory services provided to various funds and accounts, which are satisfied over time and measured using a time elapsed measure of progress as the customer receives the benefits of the services evenly throughout the term of the contract. Management and performance fees are considered variable as they are subject to fluctuation (e.g., changes in assets under management, market performance) and/ or are contingent on a future event during the measurement period (e.g., meeting a specified benchmark) and are recognized only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved. Management fees are generally based on month-end assets under management or an agreed upon notional amount and are included in the transaction price at the end of each month when the assets under management or notional amount is known. Performance fees are received when the return on assets under management for a specified performance period exceed certain benchmark returns, "high-water marks" or other performance targets. The performance period related to performance fees is annual, semiannual or at the recognition of a liquidation event. Accordingly, performance fee revenue will generally be recognized only at the end of the performance period to the extent that the benchmark return has been met.

Disaggregation of Revenue

The following presents National's revenues from contracts with customers disaggregated by major business activity for the three months ended September 30, 2018:

<i>(\$ in thousands)</i>	<b>For the Three Months Ended September 30, 2018</b>	<b>For the Nine Months Ended September 30, 2018</b>
<b>Revenues from customer contracts:</b>		
Commissions	\$ 28,397	\$ 85,422
Investment banking:		
Underwriting	2,534	12,127
Private placement	13,567	26,866
Advisory	4,915	7,062
Other	—	156
Sub-total National revenue from contracts with customers	49,413	131,633
Other National revenue	9,107	33,428
Total National revenue	<u>\$ 58,520</u>	<u>\$ 165,061</u>

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**  
Notes to Condensed Consolidated Financial Statements  
(Unaudited)

*Information on Remaining Performance Obligations and Revenue Recognized from Past Performance*

National does not disclose information about remaining performance obligations pertaining to contracts that have an original expected duration of one year or less. The transaction price allocated to remaining unsatisfied or partially unsatisfied performance obligations with an original expected duration exceeding one year was not material at June 30, 2018. Investment banking advisory fees that are contingent upon completion of a specific milestone are also excluded as the fees are considered variable and not included in the transaction price at June 30, 2018.

Contract Balances

The timing of National's revenue recognition may differ from the timing of payment by customers. National records a receivable when revenue is recognized prior to payment and the Company has an unconditional right to payment. Alternatively, when payment precedes the provision of the related services, National records deferred revenue until the performance obligations are satisfied.

Contract Costs

Incremental contract costs are expensed when incurred when the amortization period of the asset that would have been recognized is one year or less; otherwise, incremental contract costs are recognized as an asset and amortized over time as services are provided to a customer.

**22. Income 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 nine months ended September 30, 2018 and 2017 is based on the estimated annual effective tax rate. The Company has recorded \$0.9 million and \$2.4 million income tax expense to reflect National's estimated current income tax expense for the three and nine months ended September 30, 2018. No income tax expense was recorded in 2017.

## 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, 2017.*

### Overview

Fortress Biotech, Inc. ("Fortress" or the "Company") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of our subsidiary companies, also referred to herein as the "Fortress Companies." Additionally, the Company maintains a controlling interest in National Holdings Corporation, a diversified independent brokerage company (together with its subsidiaries, herein referred to as "NHLD" or "National"). In addition to its internal development programs, the Company leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. The Company and the Fortress Companies may seek licensings, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs.

### Business Strategy

Our business approach is designed for maximum flexibility, allowing us to invest in a broad array of new technologies with clinical and commercial potential. It enables us to move quickly to take advantage of time-sensitive opportunities when necessary and provides us with a range of options that allow us to select what we believe is the most advantageous corporate or financial structure for each drug candidate. We seek to acquire and invest in drugs, technologies and operating subsidiaries with high growth potential.

At September 30, 2018, in addition to National, we had several consolidated Fortress Companies, which contain 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"). We also have operational subsidiaries CB Securities Corporation, Immune Limited and FBIO Acquisition, Inc. (the acquisition vehicle we used to obtain National) and acquisition companies for which we are actively seeking product candidate licenses, including Coronado SO Co., Escala Therapeutics, Inc., GeneXion Oncology, Inc., Fortress Biotech China, Inc., FBIO Acquisition Corp. IV and FBIO Acquisition Corps. VI - XIV.

### Checkpoint

In September 2018, Checkpoint announced preliminary interim safety and efficacy data from an ongoing Phase 1/2 clinical trial of CK-101. The data were presented in an oral presentation at the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer in Toronto. Enrollment in the trial is ongoing to identify the optimal dose to maximize therapeutic effect, following which a Phase 3 trial is planned to initiate in 2019 in treatment-naïve epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer (NSCLC) patients.

## ***Cyprium***

On July 2, 2018, Cyprium announced that it had been granted Fast Track Designation by the U.S. Food and Drug Administration (“FDA”) for its Copper Histidinate, also referred to as CUTX-101, for patients diagnosed with classic Menkes disease who have not demonstrated significant clinical progression. The FDA’s Fast Track program facilitates the development of drugs intended to treat serious conditions and that have the potential to address unmet medical needs.

On September 12, 2018 Cyprium announced the publication of preclinical data for CUTX-101 (“Copper Histidinate”). The preclinical trial was conducted by the National Institute of Child Health and Human Development (“NICHD”) laboratory of Stephen G. Kaler, M.D., and evaluated low-, intermediate- and high-dose recombinant adeno-associated virus (“AAV”) serotype 9 (rAAV9)-ATP7A delivered to the cerebrospinal fluid (CSF) in combination with subcutaneous CUTX-101 in a *mottled- brindled (mo-br)* mouse model that closely mimics the biochemical and clinical phenotypes of Menkes disease. The rAAV9 construct carried the genetic instructions for a compact, reduced-size (rs) version of the Menkes copper transporter, ATP7A. Mutant mice that received high-dose CSF- directed rAAV9-rsATP7A in combination with CUTX-101 demonstrated improved long-term survival (53%) compared to mice that did not receive treatment (0%) or were administered either treatment by itself (0%, 0%). This synergistic treatment effect represents the most successful rescue to date of the *mo-br* mouse model. In addition, mutant mice treated with the high-dose CSF-directed rAAV9-rsATP7A in combination with CUTX-101 showed higher brain copper levels, normalized brain neurochemicals, improvement of brain mitochondrial abnormalities, and normal growth and neurobehavioral outcomes

## ***Mustang***

On October 15, 2018 Mustang appointed Martina A. Sersch, M.D., Ph.D., as Chief Medical Officer. Dr. Sersch will oversee the clinical development of Mustang’s pipeline in CAR T technologies and gene therapies.

On August 12, 2018 Mustang entered into an exclusive license worldwide agreement with St. Jude Children’s Research Hospital (“St. Jude”) for a clinical-stage lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (“X-SCID”), also known as bubble boy disease. X-SCID is the most common form of severe immune deficiency, affecting approximately one in 50,000 to 100,000 newborns worldwide. The acquisition of this license by Mustang expands their pipeline into gene-therapy, allowing them to utilize the leverage existing synergies for their Worcester Massachusetts cell-processing facility.

## **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 nine months ended September 30, 2018, we generated \$183.0 million of net revenue, of which \$165.1 million of revenue relates to National, \$0.5 million of revenue is in connection with Checkpoint and Mustang’s collaborative agreements with TG Therapeutics, Inc. (“TGTX”) and \$17.4 million of revenue relates primarily to the sale of Journey branded and generic products compared to \$142.3 million of net revenue, of which \$132.6 million related to National, \$1.4 million of revenue related to Checkpoint’s collaboration agreements with TGTX and \$8.3 million related to the sale of Journey branded products for the nine months ended September 30, 2017. At September 30, 2018, we had an accumulated deficit of \$371.4 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 nine months ended September 30, 2018, we had \$4.5 million of costs of goods sold in connection with the sale of Journey branded and generic products, compared to \$1.9 million for the nine months ended September 30, 2017.

### ***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 September 30, 2018 and 2017, research and development expenses were approximately \$16.1 million and \$15.9 million, respectively. Additionally, during the three months ended September 30, 2018 and 2017, we expensed approximately \$3.7 million and \$0.3 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 September 30, 2018 and 2017, was \$1.8 million and \$1.6 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 September 30, 2018 and 2017, by entity, are as follows:

(\$ in thousands)	Three Months Ended September 30,		% of total	
	2018	2017	2018	2017
<b>Research &amp; Development</b>				
Fortress	\$ 771	\$ 1,418	5%	10%
Subsidiaries:				
Avenue	1,547	1,860	11%	13%
Checkpoint	6,143	4,446	43%	31%
Mustang	4,532	1,785	32%	12%
Other <sup>1</sup>	1,267	4,781	9%	34%
<b>Total R&amp;D</b>	<b>\$ 14,260</b>	<b>\$ 14,290</b>	<b>100%</b>	<b>100%</b>

Note 1- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

Noncash stock-based compensation expense for the three months ended September 30, 2018 and 2017, by entity is as follows:

(\$ in thousands)	Three Months Ended September 30,		% of total	
	2018	2017	2018	2017
<b>Research &amp; Development</b>				
Noncash stock-based compensation				
Fortress	\$ 235	\$ 288	13%	18%
Subsidiaries:				
Avenue	127	78	7%	5%
Checkpoint	642	446	35%	28%
Mustang	722	340	40%	21%
Other <sup>1</sup>	96	448	5%	28%
<b>Total noncash stock-based comp. – R&amp;D</b>	<b>\$ 1,822</b>	<b>\$ 1,600</b>	<b>100%</b>	<b>100%</b>

Note 1- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

Research and development costs associated with the development of our licenses, net of noncash stock-based compensation expenses for the nine months ended September 30, 2018 and 2017, by entity are as follows:

(\$ in thousands)	Nine Months Ended September 30,		% of total	
	2018	2017	2018	2017
<b>Research &amp; Development</b>				
Fortress	\$ 4,702	\$ 4,579	9%	15%
Subsidiaries:				
Avenue	14,280	2,303	27%	8%
Checkpoint	18,115	10,779	34%	36%
Mustang	10,226	4,796	19%	16%
Other <sup>1</sup>	6,265	7,398	11%	25%
<b>Total R&amp;D</b>	<b>\$ 53,588</b>	<b>\$ 29,855</b>	<b>100%</b>	<b>100%</b>

Note 1- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

Noncash stock-based compensation expense for the nine months ended September 30, 2018 and 2017, by entity was as follows:

(\$ in thousands)	Nine Months Ended September 30,		% of total	
	2018	2017	2018	2017
<b>Research &amp; Development</b>				
Noncash stock-based compensation				
Fortress	\$ 878	\$ 1,020	18%	21%
Subsidiaries:				
Avenue	363	90	7%	2%
Checkpoint	930	2,799	19%	58%
Mustang	2,752	404	56%	8%
Other <sup>1</sup>	17	515	-%	11%
<b>Total noncash stock-based comp – R&amp;D</b>	<b>\$ 4,940</b>	<b>\$ 4,828</b>	<b>100%</b>	<b>100%</b>

Note 1- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

Additionally, during the three and nine months ended September 30, 2018 and 2017, we expensed approximately \$3.7 million and \$3.8 million and \$0.3 million and \$3.4 million, respectively, in costs related to the acquisition of licenses.

We anticipate research and development expenses will increase in future periods, reflecting continued and increasing product development costs.

### General and Administrative Expenses

General and administrative expenses consist principally of 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 September 30, 2018 and 2017, general and administrative expenses were approximately \$12.2 million and \$15.1 million, respectively. Noncash stock-based compensation expense included in general and administrative expenses for the three months ended September 30, 2018 and 2017, was \$2.3 million and \$2.6 million, respectively.

Included in the remaining \$9.9 million and \$12.5 million figures for the three months ended September 30, 2018 and 2017, respectively are the following subsidiary level expenses:

(\$ in thousands)	Three Months Ended September 30,		% of total	
	2018	2017	2018	2017
<b>General &amp; Administrative</b>				
Fortress	\$ 3,530	\$ 3,264	36%	26%
Subsidiaries:				
Avenue	564	608	6%	5%
Checkpoint	823	819	8%	6%
Journey <sup>1</sup>	3,211	3,073	32%	25%
Mustang	1,078	4,039	11%	32%
Other <sup>2</sup>	694	718	7%	6%
<b>Total G&amp;A</b>	<b>\$ 9,900</b>	<b>\$ 12,521</b>	<b>100%</b>	<b>100%</b>

Note 1- Includes cost of outsourced sales force

Note 2- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

Noncash stock-based compensation expense included in general and administrative expense for the three months ended September 30, 2018 and 2017, by entity is as follows:

(\$ in thousands)	Three Months Ended September 30,		% of total	
	2018	2017	2018	2017
<b>General &amp; Administrative</b>				
Noncash stock-based compensation				
Fortress	\$ 1,246	\$ 1,385	55%	54%
Subsidiaries:				
Avenue	244	167	11%	6%
Checkpoint	486	463	21%	18%
Mustang	200	493	9%	19%
Other <sup>1</sup>	108	75	4%	3%
<b>Total noncash stock-based comp. – G&amp;A</b>	<b>\$ 2,284</b>	<b>\$ 2,583</b>	<b>100%</b>	<b>100%</b>

Note 1- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Helocyte, Journey and Tamid





For the nine months ended September 30, 2018 and 2017, general and administrative expenses were approximately \$38.8 million and \$36.5 million, respectively. Noncash stock-based compensation expense included in general and administrative expenses for the nine months ended September 30, 2018 and 2017, was \$7.1 million and \$6.9 million, respectively.

Included in the remaining \$31.7 million and \$29.6 million figures for the nine months ended September 30, 2018 and 2017, respectively are the following subsidiary level expenses:

(\$ in thousands)	Nine Months Ended September 30,		% of total	
	2018	2017	2018	2017
<b>General &amp; Administrative</b>				
Fortress	\$ 11,599	\$ 9,788	37%	33%
Subsidiaries:				
Avenue	2,016	1,192	6%	4%
Checkpoint	2,682	2,404	8%	8%
Journey <sup>1</sup>	9,613	8,443	30%	29%
Mustang	3,809	6,046	12%	20%
Other <sup>2</sup>	1,955	1,709	7%	6%
<b>Total G&amp;A</b>	<b>\$ 31,674</b>	<b>\$ 29,582</b>	<b>100%</b>	<b>100%</b>

Note 1- Includes cost of outsourced sales force

Note 2- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

Noncash stock-based compensation expense included in general and administrative expense for the nine months ended September 30, 2018 and 2017, by entity is as follows:

(\$ in thousands)	Nine Months Ended September 30,		% of total	
	2018	2017	2018	2017
<b>General &amp; Administrative</b>				
Noncash stock-based compensation				
Fortress	\$ 3,674	\$ 4,209	52%	61%
Subsidiaries:				
Avenue	679	179	10%	3%
Checkpoint	1,406	1,473	20%	21%
Mustang	1,137	826	16%	12%
Other <sup>1</sup>	218	221	2%	3%
<b>Total noncash stock-based comp. – G&amp;A</b>	<b>\$ 7,114</b>	<b>\$ 6,908</b>	<b>100%</b>	<b>100%</b>

Note 1- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Helocyte, Journey and Tamid

Operating expenses related to National for the three months ended September 30, 2018 and 2017 were \$55.2 million and \$47.7 million, respectively, of which \$48.6 million and \$40.0 million, respectively, related to commissions, compensation and fees.

Operating expenses related to National for the nine months ended September 30, 2018 and 2017 were \$162.3 million and \$139.2 million, respectively, of which \$141.5 million and \$119.0 million, respectively, related to commissions, compensation and fees.

We anticipate general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded research and development activities;
- support of business development activities; and
- an expanding infrastructure and increased professional fees and other costs associated therewith.

<i>Comparison of three months ended September 30, 2018 and 2017</i> (\$ in thousands, except per share amounts)	For the Three Months Ended September 30,		Change	
	2018	2017	\$	%
<b>Revenue</b>				
<i>Fortress</i>				
Product revenue, net	\$ 5,168	\$ 2,170	\$ 2,998	138%
Revenue - from a related party	5	350	(345)	-99%
Net Fortress revenue	5,173	2,520	2,653	105%
<i>National</i>				
Commissions	28,397	24,881	3,516	14%
Net dealer inventory gains	482	1,789	(1,307)	-73%
Investment banking	19,271	8,942	10,329	116%
Investment advisory	5,281	3,605	1,676	46%
Interest and dividends	771	674	97	14%
Transfer fees and clearing services	1,606	1,649	(43)	-3%
Tax preparation and accounting	2,444	2,527	(83)	-3%
Other	268	299	(31)	-10%
Total National revenue	58,520	44,366	14,154	32%
Net revenue	63,693	46,886	16,807	36%
<b>Operating expenses</b>				
<i>Fortress</i>				
Cost of goods sold - product revenue	1,406	505	901	178%
Research and development	16,082	15,890	192	1%
Research and development - licenses acquired	3,706	300	3,406	1135%
General and administrative	12,184	15,104	(2,920)	-19%
Total Fortress operating expenses	33,378	31,799	1,579	5%
<i>National</i>				
Commissions, compensation and fees	48,556	39,963	8,593	22%
Clearing fees	451	470	(19)	-4%
Communications	856	690	166	24%
Occupancy	738	972	(234)	-24%
Licenses and registration	861	391	470	120%
Professional fees	1,076	1,082	(6)	-1%
Interest	26	5	21	420%
Underwriting costs	43	-	43	100%
Depreciation and amortization	871	507	364	72%
Other administrative expenses	1,726	3,610	(1,884)	-52%
Total National operating expenses	55,204	47,690	7,514	16%
Total operating expenses	88,582	79,489	9,093	11%
Loss from operations	(24,889)	(32,603)	7,714	-24%
Other income (expenses)				
Interest income	269	204	65	32%
Interest expenses	(2,228)	(3,220)	992	-31%
Change in fair value of derivative liabilities	-	(639)	639	-100%
Change in fair value of subsidiary convertible note	(84)	(74)	(10)	14%
Change in fair value of investments	(565)	270	(835)	-309%
Other expenses	(146)	(245)	99	-40%
Total other expenses	(2,754)	(3,704)	950	-26%
<b>Loss before income taxes</b>	<b>(27,643)</b>	<b>(36,307)</b>	<b>8,664</b>	<b>-24%</b>
Income tax expense	944	-	944	100%
<b>Net loss</b>	<b>(28,587)</b>	<b>(36,307)</b>	<b>7,720</b>	<b>-21%</b>
Less: net loss attributable to non-controlling interest	(11,949)	9,191	(2,758)	30%
<b>Net loss attributable to common stockholders</b>	<b>\$ (16,638)</b>	<b>\$ (27,116)</b>	<b>\$ 10,478</b>	<b>-39%</b>

Net revenues increased \$16.8 million or 36% from the three months ended September 30, 2017 to the three months ended September 30, 2018. The increase in net revenue is related to an increase in product revenue of \$3.0 million associated with Journey's branded and generic products, offset by a decrease of \$0.3 million in collaboration revenue between Checkpoint and TGTX, and Mustang and TGTX. National's revenue increased by \$14.2 million or 32%, of which \$3.5 million is commissions, the increase is due to retail commissions increasing due to increased headcount and continuing strong equity markets. Investment banking revenue increased \$10.3 million due to higher investor demand for and quality execution of

product offerings from a diverse group of issuer clients.

Cost of goods sold increased by \$0.9 million or 178% from the three months ended September 30, 2017 to the three months ended September 30, 2018 due to the increase in Journey branded and generic product revenue in the 2018 quarter as compared to the 2017 quarter.

Research and development expenses increased \$0.2 million or 1% from the three months ended September 30, 2017 to the three months ended September 30, 2018. The following table shows the change in research and development spending for Fortress and by subsidiary:

(\$ in thousands)	Three Months Ended September 30,		change	
	2018	2017	\$	%
<b>Research &amp; Development</b>				
Noncash stock-based compensation				
Fortress	\$ 235	\$ 288	(53)	-18%
Subsidiaries:				
Avenue	127	78	49	63%
Checkpoint	642	446	196	44%
Mustang	722	340	382	112%
Other <sup>1</sup>	96	448	(352)	-79%
Sub-total noncash stock-based comp.	1,822	1,600	222	14%
R&D Costs				
Fortress	771	1,418	(647)	-46%
Subsidiaries:				
Avenue	1,547	1,860	(313)	-17%
Checkpoint	6,143	4,446	1,697	38%
Mustang	4,532	1,785	2,747	154%
Other <sup>1</sup>	1,267	4,781	(3,514)	-74%
<b>Total R&amp;D</b>	<b>\$ 16,082</b>	<b>\$ 15,890</b>	<b>\$ 192</b>	<b>1%</b>

Note 1- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

The increase in stock-based compensation across Avenue, Checkpoint and Mustang is attributable to new grants made to new hires, while the decrease in the "Other" category is due to the vesting of a grant made to a consultant at Caelum. The decrease in stock-based compensation for the three months ended September 30, 2018 for Fortress is due to the transfer of employees from Fortress to TGTX, a related-party, and the resulting forfeiture of equity grants held in Fortress by those employees.

The decrease in Fortress R&D spending is due to the lower R&D headcount subsequent to the transfer of Fortress R&D employees to TGTX, a related party, in the quarter ended September 30, 2018. Checkpoint's increase in R&D spending is attributable to the commencement of clinical trials for CK-101 & CK-301, and increased manufacturing costs. Mustang's increase in R&D spending is attributable to the fitting out of the cell processing facility, as well as increased headcount. The decrease in "Other" is attributable to costs incurred by Caelum for the start-up of CMC activities, and Helocyte for the start-up of sponsored research activities not replicated in 2018.

During the three months ended September 30, 2018, we made expenditures in connection with our research and development licenses of \$3.7 million, compared with \$0.3 million in expenditures related to licenses acquired during the three months ended September 30, 2017. The \$3.4 million increase quarter over quarter is attributable to \$1.0 million milestone payment recognized by Checkpoint for CK-301, \$1.5 million milestone recognized by Helocyte for the Triplex license, \$1.0 million recognized by Mustang for the X-SCID license, and \$0.2 million recognized by Caelum for additional shares issued to Columbia under the terms of their license agreement, offset by expense of \$0.3 million related to the Mustang license for CD20 recognized during the three months ended September 30, 2017.

General and administrative expenses decreased \$2.9 million or 19% from the three months ended September 30, 2017 to the three months ended September 30, 2018 due to the settlement of a lawsuit by Mustang in the quarter ended September 30, 2017 for \$2.2 million. The following table shows the change in general and administrative spending for Fortress and by subsidiary:

(\$ in thousands)	Three Months Ended September 30,		Change	
	2018	2017	\$	%
<b>General &amp; Administrative</b>				
Noncash stock-based compensation				
Fortress	\$ 1,246	\$ 1,385	(139)	-10%
Subsidiaries:				
Avenue	244	167	77	46%
Checkpoint	486	463	23	5%
Mustang	200	493	(293)	-59%
Other <sup>2</sup>	108	75	33	100%
Sub-total noncash stock-based comp.	2,284	2,583	(299)	-12%
G&A Costs				
Fortress	3,530	3,264	266	8%
Subsidiaries:				
Avenue	564	608	(44)	-7%
Checkpoint	823	819	4	-%
JMC <sup>1</sup>	3,211	3,073	138	4%
Mustang	1,078	4,039	(2,961)	-73%

Other <sup>2</sup>	694	718	(24)	-3%
<b>Total G&amp;A</b>	<b>\$ 12,184</b>	<b>\$ 15,104</b>	<b>\$ (2,920)</b>	<b>-19%</b>

Note 1- Includes costs of outsourced sales force

Note 2- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

For the three months ended September 30, 2018, the decrease in general and administrative expenses of \$2.9 million or 19% is primarily attributable to the settlement of the Tang litigation in the quarter ended September 30, 2017 which resulted in expense recognition of \$3.2 million, offset by an increase in expenses as a result of Mustang's build-out of their general and administrative infrastructure, which includes headcount.

National's operating expenses increased by \$7.5 million or 16% for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. Commissions, compensation, and fees increased \$8.6 million or 22%; commissions, compensation, and fees include expenses based on commission revenue earned, net dealer inventory gains and investment banking revenues, as well as compensation to our non-broker employees. The increase in commissions revenue was primarily responsible for the increase in this expense category.

Total other expense decreased \$1.0 million, or 26% from the three months ended September 30, 2017 to the three months ended September 30, 2018. The decrease is primarily related to the decrease in interest expense and financing fees of \$1.0 million or 31%. The decrease is primarily related to \$1.3 million of financing fees incurred by Caelum for the quarter ended September 30, 2017 related to the placement of \$9.9 million in convertible notes, offset by the increase in interest expense incurred on those notes.

(\$ in thousands, except per share amounts)	For the Nine Months Ended September 30,		Change	
	2018	2017	\$	%
<b>Revenue</b>				
<b>Fortress</b>				
Product revenue, net	\$ 17,366	\$ 8,309	\$ 9,057	109%
Revenue - from a related party	525	1,393	(868)	-62%
Net Fortress revenue	17,891	9,702	8,189	84%
<b>National</b>				
Commissions	85,422	73,380	12,042	16%
Net dealer inventory gains	5,601	6,666	(1,065)	-16%
Investment banking	43,012	26,595	16,417	62%
Investment advisory	15,811	10,480	5,331	51%
Interest and dividends	2,003	2,065	(62)	-3%
Transfer fees and clearing services	5,680	5,834	(154)	-3%
Tax preparation and accounting	6,835	6,527	308	5%
Other	697	1,016	(319)	-31%
Total National revenue	165,061	132,563	32,498	25%
Net revenue	182,952	142,265	40,687	29%
<b>Operating expenses</b>				
<b>Fortress</b>				
Cost of goods sold - product revenue	4,546	1,852	2,694	145%
Research and development	58,528	34,683	23,845	69%
Research and development - licenses acquired	3,804	3,394	410	12%
General and administrative	38,788	36,490	2,298	6%
Total Fortress operating expenses	105,666	76,419	29,247	38%
<b>National</b>				
Commissions, compensation and fees	141,462	118,983	22,479	19%
Clearing fees	1,772	1,826	(54)	-3%
Communications	2,429	2,094	335	16%
Occupancy	2,834	2,916	(82)	-3%
Licenses and registration	2,028	1,223	805	66%
Professional fees	3,047	3,336	(289)	-9%
Interest	30	13	17	131%
Underwriting costs	230	-	230	100%
Depreciation and amortization	2,587	1,513	1,074	71%
Other administrative expenses	5,839	7,315	(1,476)	-20%
Total National operating expenses	162,258	139,219	23,039	17%
Total operating expenses	267,924	215,638	52,286	24%
Loss from operations	(84,972)	(73,373)	(11,599)	16%
<b>Other income (expenses)</b>				
Interest income	841	530	311	59%
Interest expenses	(6,455)	(5,298)	(1,157)	22%
Change in fair value of derivative liabilities	(7,931)	5,155	(13,086)	-254%
Change in fair value of subsidiary convertible note	26	(359)	385	-107%
Change in fair value of investments	(1,390)	(241)	(1,149)	477%
Other expenses	(258)	(232)	(26)	11%
Total other expenses	(15,167)	(445)	(14,722)	3308%
<b>Loss before income taxes</b>	<b>(100,139)</b>	<b>(73,818)</b>	<b>(26,321)</b>	<b>36%</b>
Income tax expense	2,382	-	2,382	100%
<b>Net loss</b>	<b>(102,521)</b>	<b>(73,818)</b>	<b>(28,703)</b>	<b>39%</b>

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Less: net loss attributable to non-controlling interest	(43,254)	(17,355)	(25,899)	149%
<b>Net loss attributable to common stockholders</b>	<b><u>\$ (59,267)</u></b>	<b><u>\$ (56,463)</u></b>	<b><u>\$ (2,804)</u></b>	<b><u>5%</u></b>

Net revenues increased \$40.7 million or 29% from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. The increase in net revenue is related to an increase in product revenue of \$9.1 million or 109% associated with Journey's branded and generic products, offset by a decrease of \$0.9 million or 62% in collaboration revenue between Checkpoint and TGTX, and Mustang and TGTX. National's revenue increased by \$32.5 million or 25%, of which \$12.0 million is commissions, the increase is due to retail commissions increasing due to favorable markets, focus on a diversified product base and quality new hires. Investment banking revenue increased \$16.4 million due to continuing high demand and quality execution of product offerings from a diverse group of issuers. Investment advisory revenue increased \$5.3 million due to higher levels of assets under management and continued strength in equity markets.

Cost of goods sold increased by \$2.7 million or 145% from the nine months ended September 30, 2017 to the nine months ended September 30, 2018 due to the increase in Journey branded and generic product revenue in the first nine months of 2018 as compared to the first nine months of 2017. This increase was due to the addition of generic options to some branded products, as well as the addition of Exelderm® to the Journey stable of branded products in the quarter ended September 30, 2018.

Research and development expenses increased \$23.8 million or 69% from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. This increase is attributable to increases in spending of:

(\$ in thousands)	Nine Months Ended September 30,		Change	
	2018	2017	\$	%
<b>Research &amp; Development</b>				
Noncash stock-based compensation				
Fortress	\$ 878	\$ 1,020	\$ (142)	-14%
Subsidiaries:				
Avenue	363	90	273	303%
Checkpoint	930	2,799	(1,869)	-67%
Mustang	2,752	404	2,348	581%
Other <sup>1</sup>	17	515	(498)	-97%
Sub-total noncash stock-based comp.	4,940	4,828	112	2%
R&D Costs				
Fortress	4,702	4,579	123	3%
Subsidiaries:				
Avenue	14,280	2,303	11,977	520%
Checkpoint	18,115	10,779	7,336	68%
Mustang	10,226	4,796	5,430	113%
Other <sup>1</sup>	6,265	7,398	(1,133)	-15%
<b>Total R&amp;D</b>	<b>\$ 58,528</b>	<b>\$ 34,683</b>	<b>\$ 23,845</b>	<b>69%</b>

Note 1- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid



The increase in both Avenue and Checkpoint research and development spending is attributable to clinical trials, bunionectomy and safety studies for IV tramadol in the case of Avenue, and CK-101 & CK-301 for Checkpoint. Checkpoint's increase was also partially caused by an increase in manufacturing costs for CK-301. Mustang's increase is due to the building of the cell processing facility in Worcester, Massachusetts, as well as the research costs associated with new licenses acquired, consisting of Harvard's CRISPR, City of Hope manufacturing, St. Jude's X-SCID, and a sponsored research agreement with Fred Hutch for CD20, as well as an increase in Mustang R&D headcount from 4 at 9/30/2017 to 32 at 9/30/2018.

During the nine months ended September 30, 2018, we made expenditures totaling \$3.8 million in connection with research and development licenses, compared with \$3.4 million in expenditures related to licenses acquired during the nine months ended September 30, 2017.

(\$ in thousands)	Nine Months Ended September		Change	
	2018	2017	\$	%
<b>Research &amp; Development - licenses acquired</b>				
Milestones				
Checkpoint	\$ 1,000	\$ 400	\$ 600	150%
Helocyte	1,500	-	1,500	100%
Mustang	1,000	250	750	233%
Fortress	-	300	(300)	-100%
New licenses				
Mustang	75	2,125	(2,050)	-96%
Caelum	-	219	(219)	-100%
Cyprium	-	100	(100)	-100%
Other				
Caelum	201	-	201	100%
Cellvation	1	-	1	100%
Helocyte	21	-	21	100%
Aevitas	6	-	6	100%
<b>Total</b>	<b>\$ 3,804</b>	<b>\$ 3,394</b>	<b>\$ 410</b>	<b>12%</b>

General and administrative expenses increased \$2.3 million or 6% from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. The following table shows the change in general and administrative spending for Fortress and by subsidiary:

(\$ in thousands)	Nine Months Ended September 30,		Change	
	2018	2017	\$	%
<b>General &amp; Administrative</b>				
Noncash stock-based compensation				
Fortress	\$ 3,674	\$ 4,209	\$ (535)	-13%
Subsidiaries:				
Avenue	679	179	500	279%
Checkpoint	1,406	1,473	(67)	-5%
Mustang	1,137	826	311	38%
Other <sup>2</sup>	218	221	(3)	-1%
Sub-total noncash stock-based comp.	7,114	6,908	206	3%
G&A Costs				
Fortress	11,599	9,788	1,811	19%
Subsidiaries:				
Avenue	2,016	1,192	824	69%
Checkpoint	2,682	2,404	278	12%
JMC <sup>1</sup>	9,613	8,443	1,170	14%
Mustang	3,809	6,046	(2,237)	-37%
Other <sup>2</sup>	1,955	1,709	246	14%
<b>Total G&amp;A</b>	<b>\$ 38,788</b>	<b>\$ 36,490</b>	<b>\$ 2,298</b>	<b>6%</b>

Note 1- Includes costs of outsourced sales force

Note 2- Includes the following subsidiaries: Aevitas, Caelum, Cellvation, Cyprium, Escala, Helocyte and Tamid

The composition of the \$2.3 million or 6% increase is comprised of the following:

- an increase of \$0.8 million in Avenue related to increased professional fees;
- an increase of \$1.2 million in Journey related to their increased outsourced sales force to support the growing portfolio of branded and generic products;
- \$1.0 million increase at Fortress for increased headcount due to growth of its Business Development infrastructure as well as an increase of \$0.8 million in professional fees;
- \$0.3 million increase at Checkpoint related to increased professional fees as well as an increase in headcount costs;
- offset by a decrease of \$2.2 million for Mustang related to the Tang settlement for the quarter ended September 20, 2017; and
- a \$0.2 million increase in overall noncash stock-based compensation relates to additional equity grants at the subsidiary level offset by

lower noncash stock-based compensation expense at the Fortress level due to completion of vesting periods.

National's operating expenses increased by \$23.0 million or 17% for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017. Commissions, compensation, and fees increased \$22.5 million or 19%; commissions, compensation, and fees include expenses based on commission revenue, net dealer inventory gains, investment banking and investment advisory, as well as compensation to our non-broker employees. The increase in commissions expense is primarily due to higher revenues earned in both commissions and investment banking revenues. Strategic new hires, increases in benefits expenses, and increases in stock-based compensation for stock grants also contributed to the increase. Licenses and registration expenses increased \$0.8 million or 66% due to new licenses for software applications as National continues to invest in and implement multiple technology solutions. Professional fees decreased \$0.3 million or 9% due to a reduction in the use of outside providers and more work being handled internally by employees. Other administrative expenses decreased \$1.5 million or 20% due to a more normalized level of spending in the current year, as the prior period included a higher provision for potential arbitration settlements and an increase in certain insurance costs.

Total other expense increased \$14.7 million, or 3308% from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. The increase is primarily related to the change in fair value of derivative liabilities of \$13.1 million, or 254%, driven by the write-down of the warrants held by National, and an increase in the write-down of the fair value of investments of \$1.1 million or 477%, driven by the write off of our investment in Origo.

### Liquidity and Capital Resources

We may require additional financing to fully develop and prepare regulatory filings, 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, 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. A 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, or through other sources of financing.

(\$ in thousands)	For the Nine Months Ended September 30,	
	2018	2017
<b>Statement of cash flows data:</b>		
Total cash (used in) provided by:		
Operating activities	\$ (77,835)	\$ (60,444)
Investing activities	5,054	(46,001)
Financing activities	53,999	129,723
Net (decrease) increase in cash and cash equivalents, cash deposits with clearing organizations and restricted cash	\$ (18,782)	\$ 23,278

### Operating Activities

Net cash used in operating activities increased \$17.4 million from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. The increase was primarily due to the increase of \$28.7 million in net loss, offset by the decrease of \$13.1 million in the fair value of derivative liabilities, a decrease in the fair value of investments of \$1.1 million, and a decrease of \$5.5 million in changes in operating assets and liabilities partially offset by an increase of \$0.7 million of amortization expense related to intangible assets associated with our ownership in National, a \$0.4 million increase of expense related to research and development-licenses acquired, an increase of \$1.6 million in stock based compensation expense, and a decrease of \$0.4 million related to the value of subsidiary convertible notes.

### Investing Activities

Net cash used in investing activities decreased \$51.1 million from the nine months ended September 30, 2017 to the nine months ended September 30, 2018. The decrease is primarily due to a \$3.5 million increase in the purchase of short-term investments with the purchase of certificates of deposit by Mustang, offset by the \$61.0 million redemption of certificates of deposit, also held by Mustang, an increase of \$5.8 million in the purchase of property and equipment as the build-out of the cell processing facility in Worcester, Massachusetts by Mustang continues, 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 \$54.0 million for the nine months ended September 30, 2018, compared to \$129.7 million of net cash provided by financing activities for the nine months ended September 30, 2017. During the nine months ended September 30, 2018, net proceeds from subsidiaries' offerings were \$23.0 million, net proceeds from the 2018 Venture Notes were \$21.7 million, and \$4.1 million was used to pay subsidiaries' Convertible Notes. Additionally, \$1.3 million of costs were incurred in connection with the issuance of Series A preferred stock, and \$1.8 million was paid in Preferred A dividends, offset by \$7.0 million in net proceeds from at-the-market offering and \$8.0 million in net proceeds from Checkpoint's at-the-market offering.

## **Contractual Obligations and Commitments**

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments" in our Annual Report on Form 10-K for the year ended December 31, 2017 except for the addition of the 2018 Venture Notes. Total owed under the 2018 Venture Notes at September 30, 2018 is \$21.7 million. The notes mature 36 months from issuance, provided that during the first 24 months the Company may extend the maturity date by six months. No principal amount will be due for the first 24 months (or the first 30 months if the maturity date is extended). Interest accrues at 8% payable quarterly for the first 24 months (or the first 30 months if the note is extended), and monthly during the last 12 months.

## **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, 2016, December 31, 2017 and for the interim period through September 30, 2018, 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**

Dr. Falk Pharma, GmbH v. Fortress Biotech, Inc. (Frankfurt am Main Regional Court, Ref. No. 3-06 0 28/16). Dr. Falk Pharma, GmbH (“Dr. Falk Pharma”) and Fortress are among the parties to that certain Collaboration Agreement dated March 20, 2012, whereby they agreed to collaborate to develop a product for treatment of Crohn’s disease. A dispute has arisen between Dr. Falk Pharma and Fortress with respect to their relative rights and obligations under the Collaboration Agreement. Specifically, Dr. Falk Pharma contends that it fulfilled its contractual obligations to Fortress and is entitled to the final milestone payment due under the Collaboration Agreement - EUR 2.5 million. Fortress contends that no such payment is due because a condition of the EUR 2.5 million payment was the delivery of a Clinical Study Report that addressed the primary and secondary objectives of a Phase II trial, and Fortress contends that Dr. Falk Pharma failed to deliver such a Clinical Study Report. Dr. Falk Pharma disputes that it failed to deliver such a report and further disputes that the delivery of such a report is a condition of Fortress’s obligation to make the EUR 2.5 million payment. After the parties’ attempts to negotiate a settlement of the dispute were unsuccessful, Dr. Falk Pharma filed a lawsuit against Fortress in the above-referenced Court in Frankfurt, Germany to recover the EUR 2.5 million plus interest and attorneys’ fees, and Fortress was served with the English translation of the lawsuit on August 11, 2016. Fortress retained local counsel and, on December 14, 2016, filed an answer to the complaint, denying that it had any liability to Dr. Falk Pharma. On July 27, 2017, Fortress received a judgment from the court in Frankfurt awarding the full amount (EUR 2.5 million) plus interest to Dr. Falk Pharma. Fortress appealed the decision to the Higher Regional Court of Frankfurt on August 28, 2017, and the initial response of Dr. Falk Pharma to the appeal was filed on February 16, 2018. At an appellate hearing in the Higher Regional Court on June 12, 2018, the court issued an oral ruling upholding the lower court’s judgment and indicating that an impending written, enforceable judgment would do the same. On July 12, 2018, the Higher Regional Court approved and recorded terms of settlement between Fortress and Dr. Falk Pharma pursuant to which Fortress will pay \$3.3 million to Dr. Falk Pharma over the course of a year, and approximately \$37,000 to the court in mandated administrative fees. In August 2018, pursuant to the terms of the settlement agreement, the Company paid Dr. Falk Pharma \$2.0 million, as well as, \$39,500 in mandated court fees.

### **Item 1A. Risk Factors**

Investing in our Common Stock or any other of our equity 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 majority-controlled subsidiaries National, Checkpoint, Mustang, and Avenue with the SEC, before deciding to invest in shares of our Common Stock or any other of our equity securities. If any of the following risks or the risks included in the public filings of National, 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 Common Stock or that of any other of our equity securities could decline, and you could lose part of or all of your investment in our Common Stock or in our any other of our equity securities.

#### **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 Common Stock thereby diluting stockholder value and disrupting our business.*

As part of our growth strategy, we might acquire, enter into joint ventures with, or obtain a significant ownership stake 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 costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities.

*If certain of our subsidiaries 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 and our subsidiaries' ability to generate revenue. If we and our subsidiaries 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 subsidiaries, most 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 investments in our subsidiaries, which at the time of investment generally 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 one or more of our subsidiaries' ability 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 subsidiaries do not successfully obtain additional third-party financing to commercialize products, successfully acquire companies or participate in the financial services industry, as applicable, the value of our businesses and our ownership stakes in our subsidiaries may be materially adversely affected.

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

Our and certain of our subsidiaries' research and development ("R&D") programs will require substantial additional capital to conduct research, preclinical testing and human studies, 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 and certain of our subsidiaries' R&D activities from a combination of cash generated from royalties and milestones from our partners in various past, ongoing and future collaborations and additional equity or debt financings from third parties. These financings could depress our stock price. If additional funds are required to support our or our subsidiaries' operations and such funds cannot be obtained on favorable terms, we and certain of our subsidiaries may not be able to develop products, which will adversely impact our growth strategy.

*Collaborative relationships with third parties could cause us or certain of our subsidiaries 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 and certain of our subsidiaries' existing product candidates, and we and our subsidiaries may rely even more on strategic collaborations for R&D of other product candidates. We and certain of our subsidiaries may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies. If we or our subsidiaries 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 or certain of our subsidiaries enter into R&D collaborations during the early phases of drug development, success will in part depend on the performance of research collaborators. Neither we nor certain of our subsidiaries will 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 or our subsidiaries' 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 or our subsidiaries. Finally, if we or certain of our subsidiaries 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 and certain of our subsidiaries' 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 and our subsidiaries' financial, regulatory or intellectual property position. 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 or our subsidiaries 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 or our subsidiaries enter into collaborative arrangements, the related product revenues are likely to be lower than if we or our subsidiaries 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 whether such a collaboration could be more attractive than the one with us or our subsidiaries for any future product candidate.

Management of our relationships with collaborators will require:

- significant time and effort from our management team, as well as from the management teams of our subsidiaries;
- coordination of our and certain of our subsidiaries' marketing and R&D programs with the respective marketing and R&D priorities of our collaborators; and
- effective allocation of our and our subsidiaries' 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 funds 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 for our Company, and in some cases, our subsidiaries, 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 for us and, in some cases, our subsidiaries as we continue to implement our growth strategy and acquire and invest in companies with varied businesses. During our and our subsidiaries' operating history, many essential responsibilities have been assigned to a relatively small number of individuals. However, as we continue to implement our growth strategy and our subsidiaries grow, the demands on our key employees will expand and we will need to recruit additional qualified employees for us and, possibly, for our subsidiaries. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our or our subsidiaries' 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 subsidiaries. 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, nor are we the beneficiary of key-person life insurance for any of our and our subsidiaries' 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 and our subsidiaries' ability to continue operations.

*Our and our subsidiaries' 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 and our subsidiaries 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 manufacturing standards we have established, 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 and our subsidiaries. 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 and our subsidiaries take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us and our subsidiaries 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 or our subsidiaries, and we or our subsidiaries 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 and our subsidiaries 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 and our subsidiaries 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 and our subsidiaries to monetary damages and/or injunctive or equitable relief. The notes, analyses and memoranda that we and our subsidiaries have generated based off such information are also valuable to our businesses, and the unauthorized disclosure or misappropriation of such materials by our and our subsidiaries' 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 with our subsidiaries, affiliates, related parties and other parties with whom we transact business; 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 subsidiaries, affiliates, related parties or other companies with which we transact business, 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 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 and our subsidiaries to lost profits, claims by our investors and creditors, and harm to our and our subsidiaries' 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; we also have numerous early-stage subsidiaries that 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 subsidiaries, on whose success we largely rely, are also early-stage biopharmaceutical companies. To date, we and certain of our subsidiaries have engaged primarily in R&D and investment activities and have not generated any revenues from product sales. We and certain of our subsidiaries have incurred significant net losses since our inception. As of September 30, 2018, we had an accumulated deficit of approximately \$371.4 million. We and certain of our subsidiaries have not demonstrated the ability to perform the functions necessary for the successful commercialization of any of our products, should any of them be approved for marketing. If we and/or our subsidiaries were to have products approved, the successful commercialization of such products would require us and our subsidiaries to perform or contract with third parties for performance of a variety of critical functions, including, but not necessarily limited to:

- identifying, developing, and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- continuing to undertake pre-clinical development and designing and executing clinical trials;
- 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, and making investments in other companies. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to commercialize product candidates, develop potential product candidates and make successful investments in other companies, 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 or certain of our subsidiaries 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, neither we nor our subsidiaries may be able to effectively market and sell products and generate product revenue.*

Neither we nor our biopharmaceutical subsidiaries (other than Journey Medical Corporation) currently have the infrastructure for the sales, marketing and distribution of any of our product candidates, and we and certain of our subsidiaries must build and maintain such an infrastructure 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, certain of our subsidiaries or jointly with a partner, or the establishment of a contract sales force to market any products for which we or our subsidiaries 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, certain of our subsidiaries, or our respective partners, 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 or certain of our subsidiaries will need to contract with third parties to market and sell such products. We or certain of our subsidiaries may not be able to establish arrangements with third parties on acceptable terms, or at all.

*If any of our or certain of our subsidiaries' 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 or certain of our subsidiaries' 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 or certain of our subsidiaries' 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 or certain of our subsidiaries 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 our product. 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
- neither experimental nor 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. This lawsuit is ongoing and the outcome 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 a hospital payment reduction for drugs acquired through the 340B Drug Pricing Program and has proposed to expand this payment reduction to other hospital settings. HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits. 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 have been, and 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.

*The United Kingdom's announced withdrawal from the EU could have a negative effect on global economic conditions and financial markets, EU regulatory procedures and our business.*

In June 2016, a majority of voters in the United Kingdom, or the UK, elected in a national referendum to withdraw from the EU. In March 2017, the UK government formally initiated the withdrawal process. That pending withdrawal, currently scheduled to occur in or before March 2019, has created significant uncertainty about the future relationship between the UK and the EU, including with respect to the laws and regulations that will apply as the UK determines which EU laws to replace or replicate upon withdrawal. The pending withdrawal has also given rise to calls for the governments of other EU member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict access to capital, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The UK's withdrawal from the EU also means that the EMA, from which we and certain of our subsidiaries must obtain approval to sell any product in the EU, must relocate from its current headquarters in the UK to a new location within the EU. This relocation of the EMA could significantly disrupt its operations, which could cause delays in the EMA's review and approval of marketing authorization applications. Such a disruption could impact any future applications for EMA approval of our and our subsidiaries' drug candidates, which could have a material adverse effect on our business, financial condition and results of operations and growth prospects.

*Our, and our subsidiaries 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 or our subsidiaries 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, or our subsidiaries, obtain marketing approval. Our, and our subsidiaries', 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 and our subsidiaries sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we or our subsidiaries 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, or our subsidiaries' 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 physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. 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 and our subsidiaries’ 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 or our subsidiaries’ 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 or our subsidiaries’ 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 business. 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 business.

*Failure to be included in formularies developed by managed care organizations and coverage by other organizations may negatively impact the utilization of our and certain of our subsidiaries’ products, which could harm our and our subsidiaries’ 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 and certain of our subsidiaries’ products. If our and our subsidiaries’ 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.

*Our product candidates and certain of our subsidiaries’ product candidates are at an early stage of development and may not be successfully developed or commercialized.*

Our existing product candidates, and most of our subsidiaries’ product candidates remain in the early stage of development and will require substantial further capital expenditures, development, testing and regulatory clearances/approvals prior to commercialization. The development and regulatory approval process takes several years, and it is not likely that our product candidates or all our subsidiaries’ 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 and our subsidiaries are able to obtain the requisite financing to fund development programs, we cannot assure you that any of our or our subsidiaries’ 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 and certain of our subsidiaries in-license certain product candidates from third parties, any dispute with the licensors or the non-performance of such license agreements may adversely affect our and our subsidiaries' ability to develop and commercialize the applicable product candidates.*

All of our existing product candidates and certain of our subsidiaries' product candidates, including related intellectual property rights, were in-licensed from third parties. Under the terms of the license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach. The licenses require us and certain of our subsidiaries to make annual, milestone or other payments prior to commercialization of any product and our and our subsidiaries' 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 subsidiaries, 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 our subsidiaries and the third parties from whom we and our subsidiaries license intellectual property include, but are not limited to:

- the scope of rights granted under such license agreements and other interpretation-related issues;
- the extent to which our technology and processes do or do not infringe on intellectual property of the licensor that is not subject to such license 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;
- 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, sublicense revenue and other payment obligations under such license agreements;
- the extent to which license 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;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we and our subsidiaries 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 and our subsidiaries' rights to the relevant intellectual property or technology, or increase what we believe to be our and our subsidiaries' 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 or our subsidiaries have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we or our subsidiaries 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 or certain of our subsidiaries advance into clinical trials may not receive regulatory approval.*

Pharmaceutical development has inherent risk. We and certain of our subsidiaries 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 or our subsidiaries 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 or our subsidiaries advance into clinical trials may not receive regulatory approval.

In addition, even if our or certain of our subsidiaries' product candidates were to obtain approval, regulatory authorities may approve any of such product candidates or any future product candidate for fewer or more limited indications than we or our subsidiaries request, may not approve the price we or our subsidiaries 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. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of that product. Any of these scenarios could compromise the commercial prospects for one or more of our or our subsidiaries current or future product candidates.

*Any product candidates we or certain of our subsidiaries 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, and certain of our subsidiaries' 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, neither we nor our subsidiaries are permitted to market our product candidates until such product candidate's Biologics License Application ("BLA") or New Drug Application 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 the significant clinical testing requirements, our and our subsidiaries' 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 and our subsidiaries' product candidates and validation of our and our subsidiaries' manufacturing processes. The FDA may determine that our or our subsidiaries' 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 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 or those of certain of our subsidiaries;
- our or certain of our subsidiaries' inability to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are 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 fail to approve the manufacturing processes or facilities or those of third-party manufacturers with which we, or certain of our subsidiaries 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 or our subsidiaries from commercializing our product candidates.

*Any product candidate we or certain of our subsidiaries 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 or certain of our subsidiaries' 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 or certain of our subsidiaries 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.

Neither we nor certain of our subsidiaries have completed testing of all our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our or our subsidiaries' product candidates. If any of our or our subsidiaries' product candidates cause unacceptable adverse events in clinical trials, neither we nor our subsidiaries may 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 or certain of our subsidiaries to withdraw such products from the market.

*Delays in the commencement of our and certain of our subsidiaries' clinical trials could result in increased costs and delay our or certain of our subsidiaries' 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 to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement 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; and
- retaining (or replacing) patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

Any delays in the commencement of our or certain of our subsidiaries' clinical trials will delay our or our subsidiaries' 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 or certain of our subsidiaries' 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 or our subsidiaries, 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 or our subsidiaries' 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 or certain of our subsidiaries may need to amend clinical trial protocols to reflect these changes. Amendments may require us or certain of our subsidiaries 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 or our subsidiaries experience delays in the completion of, or if we must suspend or terminate, any clinical trial of any product candidate, our ability or the ability of our subsidiaries 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 or certain of our subsidiaries may develop and market may be later withdrawn from the market or subject to promotional limitations.*

Neither we nor certain of our subsidiaries may be able to obtain the labeling claims necessary or desirable for the promotion of our product candidates if approved. We and certain of our subsidiaries 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 agency in another country may withdraw marketing authorization or may condition continued marketing on commitments from us or our subsidiaries that may be expensive and/or time consuming to complete. In addition, if we or others identify adverse side effects after any of our or our subsidiaries' products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our or our subsidiaries' products, additional clinical trials, changes in labeling of our or our subsidiaries' products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of such products if approved.

*We and certain of our subsidiaries 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 business.*

We and certain of our subsidiaries depend heavily on third party manufacturers for product supply. If our or our subsidiaries' contract manufacturers cannot successfully manufacture material that conforms to our specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for those products. Our and our subsidiaries' 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 agencies determine that our third-party suppliers have not complied with cGMP or comparable authorities, 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. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of our third-party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our and our subsidiaries' products.

We and certain of our subsidiaries also rely on our 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 manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply the raw material components for an ongoing clinical trial could considerably delay completion of our and our subsidiaries' clinical trials, product testing and potential regulatory approval.

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

*We and certain of our subsidiaries 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 or our subsidiaries' clinical development programs could be delayed or unsuccessful and neither we nor our subsidiaries may be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.*

Neither we nor certain of our subsidiaries have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We and certain of our subsidiaries 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 and certain of our subsidiaries' 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 and our subsidiaries 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 fail to meet expected deadlines, fail to adhere to our clinical protocols or otherwise perform in a substandard manner, our or our subsidiaries' clinical trials may be extended, delayed or terminated. If any of the clinical trial sites terminate for any reason, we or our subsidiaries 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 and our subsidiaries' 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 may be jeopardized.

*We and certain of our subsidiaries rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.*

As part of the strategy implemented by us and our subsidiaries to mitigate development risk, we and certain of our subsidiaries seek to develop product candidates with validated mechanisms of action and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon 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 and certain of our subsidiaries rely upon prove to be inaccurate, unreliable or not applicable to the product candidates of us and our subsidiaries, we could make inaccurate assumptions and conclusions about the product candidates of us and our subsidiaries, and our research and development efforts could be compromised and called into question during the review or any marketing applications we submit.

*If our competitors develop treatments for any of the target indications of our or certain of our subsidiaries' product candidates that 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 and certain of our subsidiaries operate in highly competitive segments of the biopharmaceutical markets and face competition from many different sources, including commercial pharmaceutical enterprises, academic institutions, government agencies, and private and public research institutions. Our and our subsidiaries' 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 and our subsidiaries' competitors have significantly greater financial, product development, manufacturing and marketing resources than those of ours and our subsidiaries. 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 and our subsidiaries' product candidates obsolete or noncompetitive. We and our subsidiaries will also face competition from these third parties in establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

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

We and certain of our subsidiaries 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 or our subsidiaries' product candidates causes, or merely appears to have caused, personal injury or death. While we and our subsidiaries 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 or our subsidiaries may be unable to maintain such insurance. Any claims against us or our subsidiaries, regardless of their merit, could severely harm our or our subsidiaries' 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 or our subsidiaries will be able to obtain or maintain product liability insurance for any products that may be approved for marketing. Additionally, we and certain of our subsidiaries have entered into various agreements under which we indemnify third parties for certain claims relating to product candidates. These indemnification obligations may require us or our subsidiaries to pay significant sums of money for claims that are covered by these indemnifications.

*We and certain of our subsidiaries 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 certain of our subsidiaries may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our and certain of our subsidiaries' 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, neither we nor our subsidiaries can entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Neither we nor our subsidiaries 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 or any of our subsidiaries 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 and our subsidiaries' employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Neither we nor our subsidiaries 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 and certain of our subsidiaries 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 and certain of our subsidiaries' 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 and certain of our subsidiaries' 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, our subsidiaries, or our respective 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 and our subsidiaries' competitors, many of which have substantially greater resources than us, our subsidiaries, 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 or our subsidiaries' ability to make, use, and sell potential product candidates, or may affect any pending patent applications that we, our subsidiaries, or our respective partners 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 or our subsidiaries 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 position. 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 technology 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 and those of our subsidiaries, at our and their expense. If that party fails to appropriately prosecute and maintain patent protection for a product candidate, our and our subsidiaries' ability to develop and commercialize or 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 or our subsidiaries' 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 or our subsidiaries 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 subsidiaries and our respective partners also rely on trade secrets and proprietary know-how to protect product candidates. Although we have taken steps to protect our and our subsidiaries' trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions 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 breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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 trade secrets were to be lawfully obtained or independently developed by a competitor, we 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 trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also may rely on the regulatory period of market exclusivity for any of our or our subsidiaries' 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 and our subsidiaries' 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 or our subsidiaries' products, which would materially adversely affect us.

*If we, certain of our subsidiaries or our respective partners 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, many of our subsidiaries' abilities 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 and our subsidiaries are developing products, some of which may be directed at claims that overlap with the subject matter of our or our subsidiaries' 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 or our subsidiaries' product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our or our subsidiaries' product candidates of which we 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 and our subsidiaries cannot know with certainty whether we and our subsidiaries or our licensors were the first to make the inventions claimed in patents or pending patent applications that we and our subsidiaries own or licensed, or that we and our subsidiaries or 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, our subsidiaries' or any of our respective 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, our subsidiaries or any of our respective licensors, suppliers or collaborators infringe the third party's intellectual property rights, we or our subsidiaries may have to, among other things:

- obtain 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 or certain of our subsidiaries 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 certain of our subsidiaries' patents or the patents of our respective licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we or our subsidiaries assert against accused infringers could provoke these parties to assert counterclaims against us or our subsidiaries alleging invalidity of our or certain of our subsidiaries' patents or that we or our subsidiaries 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 subsidiaries 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 subsidiaries' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our or our subsidiaries' 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 or our subsidiaries' confidential information could be compromised by disclosure during this type of litigation.

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

As is common in the biopharmaceutical industry, we and certain of our subsidiaries 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 and our subsidiaries' competitors or potential competitors. We or our subsidiaries 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 or our subsidiaries are successful in defending these claims, litigation could result in substantial costs and be a distraction to management.

*Any product for which we or our subsidiaries obtain marketing approval could be subject to restrictions or withdrawal from the market and we or our subsidiaries 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 or our subsidiaries 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 or our subsidiaries 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 or our subsidiaries also may be subject to state laws and registration requirements covering the distribution of 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 or our subsidiaries 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, our subsidiaries or our respective 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, our subsidiaries, or our respective 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.

*Internet and internal computer system failures 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, a portion of our business and the business of our subsidiaries is conducted through the Internet. 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;
- an earthquake, fire, or other natural disaster or act of God;
- hacker attacks or other intentional acts of vandalism; or
- terrorist acts or war.

*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 will 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. 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.

## **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 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 operations of approximately \$101.2 million, \$65.7 million and \$50.5 million for the years ended December 31, 2017, 2016 and 2015, respectively, and losses from operations of \$85.0 million for the nine months ended September 30, 2018. At September 30, 2018, we had an accumulated deficit of approximately \$371.4 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 subsidiaries 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 and our investments in certain of our subsidiaries, 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 September 30, 2018, the total amount of debt outstanding was \$85.1 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, the promissory note with IDB may limit our ability to finance future operations or satisfy capital needs or to engage in, expand or pursue our business activities. It 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.

*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 and planned acquisitions and potentially change our growth strategy.*

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2017, 2016 and 2015 we incurred R&D expenses of approximately \$52.5 million, \$35.1 million and \$29.8 million, respectively. For the nine months ended September 30, 2018, we incurred research and development expenses of approximately \$58.5 million. 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 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 financing 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 investments 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 or our subsidiaries' 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 statement could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our Common Stock.*

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 Common Stock to decline.

## **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 September 30, 2018, Lindsay A. Rosenwald, M.D. our Chairman, President and Chief Executive Officer, beneficially owned 13.2% of our issued and outstanding capital stock, including 40,000 Series A Preferred Shares. At September 30, 2018, Michael S. Weiss, our Executive Vice Chairman, Strategic Development, beneficially owned 15.3% 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 Common Stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.*

Our stock price may experience substantial volatility as a result of a number of factors, including, but not necessarily limited to:

- announcements we make regarding our or our subsidiaries' current product candidates, acquisition of potential new product candidates and companies and/or in-licensing through multiple subsidiaries;
- sales or potential sales of substantial amounts of our Common Stock or issuance of debt;
- our or our subsidiaries' delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of any of these trials;
- announcements about us, our subsidiaries or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our or our subsidiaries' licensors and/or product manufacturers;
- litigation and other developments relating to our or our subsidiaries' 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 price of our Common Stock, 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 56.2 million outstanding shares of our Common Stock, inclusive of outstanding equity awards, as of September 30, 2018, 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, we may issue and sell shares of our common stock having an aggregate offering price of up to \$53.0 million from time to time. Any sale of a substantial number of shares of our Common Stock could cause a drop in the trading price of the Common Stock on the Nasdaq Stock Market.

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

We and certain of our subsidiaries have never paid cash dividends on any of our or their capital stock, or made stock dividends, except for the dividend we pay on our Preferred A shares, and we and many of our subsidiaries 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 and certain of our subsidiaries from paying cash or stock dividends. Equally, our subsidiaries are governed by their own boards of directors with individual governance and decision-making regimes and mandates to oversee such subsidiaries in accordance with their respective fiduciary duties. As a result, we alone cannot determine the acts of our subsidiaries that could maximize value to you, 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.*

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 could receive a premium for your Common Stock in 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

<b>Exhibit Number</b>	<b>Exhibit Title</b>
<u>31.1</u>	<u>Certification of Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>31.2</u>	<u>Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>32.1</u>	<u>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.</u>
<u>32.2</u>	<u>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.</u>
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

## SIGNATURES

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

November 9, 2018

FORTRESS BIOTECH, INC.

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

November 9, 2018

By: /s/ Robyn M. Hunter  
Robyn M. Hunter Chief Financial Officer (Principal Financial Officer)

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## Section 2: 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: November 9, 2018

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 3: 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: November 9, 2018

By: /s/ Robyn M. Hunter  
Robyn M. Hunter  
Chief Financial Officer  
(Principal Financial Officer)

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## Section 4: 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 September 30, 2018, 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: November 9, 2018

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 5: 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 September 30, 2018, 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: November 9, 2018

By: /s/ Robyn M. Hunter  
Robyn M. Hunter  
Chief Financial Officer  
(Principal Financial Officer)

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