

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

TRANSITION REPORT UNDER SECTION 13 OF 15(d) OF THE EXCHANGE ACT OF 1934

From the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number 001-35366

**FORTRESS BIOTECH, INC.**  
(Exact name of small business issuer as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-5157386**  
(IRS Employer  
Identification No.)

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

**(781) 652-4500**  
(Issuer's telephone number)

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 and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

As of August 9, 2016, there were 48,668,630 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>June 30, 2016</u>	<u>December 31, 2015</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 71,336	\$ 98,182
Accounts receivable	967	-
Inventory	100	-
Other receivables - related party	2,570	156
Prepaid expenses and other current assets	1,579	1,599
Total current assets	<u>76,552</u>	<u>99,937</u>
Property and equipment, net (Note 3)	4,535	309
Restricted cash	14,586	14,586
Long-term investments, at fair value (Note 4)	766	2,485
Intangible asset - license (Note 7)	1,579	1,250
Other assets	44	43
<b>Total assets</b>	<b><u>\$ 98,062</u></b>	<b><u>\$ 118,610</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 5,126	\$ 1,868
Accrued expenses	8,883	8,570
Interest payable	26	27
Derivative liabilities (Note 4)	302	114
Total current liabilities	<u>14,337</u>	<u>10,579</u>
Notes payable, long-term (net of debt discount of \$412 and \$835 at June 30, 2016 and December 31, 2015, respectively)	20,805	23,174
Convertible note, at fair value	1,000	-
Other long-term liabilities	3,706	584
<b>Total liabilities</b>	<b><u>39,848</u></b>	<b><u>34,337</u></b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Convertible Preferred stock, \$.001 par value, 129,767 Series C shares authorized, 0 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	-	-
Common Stock, \$.001 par value, 100,000,000 shares authorized, 48,668,630 and 47,147,032 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	49	47
Additional paid-in-capital	250,127	246,955
Accumulated deficit	(214,839)	(190,156)
Total stockholders' equity attributed to the Company	<u>35,337</u>	<u>56,846</u>
Non-controlling interests (Note 10)	22,877	27,427
Total stockholders' equity	<u>58,214</u>	<u>84,273</u>
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 98,062</u></b>	<b><u>\$ 118,610</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)

	<u>For the Three Months Ended June 30,</u>		<u>For the Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Product revenue, net	\$ 981	\$ -	\$ 1,364	\$ -
Revenue - from a related party	1,249	-	1,526	500
<b>Total revenue</b>	<b>2,230</b>	<b>-</b>	<b>2,890</b>	<b>500</b>
Cost of goods sold - product revenue	324	-	324	-
<b>Gross margin</b>	<b>1,906</b>	<b>-</b>	<b>2,566</b>	<b>500</b>
<b>Operating expenses</b>				
Research and development	6,347	2,411	14,100	4,066
Research and development – licenses acquired	2,060	1,548	2,143	8,987
General and administrative	8,635	3,803	16,550	7,280
<b>Total operating expenses</b>	<b>17,042</b>	<b>7,762</b>	<b>32,793</b>	<b>20,333</b>
<b>Loss from operations</b>	<b>(15,136)</b>	<b>(7,762)</b>	<b>(30,227)</b>	<b>(19,833)</b>
<b>Other income (expenses)</b>				
Interest income	77	74	152	156
Interest expense and financing fees	(529)	(352)	(1,149)	(683)
Change in fair value of derivative liabilities	-	-	(89)	-
Change in fair value of investments	(801)	1,622	(1,719)	1,407
<b>Total other income (expenses)</b>	<b>(1,253)</b>	<b>1,344</b>	<b>(2,805)</b>	<b>880</b>
<b>Net loss</b>	<b>(16,389)</b>	<b>(6,418)</b>	<b>(33,032)</b>	<b>(18,953)</b>
Less: net loss attributable to non-controlling interests	3,911	243	8,349	722
<b>Net loss attributable to common stockholders</b>	<b>\$ (12,478)</b>	<b>\$ (6,175)</b>	<b>\$ (24,683)</b>	<b>\$ (18,231)</b>
Basic and diluted net loss per common share	\$ (0.31)	\$ (0.16)	\$ (0.62)	\$ (0.47)
Weighted average common shares outstanding—basic and diluted	39,867,724	39,119,606	39,762,956	38,848,660

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 Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash Flows from Operating Activities:</b>		
Net Loss	\$ (33,032)	\$ (18,953)
<b>Reconciliation of net loss to net cash used in operating activities:</b>		
Depreciation expense	74	11
Noncash interest expense	-	167
Amortization of debt discount	423	84
Amortization of product revenue license fee	21	-
Stock-based compensation expense	5,889	3,395
Issuance of subsidiaries' common shares for license expenses	48	-
Financing fees on Helocyte Convertible Note, at fair value	249	-
Change in fair value of investments	1,719	(1,407)
Change in fair value of derivative liabilities	89	-
Research and development-licenses acquired, expense	2,095	8,629
Unrealized loss on marketable securities	-	2
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(967)	-
Inventory	(100)	-
Other receivables - related party	(2,414)	(42)
Prepaid expenses and other current assets	195	(253)
	3,571	920
Accounts payable and accrued expenses		
Interest payable	(1)	(2)
Other long-term liabilities	3,122	(624)
Net cash used in operating activities	<u>(19,019)</u>	<u>(8,073)</u>
<b>Cash Flows from Investing Activities:</b>		
Purchase of research and development licenses	(2,095)	(8,629)
Purchase of property and equipment	(4,300)	(49)
Purchase of license	(350)	(1,250)
Security deposits collected	(1)	-
Investment in Origo Acquisition Corp.	(175)	(108)
Net cash used in investing activities	<u>(6,921)</u>	<u>(10,036)</u>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from exercise of stock options	-	216
Proceeds from issuance of common stock under ESPP	81	26
Proceeds from subsidiary's offering	570	-
Proceeds from at-the-market offering	434	-
Payment of cost related to at-the-market offering	(49)	-
Payment of NSC note	(2,792)	-
Proceeds from NSC note	-	10,000
Payment of debt issuance costs associated with NSC Note	-	(855)
Proceeds from Helocyte Convertible Note	1,000	-
Payment of debt issuance costs associated with Helocyte Convertible Note	(150)	-
Net cash (used in) provided by financing activities	<u>(906)</u>	<u>9,387</u>
Net decrease in cash and cash equivalents	(26,846)	(8,722)
Cash and cash equivalents at beginning of period	98,182	49,759
<b>Cash and cash equivalents at end of period</b>	<b><u>\$ 71,336</u></b>	<b><u>\$ 41,037</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 Cash Flows**  
(\$ in thousands)  
(Unaudited)

**Supplemental disclosure of cash flow information:**

Cash paid for interest	\$	158	\$	80
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**Supplemental disclosure of non-cash financing and investing activities:**

Issuance of restricted stock	\$	2	\$	1
Issuance of subsidiaries common shares for license	\$	48	\$	-
Issuance of warrants in connection with the Helocyte Convertible Note	\$	99	\$	-

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 plans to continue to develop and commercialize products both within Fortress and its subsidiaries, also referred to herein as the “Fortress Companies”. In addition to its internal development programs, the Company plans to leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies innovate, develop and commercialize products. Additionally, the Company will provide funding and management services to each of the Fortress Companies and, from time to time, the Company and the Fortress Companies will seek licensing, 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 June 30, 2016, the Company has several consolidated Fortress Companies, which contain product licenses, including Avenue Therapeutics, Inc. (“Avenue”), Journey Medical Corporation (“JMC”), Coronado SO Co. (“Coronado SO”), Checkpoint Therapeutics, Inc. (“Checkpoint”), Mustang Bio, Inc. (“Mustang”), Helocyte, Inc. (“Helocyte”), Escala Therapeutics, Inc. (“Escala”) and other consolidated Fortress subsidiaries which have minimal activity, including Innmune Limited, CB Securities Corporation (holds investments classified as cash and cash equivalents in 2016 and 2015), and Cyprium Therapeutics, Inc.

**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 consolidated financial statements for the preceding fiscal year. 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 15, 2016, from which the Company derived the balance sheet data at December 31, 2015.

The Company’s unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries: Innmune Limited, Coronado SO, Cyprium Therapeutics, Inc., Escala, JMC, CB Securities Corporation, Avenue, Checkpoint, Mustang and Helocyte. All intercompany balances and transactions have been eliminated.

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

**Use of Estimates**

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

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

**Fair Value Measurement**

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured at fair value on a recurring basis. Under the accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires that fair value measurements be classified and disclosed in one of the following three categories:

- Level 1:* Quoted prices in active markets for identical assets or liabilities.
- Level 2:* Observable inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
- Level 3:* Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

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. The carrying value of the amount owed to Ovamed GmbH ("Ovamed") upon the acquisition of certain manufacturing rights in December 2012 under the amendment to the Company's sublicense agreement with Ovamed has been recorded at its net present value, which approximates its fair value. The amounts due to Ovamed are included in current liabilities at June 30, 2016 and at December 31, 2015 on the Condensed Consolidated Balance Sheets (see Note 9).

**Segment Reporting**

Effective April 1, 2016, consistent with the increase in JMC's operations, the Company now operates in two operating and reportable segments, Dermatology Product Sales and Pharmaceutical and Biotechnology Product Development. The chief operating decision-maker ("CODM") is the Company's Chief Executive Officer. There are no significant inter-segment sales. The Company evaluates the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

**Cash and Cash Equivalents**

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at June 30, 2016 and at December 31, 2015 consisted of cash, money market funds and certificates of deposit in institutions in the United States. Balances at certain institutions have exceeded Federal Deposit Insurance Corporation insured limits and U.S. government agency securities.

**Property and Equipment**

Office equipment is recorded at cost and depreciated using the straight-line method over the estimated useful life of each asset. Leasehold improvements are amortized over the shorter of the estimated useful lives or the term of the respective leases.

**Impairment of Long-Lived Assets**

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows.

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

**Restricted Cash**

The Company records cash held in trust or pledged to secure certain debt obligations as restricted cash. As of June 30, 2016, the Company has \$14.6 million of restricted cash collateralizing a note payable of \$14.0 million (see Note 8) and a pledge to secure a letter of credit in connection with a new lease of \$0.6 million.

**Inventories**

Inventories comprise finished goods, which are valued at the lower of cost or market, on a first-in, first-out basis. The Company evaluates the carrying value of inventories on a regular basis, taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand.

**Accounts Receivable**

Accounts receivable consists of amounts due to the Company for product sales from JMC. The Company's accounts receivable reflects discounts for early payment and for product returns.

**Investments at Fair Value**

The Company elects the fair value option for its long-term investments at fair value (see Note 4). The decision to elect the fair value option, which is irrevocable once elected, is determined on an instrument-by-instrument basis and applied to an entire instrument. The net gains or losses, if any, on an investment for which the fair value option has been elected are recognized as a change in fair value of investments on the Condensed Consolidated Statements of Operations.

The Company has various processes and controls in place to ensure that fair value is reasonably estimated. While the Company believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

**Fair Value Option**

As permitted under the Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 825, *Financial Instruments*, ("ASC 825"), the Company has elected the fair value option to account for its Helocyte convertible notes that were issued during the quarter ended June 30, 2016. In accordance with ASC 825, the Company records these convertible notes at fair value with changes in fair value recorded in the Condensed Consolidated Statement of Operations. As a result of applying the fair value option, direct costs and fees related to the Helocyte convertible notes were recognized in earnings as incurred and were not deferred.

**Accounting for Warrants at Fair Value**

The Company classifies as liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The fair value of warrants that include price protection reset provision features are deemed to be "down-round protection" and, therefore, do not meet the scope exception for treatment as a derivative under ASC 815 "Derivatives and Hedges", since "down-round protection" is not an input into the calculation of the fair value of warrants and cannot be considered "indexed to the Company's own stock" which is a requirement for the scope exception as outlined under ASC 815. The accounting treatment of derivative financial instruments requires that the Company record the warrants at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification.

The Company assessed the classification of warrants (the "June 2016 Warrants") issued, in connection with the Helocyte convertible note financing in June 2016, and determined that the June 2016 Warrants met the criteria for liability classification. Accordingly, the Company classified the June 2016 Warrants as a liability at their fair value and adjusts the instruments to fair value at each balance sheet date until the warrants are exercised or expired. Any change in the fair value of the June 2016 Warrants is recognized as "change in the fair value of warrant liabilities" in the Condensed Consolidated Statements of Operations.

**Issuance of Debt and Equity**

The Company issues complex financial instruments which include both equity and debt features. The Company analyzes each instrument under FASB ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), *Derivatives and Hedging* and FASB ASC 470, *Debt* in order to establish whether such instruments include any embedded derivatives.

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

**Valuation of Warrants Related to NSC Note**

In accordance with FASB No. ASC 815, the Company classified the fair value of the warrants granted in connection with the NSC Note transferred to Avenue effective February 2015 (the “Contingently Issuable Warrants”) as a derivative liability. The Company valued these Contingently Issuable Warrants using an option pricing model and used estimates for an expected dividend yield, a risk-free interest rate, and expected volatility together with management’s estimate of the probability of issuance of the Contingently Issuable Warrants (see Note 4 and Note 8). At each reporting period, as long as the Contingently Issuable Warrants were potentially issuable and there was a potential for an insufficient number of authorized shares available to settle the Contingently Issuable Warrants, these Contingently Issuable Warrants will be revalued, and any difference from the previous valuation date would be recognized as a change in fair value of Contingently Issuable Warrants in the Condensed Consolidated Statements of Operations.

**Intangible Asset Licenses**

The Company records the costs of acquired product distribution license rights as intangible asset-licenses in the Condensed Consolidated Balance Sheets. Upon commencement of product sales, license rights associated with those sales are amortized over the expected life of the product into product expense in the Condensed Consolidated Statements of Operations. As of June 30, 2016, product sales related to certain of the Company’s intangible asset licenses commenced and the Company commenced amortization of those licenses (see Note 7).

**Deferred Financing Costs**

Financing costs incurred in connection with the promissory note for \$15.0 million between Israel Discount Bank (“IDB”) and the National Securities Corporation’s NSC Biotech Venture Fund I LLC (the “NSC Note”) are now recorded as a reduction of principal balance due to ASU No. 2015-3 and are amortized over the appropriate expected life based on the term of the NSC Note using the effective interest rate method.

**Revenue Recognition**

The Company recognizes revenue for the performance of services or the shipment of products when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

*Reimbursement Arrangements and Collaborative Arrangements*

Checkpoint is reimbursed by TG Therapeutics, Inc. (“TGTX”), a related party, for TGTX’s share of the cost of the license and product research and development under their collaboration agreement. The gross amount of these reimbursed costs is reported as revenue in the Condensed Consolidated Statements of Operations, since the Company acts as a principal, bears credit risk and may perform part of the services required in the transactions. Consistent with ASC 605-45, *Revenue Recognition - Principal Agent Considerations*, these reimbursements are treated as revenue by the Company. The actual expenses creating the reimbursements are reflected as expenses in the condensed consolidated financial statements.

The Company follows ASC 605-25, *Revenue Recognition - Multiple-Element Arrangements* (“ASC 605-25”) and ASC 808, *Collaborative Arrangements*, if applicable, to determine the recognition of revenue under its collaborative research agreements, options to enter into collaborative research agreements and development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) grants of licenses, or options to obtain licenses, to the Company’s intellectual property, (ii) research and development services, (iii) drug product manufacturing, and/or (iv) participation on joint research and/or joint development committees. The payments we may receive under these arrangements typically include one or more of the following: non-refundable, up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified objectives; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit utilizing the relative selling price method. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

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

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as deferred revenue in the Condensed Consolidated Balance Sheets and recognized as revenue in the Condensed Consolidated Statements of Operations when the related revenue recognition criteria are met.

*Revenue Recognition – Milestone Method*

The Company follows ASC 605-28, *Revenue Recognition—Milestone Method* to evaluate whether each milestone under a license agreement is substantive. This evaluation includes an assessment of whether (i) the consideration is commensurate with either (a) the entity's performance to achieve the milestone, or (b) the enhancement of the value of the delivered item as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. In making this assessment the Company evaluates factors such as the preclinical, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. If a substantive milestone is achieved, the Company would recognize revenue related to the milestone in its entirety in the period in which the milestone was achieved, assuming all other revenue recognition criteria were met. Commercial milestones would be accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria were met.

*JMC Product Revenue*

JMC sells its products directly to wholesalers and specialty pharmacies. JMC recognizes product sales revenue when delivery has occurred, collectability is reasonably assured, and the price to the buyer is fixed or determinable, (in accordance with the specific contractual terms). Delivery occurs when title has transferred to the customer, and the customer has assumed the risks and rewards of ownership. Revenue from product sales is recognized net of provisions for estimated cash discounts, allowances, returns, rebates, chargebacks and distribution fees paid to certain of JMC's wholesale customers. JMC establishes these provisions concurrently with the recognition of product sales revenue. JMC offers cash discounts for prompt payment and allowances are recorded at the time of sale.

JMC allows customers to return product within a specified period of time before and after its expiration date. Provisions for returns are estimated based on historical levels for like products from external data sources, taking into account additional available information such as historical return and exchange levels, and inventory levels in the wholesale distribution channel through its partners. Although the company has limited history with these product sales, the Company believes based on its current level of sales that it can make reasonable estimates of returns based upon external data sources. JMC reviews its methodology and adequacy of the provision for returns on a quarterly basis, adjusting for changes in assumptions, historical internal and external results and business practices, as necessary.

JMC's co-promotion revenue for Dermalorb HC is based upon prescription volume over an established baseline.

**Research and Development**

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

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, and costs associated with regulatory filings, laboratory costs and other supplies.

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 commercial feasibility and has no alternative future use. Certain licenses purchased by the Company require substantial completion of research and development and regulatory and marketing approval efforts in order to reach commercial feasibility and have no alternative future use.

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**Contingencies**

The Company records accruals for contingencies and legal proceedings expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

If a loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material, would be disclosed.

**Stock-Based Compensation**

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates. For stock-based compensation awards to non-employees, the Company remeasures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change.

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

**Income Taxes**

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit.

**Non-Controlling Interests**

Non-controlling interests in consolidated entities represent the component of equity in consolidated entities held by third parties. Any change in ownership of a subsidiary while the controlling financial interest is retained is accounted for as an equity transaction between the controlling and non-controlling interests (see Note 10).

**Comprehensive Loss**

The Company's comprehensive loss is equal to its net loss for all periods presented.

**Recent Accounting Pronouncements**

In January 2016, FASB issued Accounting Standards Update ("ASU") No. 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 No. 2016-01 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is not permitted with the exception of certain targeted provisions. The Company is currently evaluating the impact of adoption of ASU No. 2016-01 on the condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU No. 2016-02"). ASU No. 2016-02 requires an entity to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. ASU No. 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-02 on the condensed consolidated financial statements and related disclosures.

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In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations* (“ASU No. 2016-08”). The purpose of ASU No. 2016-08 is to clarify the implementation of guidance on principal versus agent considerations. The amendments in ASU No. 2016-08 are effective for interim and annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact of adoption of ASU No. 2016-08 on the condensed consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting* (“ASU No. 2016-09”). Under ASU 2016-09, companies will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital (“APIC”). Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement and the APIC pools will be eliminated. In addition, ASU No. 2016-09 eliminates the requirement that excess tax benefits be realized before companies can recognize them. ASU No. 2016-09 also requires companies to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Furthermore, ASU No. 2016-09 will increase the amount an employer can withhold to cover income taxes on awards and still qualify for the exception to liability classification for shares used to satisfy the employer’s statutory income tax withholding obligation. An employer with a statutory income tax withholding obligation will now be allowed to withhold shares with a fair value up to the amount of taxes owed using the maximum statutory tax rate in the employee’s applicable jurisdiction(s). ASU No. 2016-09 requires a company to classify the cash paid to a tax authority when shares are withheld to satisfy its statutory income tax withholding obligation as a financing activity on the statement of cash flows. Under current GAAP, it was not specified how these cash flows should be classified. In addition, companies will now have to elect whether to account for forfeitures on share-based payments by (1) recognizing forfeitures of awards as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. These aspects of ASU No. 2016-09 are effective for reporting periods beginning after December 15, 2016, with early adoption permitted provided that all of the guidance is adopted in the same period. The Company is currently evaluating the impact of ASU No. 2016-09 on the condensed consolidated financial statements and related disclosures.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customer* (“ASU No. 2016-10”). The new guidance is an update to ASC No. 606 and provides clarity on identifying performance obligations and licensing implementation. For public companies, ASU No. 2016-10 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016. The Company does not expect ASU No. 2016-10 to have a material effect on the condensed consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* (“ASU No. 2016-13”). ASU No. 2016-13 requires that expected credit losses relating to financial assets be measured on an amortized cost basis and that available-for-sale debt securities be recorded through an allowance for credit losses. ASU No. 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. Early adoption of ASU No. 2016-13 will be available on January 1, 2019. The Company is currently evaluating the impact that ASU No. 2016-13 will have on its condensed consolidated financial statements and related disclosures.

### 3. Property and Equipment

Property and equipment consisted of the following:

<i>(\$ in thousands)</i>	Useful Life (Years)	June 30, 2016	December 31, 2015
Computer equipment	3	\$ 431	\$ 13
Furniture and fixtures	5	675	69
Leasehold improvements	5	164	21
Construction in progress (1)	N/A	3,407	274
<b>Total property and equipment</b>		<b>4,677</b>	<b>377</b>
Less: Accumulated depreciation		(142)	(68)
<b>Property and equipment, net</b>		<b>\$ 4,535</b>	<b>\$ 309</b>

(1) For build-out of the Company's new office in New York, NY.

Depreciation expense for the three months ended June 30, 2016 and 2015 was approximately \$82,000 and \$5,000, respectively, and was recorded in both research and development expense and general and administrative expense in the Condensed Consolidated Statements of Operations.

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Depreciation expense for the six months ended June 30, 2016 and 2015 was approximately \$86,000 and \$11,000, respectively, and was recorded in both research and development expense and general and administrative expense in the Condensed Consolidated Statements of Operations.

In January 2016, the Company wrote off approximately \$12,000 of fully depreciated leasehold improvements from 135 East 57<sup>th</sup> Street, New York, NY 10022 due to the termination of the lease.

#### **4. 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.

##### *Laser Device for Treatment of Migraine Headache*

On March 17, 2014, the Company invested \$250,000 for a 35% ownership position in a third-party company developing a laser device to treat migraine headaches. The Company elected the fair value option for recording this investment. In conjunction with this investment, the Company received 13,409,962 Class A Preferred Units in the third-party company, representing 83% of the total 16,091,954 Class A Preferred Units. The fair value of this investment was \$250,000 as of June 30, 2016 and December 31, 2015. The value of the Company's investment was determined based on a valuation which takes into consideration, when applicable, cash paid, cost of the investment, market participant inputs, estimated cash flows based on entity specific criteria, purchase multiples paid in other comparable third-party transactions, market conditions, liquidity, operating results and other qualitative and quantitative factors. Based on these inputs at June 30, 2016, the fair value of the Company's investment approximated cost.

##### *Origo Acquisition Corporation (formerly CB Pharma Acquisition Corporation)*

On June 10, 2016 CB Pharma Acquisition Corp ("CB Pharma") held an extraordinary general meeting of shareholders (the "Meeting"). At the Meeting, the shareholders approved each of the following items: (i) an amendment to the CB Pharma's Amended and Restated Memorandum and Articles of Association (the "Charter") to extend the date by which CB Pharma has to consummate a business combination from June 12, 2016 to December 12, 2016 (the "Extension"), (ii) an amendment to the Charter to allow the holders of the CB Pharma's ordinary shares issued in their initial public offering to elect to convert their shares into their pro rata portion of the funds held in trust, if the Extension is approved, and (iii) the change of CB Pharma's name from "CB Pharma Acquisition Corp." to "Origo Acquisition Corporation" ("Origo"). In connection with the Meeting the Company transferred 1,050,000 of its CB Pharma ordinary shares to Origo. The Company retained ownership of 265,000 Origo shares.

As of June 30, 2016, the Company valued its investment in Origo, a publicly traded company, utilizing the following assumptions: probability of a successful business combination of 34.83%, and no dividend rate, which yielded an underlying value of \$5.47 per ordinary share for the private placement shares. The rights and warrants were valued utilizing a binomial-lattice model which assumes a volatility of 25.6%, a risk free rate of return of 1.01% and a strike price of \$11.50 per share arriving at a value of \$0.55 for each right and \$0.13 for a warrant. A 34.83% probability of a successful business combination was applied to the values above arriving at an estimated value of \$1.91 for the private placement shares, \$0.19 for each right and \$0.05 for each warrant. Based upon the valuation, the Company recorded a decrease in fair-value of investment of \$1.7 million of which \$25,000 represents a realized loss on the investment of the ordinary shares and the remaining \$1.675 million was recorded as an unrealized loss. At June 30, 2016, the fair value of the Company's investment in Origo was, \$0.5 million. Additionally, as of May 31, 2016, Origo had net assets of approximately \$42.6 million. The Company's working capital note of \$0.3 million can be converted to stock upon a successful business combination.

##### *NSC Warrant*

Pursuant to the Amended NSC Note (see Note 8), if a Fortress Company has the proceeds of the NSC Note transferred to it, such Fortress Company will issue a note to NSC and NSC will also receive a warrant to purchase a number of shares of the Fortress Company's stock equal to 25% of the outstanding Fortress Company note divided by the lowest price for which the Fortress Company sells its equity in its first third party financing. The warrants issued will have a term of 10 years and an exercise price equal to the par value of the Fortress Company's common stock. In accordance with ASC 815 - *Derivatives and Hedging*, Avenue classified the fair value of the Contingently Issuable Warrants that may have been granted in connection with the \$3.0 million of the NSC Note transferred from Fortress to Avenue on October 31, 2015 (issuance date) and June 30, 2016 as a derivative liability as there was a potential that Avenue would not have a sufficient number of authorized common shares available to settle these instruments.

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The fair value of Avenue's Contingently Issuable Warrants was determined by applying management's estimate of the probability of issuance of the Contingently Issuable Warrants together with an option pricing model, with the following key assumptions:

	<b>June 30, 2016</b>
Risk-free interest rate	1.78%
Expected dividend yield	-
Expected term in years	9.59
Expected volatility	83.00%
Probability of issuance of the warrant	45.00%

*Warrant liabilities*

The fair value of Helocyte's warrant liability was measured at fair value using a Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (level 3 inputs) used in measuring the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy for the three and six months ended June 30, 2016 is as follows:

	<b>June 30, 2016</b>
Risk-free interest rate	1.01%
Expected dividend yield	-
Expected term in years	5.00
Expected volatility	89.20%
Strike price	\$ 0.43

*Convertible Notes at Fair Value*

Helocyte's convertible debt is measured at fair value using the Monte Carlo simulation valuation methodology. At June 30, 2016, the fair value equaled the proceeds received. A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the convertible debt that is categorized within Level 3 of the fair value hierarchy for the three and six months ended June 30, 2016 is as follows:

	<b>June 30, 2016</b>
Risk-free interest rate	1.01%
Expected dividend yield	-
Expected term in years	1.50
Expected volatility	72.00%
Probability of conversion	31.88%

The following tables classify into the fair value hierarchy financial instruments measured at fair value on a recurring basis on the Condensed Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015:

<i>(\$ in thousands)</i>	<b>Fair Value Measurement as of June 30, 2016</b>			
	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Long-term investments, at fair value	\$ -	\$ -	\$ 766	\$ 766
<b>Liabilities</b>				
Contingently issuable warrants	\$ -	\$ -	\$ 203	\$ 203
Warrant liabilities			99	99
Helocyte convertible note, at fair value	-	-	1,000	1,000

<i>(\$ in thousands)</i>	<b>Fair Value Measurement as of December 31, 2015</b>			
	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Long-term investments, at fair value	\$ -	\$ -	\$ 2,485	\$ 2,485
<b>Liabilities</b>				
Derivative warrant liability	\$ -	\$ -	\$ 114	\$ 114

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The table below provides a rollforward of the changes in fair value of Level 3 financial instruments for the six months ended June 30, 2016 and 2015:

<i>(\$ in thousands)</i>	<b>Investment in Origo</b>	<b>Investment in laser device</b>	<b>Contingently Issuable Warrants</b>	<b>Helocyte Convertible Note, at fair value</b>	<b>Warrant liabilities</b>	<b>Total</b>
Balance at December 31, 2015	\$ 2,235	\$ 250	\$ 114	\$ -	\$ -	\$ 2,599
Additions during the period	-	-	-	1,000	99	1,099
Change in fair value of investments	(1,719)	-	-	-	-	(1,719)
Fair value adjustment of Contingently Issuable Warrants	-	-	89	-	-	89
Balance at June 30, 2016	<u>\$ 516</u>	<u>\$ 250</u>	<u>\$ 203</u>	<u>\$ 1,000</u>	<u>\$ 99</u>	<u>\$ 2,068</u>

<i>(\$ in thousands)</i>	<b>Investment in Origo</b>	<b>Investment in laser device</b>	<b>Contingently Issuable Warrants</b>	<b>Helocyte Convertible Note, at fair value</b>	<b>Total</b>
Balance at December 31, 2014	\$ 3,910	\$ 250	\$ -	\$ -	\$ 4,160
Change in fair value of investments	1,407	-	-	-	1,407
Fair value adjustment of Contingently Issuable Warrants	-	-	-	-	-
Balance at June 30, 2015	<u>\$ 5,317</u>	<u>\$ 250</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 5,567</u>

For the six months ended June 30, 2016 and 2015, no transfers occurred between Level 1, Level 2 and Level 3 instruments.

#### 5. Licenses Acquired

In accordance with ASC No. 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 Avenue, Mustang, Checkpoint, Coronado SO, Helocyte and Escala require substantial completion of research and development, as well as regulatory and marketing approval efforts in order to reach technological feasibility. As such, the purchase prices of those licenses were classified as research and development-licenses acquired in the Condensed Consolidated Statements of Operations. For the three and six months ended June 30, 2016 and 2015, the Company's research and development-licenses acquired comprise of the following:

<i>(\$ in thousands)</i>	<b>For the Three Months Ended June 30,</b>		<b>For the Six Months Ended June 30,</b>	
	2016	2015	2016	2015
Fortress Companies:				
Avenue	\$ -	\$ 1,000	\$ -	\$ 3,000
Checkpoint	2,060	33	2,060	2,033
Coronado SO	-	428	-	1,607
Helocyte	-	200	83	200
Mustang	-	(113)	-	2,147
Total	<u>\$ 2,060</u>	<u>\$ 1,548</u>	<u>\$ 2,143</u>	<u>\$ 8,987</u>

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*Avenue Therapeutics, Inc.*

License Agreement with Revogenex Ireland Ltd

In February 2015, the Company purchased an exclusive license to IV Tramadol for the U.S. market from Revogenex, a privately held company in Dublin, Ireland. Fortress made an upfront payment of \$2.0 million to Revogenex upon execution of the exclusive license, which has been included in *research and development-licenses acquired* on the Condensed Consolidated Statements of Operations. In addition, on June 17, 2015, the Company paid an additional \$1.0 million to Revogenex after receiving all the assets specified in the agreement. Under the terms of the agreement, Revogenex is eligible to receive additional milestone payments upon the achievement of certain development milestones, in addition to royalty payments for sales of the product. Tramadol is a centrally acting synthetic opioid analgesic for moderate to moderately severe pain and is available as immediate release or extended-release tablets in the United States.

The Company transferred the Revogenex license and all other rights and obligations of Fortress under the License Agreement to Avenue pursuant to the Founders Agreement effective as of February 17, 2015. Per the terms of the agreement, Avenue assumed \$3.0 million in debt (see Note 8).

During the six months ended June 30, 2016, Avenue completed a pharmacokinetics or PK study for IV Tramadol in healthy volunteers and completed an End-of-Phase 2 (EOP) meeting with the U.S. Food and Drug Administration (the "FDA").

*Checkpoint Therapeutics, Inc.*

License Agreement with Dana-Farber Cancer Institute

In March 2015, Checkpoint entered into an exclusive license agreement with Dana-Farber Cancer Institute ("Dana-Farber") to develop a portfolio of fully human immuno-oncology targeted antibodies. The portfolio of antibodies licensed from Dana-Farber include antibodies targeting PD-L1, GITR and CAIX. Under the terms of the agreement, Checkpoint paid Dana-Farber an up-front licensing fee of \$1.0 million in 2015 and, on May 11, 2015, granted Dana-Farber 500,000 shares of Checkpoint common stock, valued at \$32,500 or \$0.065 per share. Dana-Farber is eligible to receive payments of up to an aggregate of approximately \$21.5 million for each licensed product upon the Company's successful achievement of certain clinical development, regulatory and first commercial sale milestones. In addition, Dana-Farber is eligible to receive up to an aggregate of \$60.0 million upon Checkpoint's successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Following the second anniversary of the effective date of the Dana-Farber license agreement, Dana-Farber will receive an annual license maintenance fee, which is creditable against milestone payments or royalties due to Dana-Farber. Checkpoint expects clinical trials related to the Dana-Farber licensed antibodies to start in 2017.

In connection with the 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, Executive Chairman of the Board of Directors of Checkpoint and the Company's Executive Vice Chairman, Strategic Development, is also the Executive Chairman, Interim President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the agreement, TGTX paid Checkpoint \$0.5 million, representing a reimbursement for their share of the licensing fee, and 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. Checkpoint's potential milestone payments are 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 will receive an annual license maintenance fee, which is creditable against milestone payments or royalties due to Checkpoint. The Company recognized \$3,000 and \$0, respectively, for the three months ended June 30, 2016 and 2015, and \$20,000 and \$500,000, respectively, for the six months ended June 30, 2016 and 2015, in revenue from its collaboration agreement with TGTX on the Condensed Consolidated Statements of Operations.

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NeuPharma, Inc.

In March, 2015, Checkpoint entered into an exclusive license agreement with NeuPharma, Inc. (“NeuPharma”) to develop and commercialize novel irreversible, 3rd generation epidermal growth factor receptor (“EGFR”) inhibitors including CK-101, on a worldwide basis (other than certain Asian countries). On the same date, the Company and Checkpoint entered into a Founders Agreement pursuant to which the Company assigned all of its right and interest in the EGFR inhibitors to Checkpoint in exchange for certain consideration (see Note 13). Under the terms of the agreement, Checkpoint paid NeuPharma an up-front licensing fee of \$1.0 million in 2015, and NeuPharma is eligible to receive payments of up to an aggregate of approximately \$40.0 million per licensed product upon Checkpoint’s successful achievement of certain clinical development and regulatory milestones in up to three indications, of which \$22.5 million are due upon various regulatory approvals to commercialize the products. In addition, NeuPharma is eligible to receive payments of up to an aggregate of \$40.0 million upon Checkpoint’s successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered mid to high-single digit percentage of net sales. In July 2016, Checkpoint submitted an IND application to the FDA for its EGFR inhibitor, and the application is currently under review.

In connection with the license agreement with NeuPharma, in March 2015 Checkpoint entered into an option agreement with TGTX, a related party, for a global collaboration for the future development of certain licensed compounds. The option was extended on July 8, 2016 for an additional 176 days, to December 31, 2016.

Also in connection with the license agreement with NeuPharma, Checkpoint entered into a Sponsored Research Agreement with NeuPharma for certain research and development activities. Effective January 11, 2016, TGTX, a related party, agreed to assume all costs associated with this agreement and reimbursed Checkpoint for costs previously paid by Checkpoint and Checkpoint recognized \$221,000 and \$481,000 in revenue related to this agreement for the three and six months ended June 30, 2016, respectively.

Teva Pharmaceutical Industries Ltd. (through its subsidiary, Cephalon, Inc.)

In December 2015, the Company entered into a license agreement with Teva Pharmaceutical Industries Ltd. through its subsidiary, Cephalon, Inc. (“Cephalon”), which agreement was assigned to Checkpoint by the Company on the same date pursuant to the Founders Agreement (see Note 13). Under the terms of the license agreement, Checkpoint obtained an exclusive, worldwide license to Cephalon’s patents relating to CEP-8983 and its small molecule prodrug, CEP-9722, a PARP inhibitor, which Checkpoint now refers to as CK-102. Checkpoint paid Cephalon an up-front licensing fee of \$0.5 million in 2015. Cephalon is eligible to receive milestone payments of up to an aggregate of approximately \$220.0 million upon Checkpoint’s successful achievement of certain clinical development, regulatory approval and product sales milestones, of which approximately \$206.5 million are due on or following regulatory approvals to commercialize the product. In addition, Cephalon is eligible to receive royalty payments based on a tiered low double digit percentage of net sales. Checkpoint is currently developing a clinical program for its PARP inhibitor, which it expects to commence in the next six to twelve months.

Jubilant Biosys Limited

In May 2016, Checkpoint entered into a License Agreement with Jubilant Biosys Limited (“Jubilant”), whereby Checkpoint obtained an exclusive, worldwide license (the “Jubilant License”) to Jubilant’s family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment, which Checkpoint refers to as CK-103. Under the terms of the Jubilant License, Checkpoint paid Jubilant an up-front licensing fee of \$2.0 million, and Jubilant is eligible to receive payments up to an aggregate of approximately \$89.0 million upon the Company’s successful achievement of certain preclinical, clinical development, and regulatory milestones, of which \$59.5 million are due upon various regulatory approvals to commercialize the products. In addition, Jubilant is eligible to receive payments up to an aggregate of \$89.0 million upon Checkpoint’s successful achievement of certain sales milestones based on aggregate net sales, in addition to royalty payments based on a tiered low to mid-single digit percentage of net sales. Checkpoint plans to submit an IND application for its BET inhibitor in 2017. The purchase price of \$2.0 million for the license was classified as *research and development-licenses acquired* in the Condensed Consolidated Statements of Operations during the three and six months ended June 30, 2016.

In connection with the Jubilant License, Checkpoint entered into a sublicense agreement with TGTX (the “Sublicense Agreement”), a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, with Checkpoint retaining the right to develop and commercialize these compounds in the field of solid tumors. Michael Weiss, Executive Chairman of the Board of Directors of Checkpoint and the Company’s Executive Vice Chairman, Strategic Development, is also the Executive Chairman, Interim President and Chief Executive Officer and a stockholder of TGTX. Under the terms of the Sublicense Agreement, TGTX reimbursed Checkpoint \$1.0 million, representing a reimbursement for their share of the licensing fee, and Checkpoint is eligible to receive substantive potential milestone payments up to an aggregate of approximately \$87.5 million upon TGTX’s successful achievement of preclinical, clinical development, and regulatory milestones. Such potential milestone payments comprise up to of approximately \$0.3 million upon TGTX’s successful achievement of one preclinical milestone, 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 three 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. Checkpoint recognized \$1.0 million in revenue related to this arrangement during the three and six months ended June 30, 2016.



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*Coronado SO Company*

License Agreement

In February 2015, Coronado SO entered into an exclusive license agreement with a third party for a topical product used in the treatment of hand-foot syndrome, a common painful side effect of chemotherapeutics. Coronado SO paid \$0.9 million upfront, included in research and development-licenses acquired on the Condensed Consolidated Statements of Operations and issued a stock grant of 150,000 shares of Coronado SO common stock to such third party. In October 2015, Coronado SO paid an additional \$0.5 million, which is included in research and development-licenses acquired on the Condensed Consolidated Statements of Operations. Four milestones totaling \$10.7 million are due upon the achievement of certain development goals, three milestones totaling \$26.2 million are due upon certain net sales milestones and a single digit royalty on net sales is due for the term of the contract.

The Company valued the stock grant to the third party utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8% and a weighted average cost of capital of 30%, and net of debt utilized, resulting in a value of \$1.19 per share.

*Helocyte, Inc.*

License Agreement with the City of Hope

In March 2016, Helocyte entered into amended and restated license agreements for each of its PepVax and Triplex immunotherapies programs with its licensor City of Hope National Medical Center ("COH"). The amended and restated licenses expand the intellectual property and other rights granted to Helocyte by COH in the original license agreement. The financial terms of the original license have not been modified, and if Helocyte successfully develops and commercializes PepVax and Triplex, COH will receive milestones, royalties and other payments.

Helocyte entered into the original license agreement with COH on March 31, 2015, to secure: (i) an exclusive worldwide license for two immunotherapies for CMV control in the post-transplant setting (known as Triplex and PepVax); and (ii) an option for an exclusive worldwide license to an immunotherapy for the prevention of congenital CMV (known as Pentamer). In consideration for the license and option, Helocyte made an upfront payment of \$155,000. On April 28, 2015, Helocyte exercised the option and secured exclusive worldwide rights to Pentamer from COH for an upfront payment of \$50,000. If Helocyte successfully develops PepVax, COH could receive, up to \$1.5 million for the achievement of three developmental milestones, \$13.0 million for three sales milestones, single digit royalties based on net sales reduced by certain factors and a minimum annual royalty of \$0.2 million per year related to marketing approval. If Helocyte successfully develops and commercializes Triplex, COH could receive up to \$9.0 million for the achievement of three developmental milestones, \$26.0 million for four sales milestones, single digit royalties based on net sales reduced by certain factors and a minimum annual royalty of \$0.75 million per year following a first marketing approval. If Helocyte successfully develops and commercializes Pentamer, COH could receive up to \$5.5 million for the achievement of four development milestones, \$26.0 million for three sales milestones, single digit royalties based on net sales reduced by certain factors and a minimum annual royalty of \$0.75 million per year following a first marketing approval. In 2015, Triplex and PepVax both entered Phase 2 clinical studies. The programs are supported by grants awarded to COH by the National Cancer Institute.

As further consideration for the licenses, in March and May 2016, Helocyte granted COH 500,000 shares and 8,333 shares of Helocyte Class A common stock, respectively. The Company valued the stock grants to the COH utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.5% and a weighted average cost of capital of 30%, net of debt utilized resulting in a value of \$0.097 per share or \$48,500.

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License Option

In February 2016, Helocyte entered into an option agreement for \$35,000 with a third party, to acquire the exclusive rights to license certain intellectual property and clinical data for certain cell therapies. The option expires on October 1, 2016. The Company recorded a charge of \$35,000 to research and development-licenses acquired for the six months ended June 30, 2016. No fee was recorded for the three months ended June 30, 2016.

*Escala Therapeutics, Inc.*

On July 16, 2015, Escala acquired from New Zealand Pharmaceuticals Limited (“NZP”) a license from the National Institute of Health (“NIH”) and cooperative research and development agreements for the development of oral ManNAc, a key compound in the sialic biosynthetic pathway, for the treatment of hyposialylation disorders, including GNE myopathy and various forms of nephropathy. As part of this agreement, Escala provided NZP and NIH an upfront payment of approximately \$1.3 million comprised of an upfront milestone payment of \$0.7 million to NZP and reimbursement of \$0.6 million of development costs for Phase II Myopathy and Phase I Nephropathy Clinical Trial being conducted at the NIH. Additional development and sales-based milestone payments are payable upon achievement.

Seven milestones totaling approximately \$22.6 million are due upon the achievement of certain development goals, two milestones totaling \$7.0 million are due upon certain net sales milestones and a single digit royalty on net sales is due for a certain period. In addition a one-time payment is due upon the termination of the license.

*Mustang Bio, Inc.*

License Agreement with the City of Hope

In March 2015, Mustang entered into an exclusive license agreement with COH to acquire intellectual property rights pertaining to CAR-T. Pursuant to the agreement, Mustang paid COH an upfront fee of \$2.0 million in April 2015 (included in *research and development-licenses acquired expenses* on the Condensed Consolidated Statement of Operations), and granted 1.0 million shares of Mustang’s Class A Common Stock, representing 10% ownership of Mustang. Additional payments totaling \$2.0 million are due upon the completion of two financial milestones, and payments totaling \$14.5 million are due upon the completion of six development goals. Future mid-single digit royalty payments are due on net sales of licensed products, with a minimum annual royalty of \$1.0 million.

The Company valued the stock grant to COH utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8%, weighted average cost of capital of 30%, and net of debt utilized, resulting in a value of \$0.147 per share or \$0.1 million on March 31, 2015.

**6. Milestones and Sponsored Research Agreements**

*Helocyte*

In March 2016, Helocyte entered into an Investigator-Initiated Clinical Research Support Agreement with the COH, to support a Phase 2 clinical study of its PepVax immunotherapy for CMV control in allogeneic stem cell transplant recipients. The Phase 2 study is additionally supported by grants from the National Cancer Institute. Under the terms of the agreement, Helocyte made an upfront payment to COH of \$1.0 million and will pay COH up to an additional \$2.0 million upon the achievement of certain clinical milestones. Unless earlier terminated, the agreement expires upon the delivery of a final study report or December 31, 2018.

In February 2016, Helocyte entered into an Investigator-Initiated Clinical Research Support Agreement with the COH, to support a Phase 2 clinical study of its Triplex immunotherapy for CMV control in allogeneic stem cell transplant recipients. The Phase 2 study is additionally supported by grants from the National Cancer Institute. Under the terms of the agreement, Helocyte made an upfront payment to COH of \$1.0 million, and will pay COH up to an additional \$3.4 million upon the achievement of certain clinical milestones. Unless earlier terminated, the agreement expires upon the delivery of a final study report or May 31, 2018.

For the three and six months ended June 30, 2016, Helocyte incurred expense of \$0 and \$2.0 million, respectively, related to the sponsored research agreements, recorded as research and development expense in the Company’s condensed Consolidated Statement of Operations. No expenses were recorded for the three and six months ended June 30, 2015.

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*Mustang*

In March 2015, in connection with Mustang's license with COH for the development of CAR-T, Mustang entered into a Sponsored Research Agreement in which Mustang will fund continued research in the amount of \$2.0 million per year, payable in four equal annual installments, over the next five years. For the three and six months ended June 30, 2016, Mustang incurred expense of \$0.5 million and \$1.0 million, respectively, and recorded as research and development expense in the Company's Condensed Consolidated Statement of Operations. No expenses were recorded for the three and six months ended June 30, 2015.

*CNDO-109*

The Company has a license agreement with the University College London Business PLC ("UCLB") under which the Company received an exclusive, worldwide license to develop and commercialize CNDO-109 to activate NK cells for the treatment of cancer-related and other conditions. In consideration for the license, the Company made upfront payments totaling \$0.1 million and may be required to make future milestone payments totaling up to approximately \$22 million upon the achievement of various milestones related to regulatory or commercial events. In March 2016, the Company paid UCLB \$0.4 million due upon completion of the Phase 1 study for Acute Myeloid Leukemia. In the event that CNDO-109 is commercialized, the Company is obligated to pay to UCLB annual royalties ranging from 3% to 5% based upon various levels of net sales of the product. Under the terms of the license agreement, the Company is allowed to grant sublicenses to third parties without the prior approval of UCLB. In the event that the Company sublicenses CNDO-109 to a third party, the Company is obligated to pay to UCLB all or a portion of the royalties the Company receives from the sub-licensee. Through June 30, 2016, the Company has not sub-licensed CNDO-109 to a third party.

**7. Intangible Asset Licenses**

*Journey Medical Corporation*

In January 2016, JMC entered into a licensing agreement with a third party to distribute its prescription wound cream Luxamend<sup>TM</sup> and paid an upfront fee of \$50,000. Additionally, in January 2016, JMC entered into a licensing agreement with a third party to distribute its emollient Ceracade<sup>TM</sup> for the treatment of various types of dermatitis and paid an upfront fee of \$0.3 million. JMC commenced the sale of both of these products during the three months ended June 30, 2016 and accordingly commenced the amortization of these costs over their respective three year estimated useful life. For the three and six months ended June 30, 2016, JMC recognized expense of approximately \$21,000, which was recorded in costs of goods sold on the Condensed Consolidated Statement of Operations (see Note 14).

In March 2015, JMC entered into a license and supply agreement to acquire the rights to distribute a dermatological product for the treatment of acne. JMC made an upfront payment of \$1.3 million. Further payments will be made based on a revenue sharing arrangement. JMC received FDA approval for the manufacturing of this product in July 2016 and expects to commence sales of this product in the second half of 2016.

**8. Debt and Interest**

**Debt**

Long-term debt to IDB, NSC and Helocyte consists of the following as of June 30, 2016 and December 31, 2015:

<i>(\$ in thousands)</i>	<b>June 30, 2016</b>	<b>December 31, 2015</b>	<b>Interest rate</b>	<b>Maturity</b>
IDB Note	\$ 14,009	\$ 14,009	2.25%	Feb - 2017
NSC Note	7,208	10,000	8.00%	Mar - 2018
Helocyte Convertible Note, at fair value	1,000	-	5.00% -8.00%	Dec - 2017
Total notes payable, long-term	<u>22,217</u>	<u>24,009</u>		
Less: Discount on notes payable	412	835		
Total notes payable, long-term, net	<u>\$ 21,805</u>	<u>\$ 23,174</u>		

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**  
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*IDB Note*

On February 13, 2014, the Company executed a promissory note in favor of IDB in the amount of \$15.0 million (the "IDB Note"). The Company borrowed \$14 million against this note and used it to repay its prior loan from Hercules Technology Growth Capital, Inc. The Company may request revolving advances under the IDB Note in a minimum amount of \$100,000 (or the remaining amount of the undrawn balance under the IDB Note if such amount is less than \$100,000). All amounts advanced under the IDB Note are due in full at the earlier of: (i) February 27, 2017, as extended or (ii) on the IDB's election following the occurrence and continuation of an event of default. The unpaid principal amount of each advance shall bear interest at a rate per annum equal to the rate payable on the Company's money market account plus a margin of 150 basis points. The interest rate at June 30, 2016 was 2.25%. The IDB Note contains various representations and warranties customary for financings of this type.

The obligations of the Company under the IDB Note are collateralized by a security interest in, a general lien upon, and a right of set-off against the Company's money market account of \$15.0 million pursuant to the Assignment and Pledge of Money Market Account, dated as of February 13, 2014 (the "Pledge Agreement"). Pursuant to the Pledge Agreement, IDB may, after the occurrence and continuation of an event of default under the IDB Note, recover from the money market account all amounts outstanding under the IDB Note. The Pledge Agreement contains various representations, warranties, and covenants customary for pledge agreements of this type.

The Company will default on the IDB Note if, among other things, it fails to pay outstanding principal or interest when due. Following the occurrence of an event of default under the IDB Note, IDB may: (i) declare the entire outstanding principal balance of the IDB Note, together with all accrued interest and other sums due under the IDB Note, to be immediately due and payable; (ii) exercise its right of setoff against any money, funds, credits or other property of any nature in possession of, under control or custody of, or on deposit with IDB; (iii) terminate the commitments of IDB; and (iv) liquidate the money market account to reduce the Company's obligations to IDB.

Effective March 31, 2015, the Company extended the maturity date of the IDB Note to February 27, 2017. At June 30, 2016, the Company had approximately \$14.0 million outstanding under its promissory note with IDB. The Company only pays interest on the IDB Note through maturity.

*NSC Note*

In March 2015, the Company closed a private placement of a promissory note for \$10 million in favor of National Securities Corporation ("NSC") The Company used the proceeds from the NSC Note to acquire medical technologies and products. The NSC Note matures in 36 months, provided that during the first 24 months the Company can extend the maturity date by six months. No principal amount is due for the first 24 months (or the first 30 months if the maturity date is extended). Thereafter, the NSC 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, a wholly owned subsidiary of National Holdings, Inc., acted as the sole placement agent for the NSC Note. The Company paid NSC a fee of \$0.9 million during the year ended December 31, 2015 in connection with the NSC Note. The Company recorded the fee as a discount to *notes payable, long-term* on the Condensed Consolidated Balance Sheets and amortized it over the life of the NSC Note. The effective interest rate on the NSC Note was approximately 12.4%.

The NSC Note was amended and restated on July 29, 2015 to provide that any time a Fortress subsidiary receives from the Company any proceeds from the NSC Note, the Company may, in its sole discretion, cause the Fortress Company to issue to NSC Biotech Venture Fund I LLC a new promissory note (the "Amended NSC Note") on identical terms as the NSC Note, giving effect to the passage of time with respect to maturity. The Amended NSC Note will equal the dollar amount of the Fortress Company's share of the NSC Note and reduce the Company's obligations under the NSC Note by such amount. The Company will guarantee the Amended NSC Note until the Fortress Company either completes an initial public offering of its securities or raises sufficient equity capital so that it has cash equal to five times the Amended NSC Note. As of June 30, 2016, the Company transferred \$2.8 million and \$3.0 million, including debt discount, of the NSC Note to Checkpoint and Avenue, respectively, representing Checkpoint's and Avenue's pro rata share of the NSC Note. The Company applied the 10% cash flow test pursuant to ASC 470 to calculate the difference between the present value of the amended NSC's Note's cash flows and the present value of the original remaining cash flow and concluded that, because the results did not exceed the 10% factor, the debt modification is not considered substantially different. The Company did not, therefore, apply extinguishment accounting, rather accounting for the modification on a prospective basis pursuant to ASC 470.

In connection with the transfer of NSC Note proceeds to a Fortress Company, NSC will receive a warrant to purchase the Fortress Company's stock equal to 25% of the NSC Note proceeds transferred to that Fortress Company divided by the lowest price at which the Fortress Company sells its equity in its first third party financing. The warrants issued will have a term of 10 years and an exercise price equal to the par value of the Fortress Company's common stock.

As of June 30, 2016, Avenue recorded approximately \$237,000 of debt discount of which \$113,500 relates to the Contingently Issuable Warrants issued in connection with the NSC Note, based on its initial fair value (see Note 4). The entire debt discount will be amortized over the life of the note.

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In February 2016, Checkpoint repaid its NSC Debt of \$2.8 million. Approximately \$324,000, of which \$174,000 was related to the fair value of the NSC contingently issuable warrant, of unamortized debt discount was accelerated into interest expenses upon payment.

The Company's Chairman, President and Chief Executive Officer and the Company's Executive Vice President, Strategic Development, are Co-Portfolio Managers and Partners of Opus Point Partners Management, LLC ("OPPM"), which owns approximately 4.2% of National Holding's Corporation, Inc. the parent of National Securities Inc. The ownership includes shares owned by OPPM, its Co-Portfolio Managers and their affiliates.

*Helocyte Convertible Note*

On June 30, 2016, Helocyte held the first closing of the sale of convertible promissory notes. Helocyte sold eleven convertible promissory notes to investors for an aggregate of \$1.0 million. The notes have an initial term of 18 months, which can be extended at the option of the holder, on one or more occasions, for up to 180 days and accrue simple interest at the rate of 5% per annum for the first 12 months and 8% per annum simple interest thereafter. The notes are guaranteed by Fortress. The outstanding principal and interest of the notes automatically converts into the type of equity securities sold by Helocyte in the next sale of equity securities in which Helocyte realizes aggregate gross cash proceeds of at least \$10.0 million (before commissions or other expenses and excluding conversion of the notes) at a conversion price equal to the lesser of (a) the lowest price per share at which equity securities of Helocyte are sold in such sale less a 33% discount and (b) a per share price based on a pre-offering valuation of \$50.0 million divided by the number of common shares outstanding on a fully-diluted basis. The outstanding principal and interest of the notes may be converted at the option of the holder in any sale of equity securities that does not meet the \$10.0 million threshold for automatic conversion using the same methodology. The notes also automatically convert upon a "Sale" of Helocyte, defined as (a) a transaction or series of related transactions where one or more non-affiliates acquires (i) capital stock of Helocyte or any surviving successor entity possessing the voting power to elect a majority of the board of directors or (ii) a majority of the outstanding capital stock of Helocyte or the surviving successor entity (b) the sale, lease or other disposition of all or substantially all of Helocyte's assets or any other transaction resulting in substantially all of Helocyte's assets being converted into securities of another entity or cash. Upon a Sale of Helocyte, the outstanding principal and interest of the notes automatically converts into common shares at a price equal to the lesser of (a) a discount to the price per share being paid in the Sale of Helocyte equal to 33% or (b) a conversion price per share based on a pre-sale valuation of \$50.0 million divided by the fully-diluted common stock of Helocyte immediately prior to the Sale of Helocyte (excluding the notes).

In the first closing, Helocyte realized net proceeds of \$875,000 after paying Aegis Capital Corp., the exclusive placement agent, placement agent fees of \$100,000 and Aegis's legal fees of \$25,000. Additionally, Aegis received a warrant ("Helocyte Warrant") to purchase the number of shares of Helocyte's common stock equal to \$100,000 divided by the price per share at which any note sold to investors first converts into Helocyte's common stock. The Helocyte Warrant has a five-year term and has a per share exercise price equal to 110% of the price per share at which any note sold to investors first converts into Helocyte's common stock. The offering remains open and Helocyte may sell up to an aggregate of \$5.0 million in convertible notes.

Due to the complexity and number of embedded features within each convertible note and as permitted under accounting guidance, the Company elected to account for the convertible notes and all the embedded features (collectively, the "hybrid instrument") under the fair value option (see Note 4).

*IDB Letters of Credit*

The Company has several letters of credit ("LOC") with IDB securing rent deposits for lease facilities totaling approximately \$1.7 million. Interest paid on the letters of credit is 2%.

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 associated with loan transaction costs, amortized over the life of the loan:

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<i>(\$ in thousands)</i>	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	2015	2016	2015
<b>IDB Note</b>				
Interest	\$ 79	\$ 82	\$ 159	\$ 153
Amortization of fees	-	1	1	2
Total IDB Note	79	83	160	155
<b>NSC Debt</b>				
Interest	144	208	311	279
Amortization of fees	54	61	422	82
Total NSC Debt	198	269	733	361
<b>Ovamed</b>				
Interest	-	-	-	167
Total Ovamed	-	-	-	167
<b>LOC Fees</b>				
Interest	3	-	7	-
Total LOC	3	-	7	-
<b>Helocyte Convertible Note</b>				
Financing fees	249	-	249	-
Total LOC	249	-	249	-
<b>Total Interest Expense</b>	<b>\$ 529</b>	<b>\$ 352</b>	<b>\$ 1,149</b>	<b>\$ 683</b>

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

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

<i>(\$ in thousands)</i>	June 30, 2016	December 31, 2015
<b>Accrued expenses:</b>		
Professional fees	\$ 650	\$ 382
Salaries, bonuses and related benefits	1,566	2,492
Ovamed manufacturing rights - short term component	1,987	1,500
Research and development	1,018	810
Dr. Falk Pharma milestone	2,776	2,717
Accrued royalty and coupons	309	-
Lease impairment	146	146
Other	431	523
Total accrued expenses	\$ 8,883	\$ 8,570
<b>Other long-term liabilities:</b>		
Deferred rent and long-term lease abandonment charge	3,706	584
Total other long-term liabilities	\$ 3,706	\$ 584

**10. Non-Controlling Interests**

Non-controlling interests in consolidated entities are as follows:

<i>(\$ in thousands)</i>	As of June 30, 2016						
	Avenue	Coronado SO	Mustang	Checkpoint	JMC	Helocyte	Total
NCI equity share	\$ (559)	\$ (217)	\$ (350)	\$ 33,139	\$ (288)	\$ (499)	\$ 31,226
Net loss attributed to non-controlling interests	(184)	(10)	(159)	(7,513)	(229)	(254)	(8,349)
Non-controlling interests in consolidated entities	<b>\$ (743)</b>	<b>\$ (227)</b>	<b>\$ (509)</b>	<b>\$ 25,626</b>	<b>\$ (517)</b>	<b>\$ (753)</b>	<b>\$ 22,877</b>

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**As of December 31, 2015**

<i>(\$ in thousands)</i>	<u>Avenue</u>	<u>Coronado SO</u>	<u>Mustang</u>	<u>Checkpoint</u>	<u>JMC</u>	<u>Total</u>
NCI equity share	\$ 6	\$ 23	\$ 14	\$ 32,760	\$ 79	\$ 32,882
Net loss attributed to non-controlling interests	(567)	(240)	(373)	(3,855)	(420)	(5,455)
Non-controlling interests in consolidated entities	<u>\$ (561)</u>	<u>\$ (217)</u>	<u>\$ (359)</u>	<u>\$ 28,905</u>	<u>\$ (341)</u>	<u>\$ 27,427</u>

The components of non-controlling interests in loss of consolidated entities are as follows:

**For the three months ended June 30, 2016**

<i>(\$ in thousands)</i>	<u>Avenue</u>	<u>Coronado SO</u>	<u>Mustang</u>	<u>Checkpoint</u>	<u>JMC</u>	<u>Helocyte</u>	<u>Total</u>
Non-controlling interests in loss of consolidated entities	\$ (76)	\$ (5)	\$ (89)	\$ (3,476)	\$ (108)	\$ (157)	\$ (3,911)
Non-controlling ownership	11.5%	13.0%	10.0%	64.3%	8.1%	20.4%	

**For the three months ended June 30, 2015**

<i>(\$ in thousands)</i>	<u>Avenue</u>	<u>Coronado SO</u>	<u>Mustang</u>	<u>Checkpoint</u>	<u>Total</u>
Non-controlling interests in loss of consolidated entities	\$ (34)	\$ (70)	\$ (41)	\$ (98)	\$ (243)
Non-controlling ownership	11.5%	13%	10%	20.0%	

**For the six months ended June 30, 2016**

<i>(\$ in thousands)</i>	<u>Avenue</u>	<u>Coronado SO</u>	<u>Mustang</u>	<u>Checkpoint</u>	<u>JMC</u>	<u>Helocyte</u>	<u>Total</u>
Non-controlling interests in loss of consolidated entities	\$ (184)	\$ (10)	\$ (159)	\$ (7,513)	\$ (229)	\$ (254)	\$ (8,349)
Non-controlling ownership	11.5%	13.0%	10.0%	64.3%(1)	8.1%	20.4%	

(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.

**For the six months ended June 30, 2015**

<i>(\$ in thousands)</i>	<u>Avenue</u>	<u>Coronado SO</u>	<u>Mustang</u>	<u>Checkpoint</u>	<u>Total</u>
Non-controlling interests in loss of consolidated entities	\$ (34)	\$ (230)	\$ (267)	\$ (191)	\$ (722)
Non-controlling ownership	11.5%	13%	10%	20.0%	

## 11. Net Loss per Common Share

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

Included in common stock issued and outstanding as of June 30, 2016 are 8,705,137 shares of unvested restricted stock, which are excluded from the weighted average common stock outstanding since its effect would be anti-dilutive.

The Company's common stock equivalents, including unvested restricted stock, options, and warrants that 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.

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 six months ended June 30, 2016 and 2015:

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	<b>For the Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
Warrants to purchase Common Stock	515,068	685,061
Options to purchase Common Stock	1,754,365	2,064,365
Unvested Restricted Stock	8,705,137	7,704,269
Unvested Restricted Stock Units	1,374,083	36,000
<b>Total</b>	<b>12,348,653</b>	<b>10,489,695</b>

**12. Stockholders' Equity**

**Stock-based Compensation**

As of June 30, 2016, the Company had four equity compensation plans: the Fortress Biotech, Inc. 2007 Stock Incentive Plan, the Fortress Biotech, Inc. 2013 Stock Incentive Plan, the Fortress Biotech, Inc. 2012 Employee Stock Purchase Plan and the Fortress Biotech, Inc. Long Term Incentive Plan ("LTIP").

The following table summarizes the stock-based compensation expense from stock option awards, restricted common stock awards, employee stock purchase programs and warrants granted by Fortress for the three and six months ended June 30, 2016 and 2015:

<i>(\$ in thousands)</i>	<b>For the Three Months Ended June 30,</b>		<b>For the Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Employee awards	\$ 1,969	\$ 1,525	\$ 3,553	\$ 2,988
Non-employee awards	3	7	6	14
Fortress Companies (1)	1,051	393	2,330	393
<b>Total stock-based compensation expense</b>	<b>\$ 3,023</b>	<b>\$ 1,925</b>	<b>\$ 5,889</b>	<b>\$ 3,395</b>

(1) Consists of approximately \$9,000 of Avenue's compensation expenses, approximately \$0.8 million of Checkpoint's compensation expense, approximately \$147,000 of JMC's compensation expenses and approximately \$93,000 of Helocyte's compensation expenses on stock grants for the three months ended June 30, 2016, and approximately \$18,000 of Avenue's compensation expenses, approximately \$1.9 million of Checkpoint's compensation expense, approximately \$328,000 of JMC's compensation expenses and approximately \$93,000 of Helocyte's compensation expenses on stock grants for the six months ended June 30, 2016. For the three and six months ended June 30, 2015, expense consists of \$22,900 for Avenue, \$0.1 million for Mustang, \$0.2 million for Coronado SO and \$44,700 for Checkpoint.

In February 2016, the Company modified the vesting schedule on the 1.9 million share grant made to its Chief Executive Officer and Executive Chair, Strategic Development in December 2013, and the 3.9 million share inducement grant made to its Executive Chair, Strategic Development in February 2014. The modification extended the vesting on the first tranche of all the grants by twelve months. The impact of the modification was \$0.4 million, which will be amortized over the remaining life of the award.

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

	Number of shares	Weighted average exercise price	Total weighted average intrinsic value	Weighted average remaining contractual life (years)
Options vested and expected to vest at December 31, 2015	1,779,365	\$ 4.37	\$ 666,396	6.32
Granted	-	-	-	-
Forfeited	(25,000)	2.10	-	-
Options vested and expected to vest at June 30, 2016	1,754,365	\$ 4.41	\$ 597,262	5.80
Options vested and exercisable	1,065,501	\$ 3.77	\$ 573,662	5.34

As of June 30, 2016, the Company had unrecognized stock-based compensation expense related to unvested option of \$33,000 with a weighted average vesting period of 0.03 years.

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The following table summarizes Fortress' restricted stock and restricted stock unit award activity, excluding activity related to Fortress Companies (which is discussed below):

	Number of shares	Weighted average grant price
Unvested balance at December 31, 2015	8,757,935	\$ 2.47
Restricted stock granted	1,240,868	2.77
Restricted stock cancelled	(33,333)	2.69
Restricted stock vested	(173,333)	2.73
Restricted stock units granted	405,000	2.90
Restricted stock units cancelled	(101,000)	3.64
Restricted stock units vested	(16,917)	3.55
Unvested balance at June 30, 2016	<u>10,079,220</u>	\$ 2.50

As of June 30, 2016, the Company had unrecognized stock-based compensation expense related to restricted stock and restricted stock unit awards of approximately \$6.4 million and \$1.5 million, respectively, which is expected to be recognized over the remaining weighted-average vesting period of 2.4 years and 1.4 years, respectively.

**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 June 30, 2016, 125,150 shares have been purchased and 74,850 shares are available for future sale under the Company's ESPP. The Company recognized share-based compensation expense of approximately \$30,000 and \$8,000 for the three months ended June 30, 2016 and 2015, respectively, and \$56,000 and \$16,000 for the six months ended June 30, 2016 and 2015, respectively. The Company issued 33,958 shares under the ESPP for \$81,000 during the six months ended June 30, 2016.

**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, 2015	569,835	\$ 6.31	\$ 120,700	1.84
Granted	100,000	3.00	-	4.92
Expired	(129,767)	5.59	-	
Exercised (*)	(25,000)	1.37	33,000	
Outstanding as of June 30, 2016	<u>515,068</u>	<u>\$ 6.09</u>	<u>\$ 79,200</u>	<u>2.48</u>
Exercisable as of June 30, 2016	<u>415,068</u>	<u>\$ 6.83</u>	<u>\$ 79,200</u>	<u>1.89</u>

(\*) - cashless

All stock-based expense in connection with these warrants has been recognized prior to January 1, 2016.

**Long-Term Incentive Program ("LTIP")**

On July 15, 2015, the stockholders approved the LTIP for the Company's Chairman, President and Chief Executive Officer, Dr. Rosenwald, and Executive Vice Chairman, Strategic Development, Mr. Weiss. The LTIP consists of a program to grant equity interests in the Company and in the Company's subsidiaries, and a performance-based bonus program that is designed to result in performance-based compensation that is deductible without limit under Section 162(m) of the Internal Revenue Code of 1986, as amended.

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On July 15, 2015, grants of 500,000 shares of common stock in each of Mustang, Checkpoint, Avenue, Coronado SO, Helocyte, JMC and Escala, were made to Dr. Rosenwald and Mr. Weiss for their services to the Company under the LTIP. The exercise price of each warrant, which approximates its fair value, was determined by the Company utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8%, weighted average cost of capital of 30%, and net of debt utilized. The Company recorded a charge of approximately \$2.2 million related to these grants.

On January 1, 2016, the Compensation Committee granted 510,434 shares each to Dr. Rosenwald and Mr. Weiss. These equity grants, made in accordance with the LTIP, represent one percent (1%) of total outstanding shares of the Company and were granted in recognition of their performance in 2015. The shares are subject to repurchase by the Company until both of the following conditions are met: (i) the Company's market capitalization increases by a minimum of \$100,000,000, and (ii) the employee is either in the service of the Company as an employee or as a Board member (or both) on the tenth anniversary of the LTIP, or the eligible employee has had an involuntary separation from service (as defined in the LTIP). The Company's repurchase option on such shares will also lapse upon the occurrence of a corporate transaction (as defined in the LTIP) if the eligible employee is in service on the date of the corporate transaction. Since these awards contain a *market condition* as defined in ASC 718, *Compensation - Stock Compensation*, the Company valued the award using the Monte Carlo simulation model. The model generated the fair value of the award at the grant date of \$2.4 million for both grants, which is amortized over the vesting period, subject to the above performance condition being probable of being met.

**Fortress Companies**

*Checkpoint Therapeutics, Inc.*

Checkpoint has a long-term incentive plan. In March 2015, Checkpoint issued a restricted stock grant to Dr. Marasco for services in connection with its Scientific Advisory Board. Dr. Marasco was issued a grant for 1.5 million shares of Checkpoint common stock, of which 25% vested on the first anniversary of the grant date and monthly thereafter for 48 months. Checkpoint valued the restricted stock utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8% and a weighted average cost of capital of 30%, resulting in a value of \$0.065 per share on grant date. At December 31, 2015, Checkpoint re-measured this non-employee restricted stock utilizing a market approach, based upon a third party financing. Such valuation resulted in a value of \$4.39 per share utilizing a volatility of 83%, a risk free rate of return of 1.5% and a term of five years. At June 30, 2016, Checkpoint re-measured this non-employee restricted stock utilizing a market approach, based upon a third party financing. Such valuation resulted in a value of \$4.42 per share utilizing a volatility of 83%, a risk free rate of return of 1.35% and a term of five years. For the three and six months ended June 30, 2016, the Company recorded expense of \$0.5 million and \$1.2 million, respectively, in research and development expenses on the Company's Condensed Consolidated Statements of Operations.

Certain employees and directors of Checkpoint have been awarded restricted stock under Checkpoint's 2015 Incentive Plan. For the three and six months ended June 30, 2016, Checkpoint recorded stock-based compensation expense of approximately \$0.4 million and \$0.7 million, respectively, related to stock grants, which is included in general and administrative expenses on the Condensed Consolidated Statements of Operations.

*Avenue Therapeutics, Inc.*

Avenue has a long term incentive program. During 2015, Avenue granted 1.0 million shares to its acting Chief Executive Officer, Dr. Lu, who is also Chief Financial Officer of Fortress, for services to be provided. The stock price was determined utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8%, weighted average cost of capital of 30%, and net of debt utilized, resulting in a value of \$0.146 per share. The grant issued to Dr. Lu vests 50% in four annual equal tranches of 12.5%, with the remaining 50% vesting upon the achievement of certain performance goals. In connection with these grants, for the three and six months ended June 30, 2016, the Company recorded approximately \$4,000 and \$9,000, respectively, as general and administrative expenses and \$4,000 and \$9,000, respectively, as research and development expenses on the Condensed Consolidated Statements of Operations.

*Journey Medical Corporation*

In January 2016, JMC granted 290,000 of options to its employees. The fair value of stock options granted was determined on the grant date using assumptions for risk free interest rate, the expected term, expected volatility, and expected dividend yield. The stock price was determined utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.5%, weighted average cost of capital of 30%, and net of debt utilized, resulting in a value of \$0.65 per share. JMC does not expect to pay dividends in the foreseeable future so therefore the expected dividend yield is 0%. The expected term for stock options granted with service conditions represents the average period the stock options are expected to remain outstanding and is based on the expected term calculated using the approach prescribed by the Securities and Exchange Commission's Staff Accounting Bulletin No. 110 for "plain vanilla" options. JMC obtained the risk-free interest rate from publicly available data published by the Federal Reserve. The volatility rate was computed based on a comparison of average volatility rates of similar companies. The fair value of options granted in 2016 was estimated using the following assumptions:

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	<b>For the six months ended June 30, 2016</b>
Risk-free interest rate	1.46% - 1.82%
Expected dividend yield	-
Expected term in years	5.23-6.95
Expected volatility	96.89% - 102.05%

During the three and six months ended June 30, 2016, stock-based compensation associated with the amortization of stock option expense was approximately \$0.1 million and \$0.3 million, respectively. JMC also recorded approximately \$31,000 and \$66,000 related to the restricted stock during the three and six months ended June 30, 2015, respectively. Expenses were recorded in general and administrative expense on the condensed Consolidated Statements of Operations.

*Helocyte, Inc.*

On March 30, 2016, Helocyte granted 150,000 shares of restricted stock to a consultant. The shares will vest in four equal annual installments beginning on March 30, 2017. On May 6, 2016, Helocyte granted 508,333 shares of restricted stock to the same consultant. The shares will vest in twelve equal quarterly installments of which 127,084 shares were immediately vested in May 2016. The stock price was determined utilizing a market approach, based upon a third party financing. Resulting in a value of \$0.46 per share as of May 31, 2016, utilizing a volatility of 68% and a risk free rate of return of 1.3%. For the three and six months ended June 30, 2016, in connection with these grants, Helocyte re-measured this non-employee grant and recorded expense of approximately \$68,000 and \$68,000, respectively, in research and development expenses on the Condensed Consolidated Statements of Operations.

On March 30, 2016, Helocyte granted 1.0 million shares to its Chief Executive Officer, for services to be provided. The shares will vest in twelve equal quarterly installments beginning on June 30, 2016. The fair market value of the stock is \$0.097 per share based upon management's estimate of fair value. In connection with this grant, for the three and six months ended June 30, 2016, the Company recorded approximately \$25,000 and \$25,000, respectively, as general and administrative expenses on the Condensed Consolidated Statements of Operations.

**Capital Raise**

*Checkpoint*

On February 23, 2016, Checkpoint closed on gross proceeds of \$0.6 million, before expenses, in a private placement of shares and warrants to Opus Point Healthcare Fund GP, LLC, a fund managed by OPPM, a related party. The financing involved the sale of units, each consisting of 10,000 shares of common stock and a warrant exercisable for 3,500 shares of common stock at an exercise price of \$7.00 per share, for a total price of \$45,000 per unit. The warrants have a five-year term and are only exercisable for cash. Checkpoint issued 126,640 unregistered shares of common stock and 44,324 warrants in connection with this transaction. Due to the absence of a placement agent in this transaction, the net proceeds to, and warrants issued by, Checkpoint were consistent with terms of the December 2015 third-party financing, which included the payment of fees and issuance of warrants to a placement agent.

As of June 30, 2016, the Company determined that the warrants still did not meet the definition of a derivative and continued to qualify for equity recognition.

*Origo*

On May 20, 2016, the Company entered into an agreement with Origo, and several accredited investors (collectively, the "Purchasers") to, among other things, sell to the Purchasers the Company's holdings of 1,020,000 common shares of Origo for an aggregate purchase price of approximately \$0.92 per unit, subject to certain terms and conditions set forth in the agreement.

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**Amendment to At Market Issuance Sales Agreement**

On April 28, 2016, the Company entered into an amendment to its existing At Market Issuance Sales Agreement, or Sales Agreement, with MLV & Co. LLC, or MLV, pursuant to which it extended the termination date of the Sales Agreement to August 19, 2016. This amendment did not change any other material terms of the Sales Agreement.

For the three months ended June 30, 2016, the Company issued 150,556 shares of Common Stock for gross proceeds of \$0.4 million and offering costs of \$49,000.

**13. Related Party Transactions**

*Services Agreement with Opus Point Management Partners, LLC*

On April 3, 2014, the Company entered into a Shared Services Agreement with OPPM in which the parties agreed to share a rented facility as well as costs for certain services, which they individually require for the operation of their respective entities. 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. The Company incurred expense of approximately \$21,000 and \$44,000 under this agreement for the three months ended June 30, 2016 and 2015, respectively. The Company incurred expense of approximately \$84,000 and \$88,000 under this agreement for the six months ended June 30, 2016 and 2015, respectively. The agreement can be terminated by either party with thirty days' notice.

*Shared Services Agreement with TGTX*

In July 2015, 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 and six months ended June 30, 2016, the Company invoiced TGTX \$0.2 million and \$0.3 million, respectively.

*Desk Space Agreements with TGTX and OPPM*

In September 2014, the Company entered into Desk Space Agreements with OPPM and TGTX to occupy 20% and 40% of the New York, NY office space that requires TGTX and OPPM to pay their share of the average annual rent of \$0.5 million and \$1.1 million, respectively. These initial rent allocations will be adjusted periodically for each party based upon actual percentage of the office space occupied. Additionally, the Company has reserved the right to execute desk space agreements with other third parties and those arrangements will also affect the cost of the lease actually borne by the Company. The Desk Space Agreement was amended in May 2016, adjusting the initial rent allocations to 45% for TGTX and 10% for OPPM.

Each initial Desk Space Agreement has a term of five years. The Company took possession of the New York, NY office space in December 2015, commenced build out of the space shortly thereafter and took occupancy of the space in April 2016. The Company expects the total build out costs to approximate \$5.1 million and will share the costs with OPPM and TGTX under the Desk Space Agreements. At June 30, 2016, the Company paid \$199,000 of prepaid rent under the Desk Space Agreements, and was reimbursed by OPPM and TGTX for their prorated share of this prepayment (\$39,800 and \$79,800 respectively). In addition, as of June 30, 2016 the Company incurred \$4.5 million in connection with the build out of the space and recorded a receivable of \$2.0 million due from TGTX and \$0.5 million due from OPPM.

*Checkpoint Agreements with TGTX*

Checkpoint has entered into various agreements with TGTX to develop and commercialize certain assets in connection with its licenses, including a collaboration agreement for some of the Dana Farber licensed antibodies, an option agreement and sponsored research agreement for the NeuPharma EGFR inhibitor, and a sublicense agreement for the Jubilant BET inhibitor (see Note 3). Checkpoint believes that by partnering with TGTX to develop these compounds in therapeutic areas outside of its business focus, it may substantially offset its preclinical costs and milestone costs related to the development and marketing of these compounds in solid tumor indications.

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*Founders Agreement and Management Services Agreement with Checkpoint*

Effective March 17, 2015, the Company entered into a Founders Agreement with Checkpoint, which was amended and restated on July 11, 2016 (the "Founders Agreement"). The Founders Agreement provides that, in exchange for the time and capital expended in the formation of Checkpoint and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Checkpoint assumed \$2.8 million in debt (see Note 8) that the Company accumulated under the NSC Note for expenses and costs of forming Checkpoint, and Checkpoint shall also: (i) issue annually to the Company, on the anniversary date of the Founders Agreement, shares of common stock equal to 2.5% of the fully-diluted outstanding equity of Checkpoint at the time of issuance; (ii) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Checkpoint or any of its subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when the Company no longer has majority voting control in Checkpoint's voting equity, equal to 2.5% of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to 4.5% of Checkpoint's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), Checkpoint will pay a one-time change in control fee equal to five times (5x) the product of (i) net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%). The Founders Agreement has a term of fifteen years after which it automatically renews for one-year periods unless the Company gives Checkpoint notice of termination. The Founders Agreement will automatically terminate upon a change of control.

Effective March 17, 2015, the Company entered into a Management Services Agreement (the "MSA") with Checkpoint. Pursuant to the terms of the MSA, for a period of five (5) years, the Company will render advisory and consulting services to Checkpoint. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Checkpoint's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Checkpoint with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Checkpoint is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by the Company, provided those services are offered at market prices. However, Checkpoint is not obligated to take or act upon any advice rendered from the Company and the Company shall not be liable for any of Checkpoint's actions or inactions based upon the Company's advice. Fortress and its affiliates, including all members of the Checkpoint's Board of Directors, have been contractually exempt from fiduciary duties to Checkpoint relating to corporate opportunities. In consideration for the Services, Checkpoint will pay the Company an annual consulting fee of \$0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to \$1.0 million for each calendar year in which the Company has net assets in excess of \$100 million at the beginning of the calendar year.

*Founders Agreement and Management Services Agreement with Avenue*

Effective as of February 17, 2015, the Company entered into a Founders Agreement with Avenue pursuant to which the Company assigned to Avenue all of its rights and interest under the Company's license agreement with Revogenex for IV Tramadol. As consideration for the Founders Agreement, Avenue assumed \$3.0 million in debt that the Company accumulated under the NSC Note (see Note 8) for expenses and costs of forming Avenue and obtaining IV Tramadol license, of which \$3.0 million represents the acquisition of the License Agreement. As additional consideration for the transfer of rights under the Founders Agreement, Avenue will also: (i) issue annually to the Company, on the anniversary date of the Founders Agreement, shares of common stock equal to two and one half percent (2.5%) of the fully-diluted outstanding equity of Avenue at the time of issuance; (ii) pay an equity fee in shares of Avenue common stock, payable within five (5) business days of the closing of any equity or debt financing for Avenue or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Avenue's voting equity, equal to two and one half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of Avenue's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), the Company will pay a one-time change in control fee equal to five (5x) times the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%).

Effective as of February 17, 2015, the Company entered into a Management Services Agreement (the "MSA") with Avenue and each of Avenue's current directors and officers who are directors or officers of the Company to provide services to Avenue pursuant to the terms of the MSA. Pursuant to the terms of the MSA, for a period of five (5) years, the Company will render advisory and consulting services to Avenue. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Avenue's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Avenue with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Avenue is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, Avenue is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of Avenue's actions or inactions based upon their advice. Fortress and its affiliates, including all members of Avenue's Board of Directors, have been contractually exempt from fiduciary duties to Avenue relating to corporate opportunities. In consideration for the Services, the Company will pay Fortress an annual consulting fee of \$0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to \$1.0 million for each calendar year in which Avenue has net assets in excess of \$100 million at the beginning of the calendar year.



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*Founders Agreement and Management Services Agreement with Helocyte*

Effective March 20, 2015, the Company entered into a Founders Agreement with Helocyte pursuant to which the Company agreed to provide the initial funding required by the COH License Agreement for PepVax and Triplex, as well as other operating capital needed to meet Helocyte's initial capital requirements. As consideration for the Founders Agreement, upon Helocyte commencing a third party financing, Helocyte will assume the Company's accumulated debt, attributable to Helocyte's expenses and costs associated with its formation, license acquisition and expenses, under the NSC Note ("NSC Note"), or other similar debt. As additional consideration for the transfer of rights under the Founders Agreement, Helocyte will also: (i) issue annually to the Company, on the anniversary date of the Founders Agreement, shares of common stock equal to two and one half percent (2.5%) of the fully-diluted outstanding equity of Helocyte at the time of issuance; (ii) pay an equity fee in shares of Helocyte common stock, payable within five (5) business days of the closing of any equity or debt financing for Helocyte or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Helocyte's voting equity, equal to two and one half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of Helocyte's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), the Company will pay a one-time change in control fee equal to five (5x) times the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%).

Effective March 20, 2015, the Company entered into a Management Services Agreement (the "MSA") with Helocyte and each of Helocyte's current directors and officers who are directors or officers of the Company to provide services to Helocyte pursuant to the terms of the MSA. Pursuant to the terms of the MSA, for a period of five (5) years, the Company will render advisory and consulting services to Helocyte. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Helocyte's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Helocyte with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Helocyte is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, Helocyte is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of Helocyte's actions or inactions based upon their advice. Fortress and its affiliates, including all members of Helocyte's Board of Directors, have been contractually exempt from fiduciary duties to Helocyte relating to corporate opportunities. In consideration for the Services, the Company will pay Fortress an annual consulting fee of \$0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to \$1.0 million for each calendar year in which Helocyte has net assets in excess of \$100 million at the beginning of the calendar year.

*Founders Agreement and Management Services Agreement with Mustang*

Effective March 13, 2015, the Company entered a Founders Agreement with Mustang, which was amended and restated on May 17, 2016 and again on July 26, 2016. The Founders Agreement provides that, in exchange for the time and capital expended in the formation of Mustang and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, the Company will loan Mustang \$2.0 million, representing the up-front fee required to acquire Mustang's license agreement with COH. The Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by the Company or a Change in Control occurs. Concurrently with the second amendment to the Founders Agreement, we entered into an Exchange Agreement whereby we exchanged our 7.2 million Class B Common shares for 7.0 million common shares and 250,000 Class A Preferred shares. Class A Preferred Stock is identical to common stock other than as to voting rights, conversion rights and the PIK Dividend right (as described below). Each share of Class A Preferred Stock will be entitled to vote the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding Mustang common stock and (B) the whole shares of Mustang common stock into which the shares of outstanding Class A Common Stock and the Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Each share of Class A Preferred Stock is convertible, at our option, into one fully paid and nonassessable share of Mustang common stock, subject to certain adjustments. As holders of Class A Preferred Stock, we will receive on each March 13 (each a "PIK Dividend Payment Date") until the date all outstanding Class A Preferred Stock is converted into common stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock ("PIK Dividends") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to two and one-half percent (2.5%) of Mustang's fully-diluted outstanding capitalization on the date that is one (1) business day prior to any PIK Dividend Payment Date.

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As additional consideration under the Founders Agreement, Mustang will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Mustang or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when the Company no longer has majority voting control in Mustang's voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of Mustang's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control, Mustang will pay a one-time change in control fee equal to five (5x) times the product of (A) monthly net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%). The Founders Agreement has a term of fifteen years, after which it automatically renews for successive one-year periods unless the Company gives Mustang notice of termination or a change in control occurs.

Effective as of March 13, 2015, the Company entered into a Management Services Agreement (the "MSA") with Mustang. Pursuant to the terms of the MSA, for a period of five (5) years, the Company will render advisory and consulting services to Mustang. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Mustang's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Mustang with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Mustang is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, Mustang is not obligated to take or act upon any advice rendered from Fortress, and Fortress shall not be liable for any of Mustang's actions or inactions based upon Fortress's advice. Fortress and its affiliates, including all members of Mustang's Board of Directors, have been contractually exempt from fiduciary duties to Mustang relating to corporate opportunities. In consideration for the Services, Mustang will pay Fortress an annual consulting fee of \$0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to \$1.0 million for each calendar year in which Mustang has net assets in excess of \$100 million at the beginning of the calendar year.

*Chord Advisors, LLC*

In May 2015, we entered into a full service consulting agreement with Chord Advisors, LLC ("Chord") to provide advisory accounting services. Under the terms of the agreement, we pay Chord \$10,000 per month to provide technical accounting and financial reporting support. Either party upon 30-days written notice can terminate the agreement. Mr. Horin, Managing Partner of Chord, serves as Interim Chief Financial Officer to Avenue, Checkpoint, Helocyte and Mustang. Pursuant to the agreements with Avenue, Checkpoint, Helocyte and Mustang, Chord receives \$5,000 per month for Avenue, Mustang and Helocyte, and \$7,500 per month for Checkpoint to provide back office accounting support and accounting policy and financial reporting services, including the services of Mr. Horin.

**14. Segment Information**

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

Cost of goods sold is directly related to product sales only. Revenues derived from co promote revenue, which made up all of the Dermatology Product Sales in the first quarter had no cost of goods sold. As a result, cost of goods sold was only recorded in the three months ended June 30, 2016.

<b>Three Months Ended June 30, 2016</b>	<b>Dermatology Products Sales</b>	<b>Pharmaceutical and Biotechnology Product Development</b>	<b>Consolidated</b>
Net Revenue	\$ 982	\$ 1,248	\$ 2,230
Direct cost of goods	(324)	-	(324)
Sales and marketing costs	(1,998)	-	(1,998)
Research and development	-	(8,407)	(8,407)
General and administrative	-	(6,637)	(6,637)
Segment loss from operations	<u>\$ (1,340)</u>	<u>\$ (13,796)</u>	<u>\$ (15,136)</u>
Segment assets	<u>\$ 3,058</u>	<u>\$ 95,004</u>	<u>\$ 98,062</u>

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

<b>Three Months Ended June 30, 2015</b>	<b>Dermatology Products Sales</b>	<b>Pharmaceutical and Biotechnology Product Development</b>	<b>Consolidated</b>
Net Revenue	\$ -	\$ -	\$ -
Direct cost of goods	-	-	-
Sales and marketing costs	(727)	-	(727)
Research and development	-	(3,959)	(3,959)
General and administrative	-	(3,076)	(3,076)
Segment loss from operations	<u>\$ (727)</u>	<u>\$ (7,035)</u>	<u>\$ (7,762)</u>
Segment assets	<u>\$ 1,569</u>	<u>\$ 82,130</u>	<u>\$ 83,699</u>

<b>Six Months Ended June 30, 2016</b>	<b>Dermatology Products Sales</b>	<b>Pharmaceutical and Biotechnology Product Development</b>	<b>Consolidated</b>
Net Revenue	\$ 1,364	\$ 1,526	\$ 2,890
Direct cost of goods	(324)	-	(324)
Sales and marketing costs	(3,884)	-	(3,884)
Research and development	-	(16,244)	(16,244)
General and administrative	-	(12,665)	(12,665)
Segment loss from operations	<u>\$ (2,844)</u>	<u>\$ (27,383)</u>	<u>\$ (30,227)</u>
Segment assets	<u>\$ 3,058</u>	<u>\$ 95,004</u>	<u>\$ 98,062</u>

<b>Six Months Ended June 30, 2015</b>	<b>Dermatology Products Sales</b>	<b>Pharmaceutical and Biotechnology Product Development</b>	<b>Consolidated</b>
Net Revenue	\$ -	\$ 500	\$ 500
Direct cost of goods	-	-	-
Sales and marketing costs	(1,300)	-	(1,300)
Research and development	-	(13,053)	(13,053)
General and administrative	-	(5,980)	(5,980)
Segment loss from operations	<u>\$ (1,300)</u>	<u>\$ (18,533)</u>	<u>\$ (19,833)</u>
Segment assets	<u>\$ 1,569</u>	<u>\$ 82,130</u>	<u>\$ 83,699</u>

*Significant Customers*

For the three months ended June 30, 2016, three of our customers accounted for more than 10.0% of our total revenue in the amount of \$0.3 million, \$0.3 million, and \$0.3 million, respectively. The revenue from these customers is captured in the product revenue, net line item within the Condensed Consolidated Statement of Operations. For the six months ended June 30, 2016, three of our customers accounted for more than 10.0% of our total revenue in the amount of \$0.6 million, \$0.3 million, and \$0.3 million, respectively.

At June 30, 2016, three of our customers accounted for more than 10.0% of our total accounts receivable balance in the amount of \$0.4 million, \$0.4 million and \$0.1 million, respectively.

**15. Merger Agreement with National Holdings Corporation**

On April 27, 2016, the Company, its wholly owned subsidiary, FBIO Acquisition, Inc. (“Acquisition Sub”), a Delaware corporation and National Holdings Corporation (“NHLD”), a Delaware corporation, entered into an Agreement and Plan of Merger (“Merger Agreement”) for the acquisition of NHLD by Acquisition Sub. Fortress entered into the transaction in part because of NHLD’s ability to finance emerging biotech transactions.

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

Pursuant to the Merger Agreement and upon the terms and subject to the conditions therein, Fortress has agreed to cause Acquisition Sub to commence a tender offer (the "Offer") as promptly as practicable and in no event later than 30 days after the Financial Industry Regulatory Authority ("FINRA") declares the application required under NASD Rule 1017 regarding the potential change of control of the broker-dealer subsidiary of NHLD as substantially complete, for all of the issued and outstanding shares of NHLD's common stock, par value \$0.02 per share at the purchase price of \$3.25 per share in cash.

If more than 80% of the NHLD shares are tendered in the Offer, NHLD will undergo a merger and will no longer be a public company. Following the consummation of the Offer, if less than 80% of the NHLD shares are tendered in the Offer, NHLD will remain a publicly traded company. The consummation of the Offer is not subject to any financing condition or any condition regarding a minimum number of shares being validly tendered in the Offer but is subject to certain customary conditions.

Following the consummation of the Offer, regardless of the number of shares purchased, Fortress will have the right to appoint a majority of the board of NHLD.

If the Merger Agreement is terminated under certain circumstances as indicated in the Merger Agreement NHLD would be responsible for a termination fee of approximately \$1.8 million and Fortress would be responsible for a termination fee of approximately \$4.4 million. In addition, Fortress and NHLD would both be responsible to reimburse the other for certain transaction expenses of up to approximately \$0.8 million if the Merger Agreement is terminated.

**16. Subsequent Events**

*NSC Note*

On July 5, 2016, Fortress transferred \$3.6 million of Mustang's indebtedness to its NSC Note. In connection with the debt transfer a contingently issuable warrant equal to 25% of the transferred indebtedness will be recorded.

*Settlement Agreement with Ovamed GmbH ("Ovamed")*

On August 1, 2016, the Company entered into a Settlement and Forbearance Agreement with Ovamed to settle contractual obligations of approximately \$1.9 million. Under the terms of the agreement, within ten days of execution of the agreement, the Company will make a payment of \$1.1 million, followed in nine months by a second payment of \$0.8 million. The combined settlement amount reflects a payment of an obligation previously recorded by the Company.

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

References in this report to “we,” “us,” “our,” “the Company” and “Fortress” refer to Fortress Biotech, Inc. and its subsidiaries.

### 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, 2015.*

### Overview

Since inception on June 28, 2006, we have been a biopharmaceutical company involved in the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer. In 2015, as part of our growth strategy, we focused on acquiring, developing and commercializing novel pharmaceutical and biotechnology products. We plan to continue to develop and commercialize products both within Fortress and our subsidiaries, which are sometimes referred to herein as the “Fortress Companies”. In addition to our internal development programs, we plan to leverage our biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies innovate, develop and commercialize products. Additionally, we will provide funding and management services to each of the Fortress Companies and, from time to time, we and the Fortress Companies will seek licensing, 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 investment candidate. We seek to acquire and invest in drugs, technologies and operating subsidiaries with high growth potential. We have made significant progress with the above initiatives and believe our novel business approach will provide opportunities to achieve synergies across multiple Fortress Companies.

As of June 30, 2016, we had several consolidated Fortress Companies, some of which contain product licenses, including Avenue Therapeutics, Inc. (“Avenue”), Journey Medical Corporation (“JMC”), Coronado SO Co. (“Coronado SO”), Checkpoint Therapeutics, Inc. (“Checkpoint”), Mustang Bio, Inc. (“Mustang”), Helocyte, Inc. (“Helocyte”), Escala Therapeutics, Inc. (“Escala”), CB Securities Corporation and Cyprium, Inc.

### Recent Events

#### *Fortress*

In April 2016, our wholly owned subsidiary, FBIO Acquisition, Inc. entered into an Agreement and Plan of Merger for the acquisition of National Holdings Corporation (“NHLD”). We entered into the transaction in part because of NHLD’s ability to finance emerging biotech transactions.

#### *Avenue*

In June 2016, Avenue completed an End-of-Phase 2 (“EOP2”) meeting with the U.S. Food and Drug Administration (“FDA”) and, based on the outcome of the EOP2 meeting, Avenue anticipates that the Phase 3 program will consist of three studies: an efficacy and safety study in an orthopedic model, an efficacy and safety study in a soft tissue model, and an open label safety study

In March 2016, Avenue completed a pharmacokinetics (PK) study for IV Tramadol in healthy volunteers.

### *Checkpoint*

In July 2016, Checkpoint submitted an IND application to the FDA for its EGFR inhibitor and the application is currently under review.

In May 2016, Checkpoint entered into a License Agreement with Jubilant Biosys Limited (“Jubilant”), whereby Checkpoint obtained an exclusive, worldwide license to Jubilant’s family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment, which the Company refers to as CK-103. In connection with this license, Checkpoint entered into a sublicense agreement with TG Therapeutics, Inc. (“TGTX”), a related party, to develop and commercialize the compounds licensed in the field of hematological malignancies, while Checkpoint retains the right to develop and commercialize these compounds in the field of solid tumors.

In February 2016, Checkpoint repaid its NSC debt of \$2.8 million

### *Helocyte*

On June 30, 2016, Helocyte held the first closing of the sale of convertible promissory notes. Helocyte sold eleven convertible promissory notes to investors for an aggregate of \$1.0 million.

In March 2016, Helocyte entered into an Investigator-Initiated Clinical Research Support Agreement with the City of Hope National Medical Center (“COH”) to support a Phase 2 clinical study of its PepVax immunotherapy for CMV control in allogeneic stem cell transplant recipients. The Phase 2 study is additionally supported by grants from the National Cancer Institute.

In February 2016, Helocyte entered into a Clinical Trial Agreement with COH to support a Phase 2 clinical study of its Triplex immunotherapy for CMV control in allogeneic stem cell transplant recipients. The Phase 2 study is additionally supported by grants from the National Cancer Institute.

### *Mustang*

In May 2016, an oral presentation related to MB-101 (IL13R $\alpha$ 2-specific CAR T cells) was presented by COH investigators at the American Society of Gene and Cell Therapy 19th Annual Meeting (ASGCT) at the Marriott Wardman Park Hotel in Washington, DC.

### *JMC*

In July 2016, JMC received FDA approval to manufacture its product for the treatment of acne. Sales are expected to commence in the second half of 2016.

During the second quarter of 2016, JMC began sales of “Journey” branded products including Luxamend<sup>TM</sup>, its prescription wound cream, and Ceracade<sup>TM</sup>, its emollient for the treatment of various types of dermatitis.

### **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 and the Fortress Companies’ early stage of development. The following provides a summary of revenues and expenses for the periods presented.

## Results of Operations

### *General*

To date, we have revenues of \$2.9 million, consisting of \$1.4 million from the sale JMC products and \$1.5 million from TGTX, a related party, in connection with certain collaboration arrangements with Checkpoint. At June 30 2016, we had an accumulated deficit of \$214.8 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.

We had \$0.3 million of costs of goods sold in connection with the sale of JMC branded products.

In connection with JMC's licensing agreement to distribute its prescription wound cream Luxamend™, JMC paid an upfront fee of \$50,000, and a \$0.3 million upfront fee for the licensing agreement to distribute Ceracade™, its emollient for the treatment of various types of dermatitis. JMC commenced the sale of both of these products during the three months ended June 30, 2016 and accordingly commenced the amortization of these costs over their respective three year estimated useful life.

### *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.

Also included in research and development expense is the total purchase price for the licenses acquired during the applicable reporting period.

For the three months ended June 30, 2016 and 2015, research and development expenses were approximately \$6.3 million and \$2.4 million, respectively. Additionally, during the three months ended June 30, 2016 and 2015, we expensed \$2.1 million and \$1.5 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 June 30, 2016 and 2015, was \$1.1 million and \$0.6 million, respectively.

Included in the \$6.3 million and \$2.4 million figures for the three months ended June 30, 2016 and 2015, respectively, are the following subsidiary level expenses related to license development: Avenue: \$0.3 million and \$0.1 million; Checkpoint: \$2.8 million and \$0.4 million; Escala: \$0.3 million and nil; Helocyte: \$0.1 million and nil; and Mustang \$0.5 million and \$0.5 million. Additionally, for the three months ended June 30, 2016 and 2015, expenses related to CNDO-109 and TSO were \$0.1 million and nil, and \$0.2 million and \$0.1 million, respectively. Also included in research and development expenses for the three months ended June 30, 2016 and 2015, were \$0.9 million and \$0.7 million, respectively, of employee costs.

For the six months ended June 30, 2016 and 2015, research and development expenses were approximately \$14.1 million and \$4.1 million, respectively. Additionally, during the six months ended June 30, 2016 and 2015, we expensed \$2.1 million and \$9.0 million, respectively, in costs related to the acquisition of licenses. Noncash, stock-based compensation expense included in research and development for the six months ended June 30, 2016 and 2015, was \$2.4 million and \$0.6 million, respectively.

Included in the \$14.1 million and \$4.1 million research and development expense figures for the six months ended June 30, 2016 and 2015, respectively are the following subsidiary level expenses related to license development: Avenue: \$0.8 million and \$0.1 million; Checkpoint: \$4.4 million and \$0.4 million; Escala: \$0.6 million and nil; Helocyte: \$2.1 million and nil; and Mustang: \$1.0 million and \$0.5 million. Additionally, for the six months ended June 30, 2016 and 2015, expenses related to CNDO-109 and TSO were \$0.6 million and \$0.1 million, and \$0.4 million and \$0.3 million respectively. Employee costs of \$2.0 million and \$1.6 million were also included in research and development expenses for the six-months ended June 30, 2016 and 2015, respectively.

### *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 June 30, 2016 and 2015, general and administrative expenses were approximately \$8.8 million and \$3.8 million, respectively. Noncash, stock-based compensation expense included in general and administrative expenses for the three months ended June 30, 2016 and 2015, was \$1.9 million and \$1.3 million, of which \$1.4 million and \$1.3 million relates to Fortress, \$0.2 million and nil relates to JMC and \$0.4 million and nil relates to Checkpoint, respectively.

Included in the remaining \$7.1 million and \$2.5 million figures for the three months ended June 30, 2016 and 2015, respectively are the following subsidiary level expenses which include subsidiary employee costs: JMC: \$1.9 million and \$0.7 million; Checkpoint: \$1.0 million and \$33,000; Helocyte: \$0.5 million and \$17,000; Mustang: \$0.4 million and \$23,000. Also included in general and administrative expenses for the three months ended June 30, 2016 and 2015, respectively were \$1.0 million and \$0.5 million of employee costs, \$0.9 million and \$0.2 million of legal costs, and \$1.2 million and \$0.9 million of public company costs, related to us.

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 six months ended June 30, 2016 and 2015, general and administrative expenses were approximately \$16.7 million and \$7.4 million, respectively. Noncash, stock-based compensation expense included in general and administrative expenses for the six months ended June 30, 2016 and 2015, was \$3.5 million and \$2.5 million, of which \$2.4 million and \$2.5 million relates to Fortress, \$0.3 million and nil relates to JMC, \$25,000 and nil relates to Helocyte, \$8,900 and nil relates to Avenue and \$0.7 million and nil relates to Checkpoint, respectively. 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.

Included in the remaining \$13.2 million and \$5.0 million figures for the six months ended June 30, 2016 and 2015, respectively are the following subsidiary level expenses: JMC: \$3.6 million and \$1.3 million; Checkpoint: \$1.6 million and \$0.1 million; Helocyte: \$0.7 million and \$24,000; Escala: \$0.7 million and nil; and Mustang: \$0.6 million and nil. Also included in general and administrative expenses for the six months ended June 30, 2016 and 2015, respectively were \$2.1 million and \$1.1 million of employee costs, \$1.8 million and \$0.6 million of legal costs, \$0.9 million and \$0.1 million of rent, and \$1.7 million and \$1.4 million of public company costs.

**Comparison of three months ended June 30, 2016 and 2015**

(\$ in thousands)	For the Three Months Ended June 30,		Change	
	2016	2015	\$	%
Product revenue, net	\$ 981	\$ -	\$ 981	100%
Revenue - from a related party	1,249	-	1,249	100%
<b>Total revenue</b>	<b>2,230</b>	<b>-</b>	<b>2,230</b>	<b>100%</b>
Cost of goods sold	324	-	324	100%
Gross margin	1,906	-	1,906	100%
<b>Operating expenses</b>				
Research and development	6,347	2,411	3,936	163%
Research and development – licenses acquired	2,060	1,548	512	33%
General and administrative	8,635	3,803	4,832	127%
<b>Total operating expenses</b>	<b>17,042</b>	<b>7,762</b>	<b>9,280</b>	<b>120%</b>
Loss from operations	(15,136)	(7,762)	(7,374)	95%
<b>Other income (expenses)</b>				
Interest income	77	74	3	4%
Interest expense and financing fees	(529)	(352)	177	50%
Change in fair value of investments	(801)	1,622	(2,423)	(149)%
<b>Total other expenses</b>	<b>(1,253)</b>	<b>1,344</b>	<b>(2,597)</b>	<b>(193)%</b>
<b>Net loss</b>	<b>(16,389)</b>	<b>(6,418)</b>	<b>(9,971)</b>	<b>155%</b>
Less: net loss attributable to non-controlling interest	3,911	243	3,668	1509%
<b>Net loss attributable to common stockholders</b>	<b>\$ (12,478)</b>	<b>\$ (6,175)</b>	<b>\$ (6,303)</b>	<b>102%</b>

Total revenues increased \$2.2 million or 100% from the three months ended June 30, 2015 to the three months ended June 31, 2016. Revenue from sales of JMC products increased by \$1.0 million and revenue from a related party attributed to Checkpoint increased by \$1.2 million: \$1.0 million from TGTX upon the signing of the sublicense agreement for CK-103 and approximately \$0.2 million from TGTX in connection with the reimbursement of costs for the Sponsored Research Agreement with NeuPharma.

Research and development expenses increased \$3.9 million, or 163%, from the three months ended June 30, 2015 to the three months ended June 30, 2016. \$3.0 million of the increase is attributable to the development of our subsidiary licenses as follows: \$0.2 million for Avenue related to their PK study for IV Tramadol; \$2.4 million for Checkpoint, related to preclinical and product development activities primarily comprised of (i) \$1.0 million related to the Dana-Farber license and (ii) \$1.3 million related to NeuPharma programs; \$0.1 million related to sponsored research agreement for Helocyte with COH; \$0.3 million for Escala for the funding of their research programs with the NIH. Additionally, non-cash compensation expenses increased by \$0.8 million from the three months ended June 30, 2015 to the three months ended June 30, 2016. The increase is primarily related to \$0.3 million increase of expenses related to a stock grant by Checkpoint, \$0.3 million related to the new stock grant made to our Senior Vice President of research and development and new stock grants made by Avenue and Helocyte.

During the three months ended June 30, 2016, we invested \$2.1 million in new research and development programs purchased by Helocyte and Checkpoint compared with approximately, \$1.5 million for the acquisition of licenses during the three months ended June 30, 2015, primarily consisting of the following: IV Tramadol for Avenue of \$1.0 million, \$0.4 million for Uracil Topical Cream and \$0.2 million for the licenses for the CMV for Helocyte.

General and administrative expenses increased \$5.0 million, or 131%, from the three months ended June 30, 2015 to the three months ended June 30, 2016. The \$5.0 million increase is largely due to \$1.2 million spent in building of our sales and marketing infrastructure at JMC and the hire of an out-sourced sales force and approximately \$1.0 million spent by Checkpoint for legal, professional fees, and salary expense. Professional fees increased by \$2.0 million primarily due to an increase in legal fees of \$1.5 million of which \$0.6 million relates to the tender offer to NHLD and \$0.9 million relates to business development activity. Personnel costs increased by \$0.5 million as we continued to build our business development capabilities. Stock-compensation expense increased by \$0.6 million as a result of grants made by JMC and Checkpoint.

During the three months ended June 30, 2016, we restructured our holdings in CB Acquisition Corp, which resulted in a decline in the fair value of our investment of \$2.4 million or 149%. Interest expense and financing fees increased by \$0.2 million primarily due to financing fees of \$0.3 million associated with Helocyte's convertible notes offset by a decrease in interest expense of \$0.1 million.

Non-controlling interests increased \$3.6 million, or 1,501%, from the three months ended June 30, 2015 to the three months ended June 30, 2016. This increase reflects the increase in costs related to our subsidiaries.

#### Comparison of six months ended June 30, 2016 and 2015

(\$ in thousands)	For the Six Months Ended June 30,		Change	
	2016	2015	\$	%
Product revenue, net	\$ 1,364	\$ -	\$ 1,364	100%
Revenue - from a related party	1,526	500	1,026	205%
Total revenue	2,890	500	2,390	478%
Cost of goods sold	324	-	324	100%
Gross margin	2,566	500	2,066	413%
<b>Operating expenses</b>				
Research and development	14,100	4,066	10,034	247%
Research and development – licenses acquired	2,143	8,987	(6,844)	(76)%
General and administrative	16,550	7,280	9,270	127%
Total operating expenses	32,793	20,333	12,460	61%
Loss from operations	(30,227)	(19,833)	(10,394)	52%
<b>Other income (expenses)</b>				
Interest income	152	156	(4)	(3)%
Interest expense and financing fees	(1,149)	(683)	(466)	68%
Change in fair value of subsidiary's warrant liabilities	(89)	-	(89)	100%
Change in fair value of investments	(1,719)	1,407	(3,126)	(222)%
Total other expenses	(2,805)	880	(3,685)	(419)%
<b>Net loss</b>	(33,032)	(18,953)	(14,079)	74%
Less: net loss attributable to non-controlling interest	8,349	722	7,627	1056%
<b>Net loss attributable to common stockholders</b>	<u>\$ (24,683)</u>	<u>\$ (18,231)</u>	<u>\$ (6,452)</u>	<u>35%</u>

Total revenues increased \$2.4 million or 478% from the six months ended June 30, 2015 to the six months ended June 30, 2016. The increase is due to: (i) an increase in JMC product revenue of \$1.4 million primarily related revenue generated from the sale of JMC's two branded products: Luxamend™ and Ceracade™ and (ii) \$1.0 million in revenue primarily related to Checkpoint's sublicense arrangement with TGTX .

Research and development expenses increased \$10.0 million, or 247%, from the six months ended June 30, 2015 to the six months ended June 30, 2016. \$7.8 million of the increase is attributable to the development of our subsidiary licenses as follows: \$0.6 million for Avenue related to its PK study for IV Tramadol; \$3.9 million for Checkpoint, related to preclinical and product development activities primarily comprised of \$1.6 million related to Dana-Farber programs and \$2.0 million related to Checkpoint's agreement with NeuPharma; \$2.1 million for Helocyte related to its sponsored research agreement with COH; \$0.5 million for Mustang related to its sponsored research agreement with COH; \$0.6 million for Escala related to its funding of research with the NIH. In addition, expenses related to CNDO -109 increased by \$0.2 million, as a result of a milestone payment due to University College of London for completion of the Phase 1 study offset by a decline in spending of \$0.1 million for CNDO - 201. Additionally, non-cash compensation expenses increased by \$1.9 million from the six months ended June 30, 2015 from the six months ended June 30, 2016. The increase is primarily related to the \$1.2 million of expenses related to the stock grant by Checkpoint to a consultant and \$0.6 million related to the new stock grant made to our Senior Vice President of research and development.

During the six months ended June 30, 2016, we invested \$2.0 million in a new license acquisition by Checkpoint from Jubilant for compounds that inhibit BRD4, a member of the BET domain for cancer treatment, or CK-103, compared with \$9.0 million for the acquisition of licenses during the six months ended June 30, 2015, including \$3.0 million for Avenue for IV Tramadol, \$2.0 million for preclinical and product development activities, \$2.2 million for Mustang for CAR-T from the City of Hope and \$1.6 million for Coronado SO for Uracil Topical Cream.

General and administrative expenses increased \$9.4 million, or 129%, from the six months ended June 30, 2015 to the six months ended June 30, 2016. This increase is largely due to a \$2.3 million increase in spending related to building the sales and marketing infrastructure at JMC including the hiring of an out-sourced sales force and a \$1.5 million increase in spending primarily related to Checkpoint's primarily salary and legal expenses. Professional fees increased by \$3.5 million primarily due to an increase in legal fees of \$2.6 million related to business development outreach as well as approximately \$1.0 million in costs related to our acquisition of NHLD. Rent expense increased by \$0.8 million upon the commencement of our lease for our new offices in New York City. An additional increase of \$1.0 million is related to an increase in headcount primarily attributed to the building of our business development infrastructure. Stock-compensation expense increased by \$1.0 million as a result of a stock grants made by JMC and Checkpoint employees.

Interest expense and financing fees increased \$0.5 million, or 68%, from the six months ended June 30, 2015 to the six months ended June 30, 2016, primarily due to \$0.3 million of fees related to the Helocyte debt offering.

Non-controlling interests increased \$7.6 million, or 1,054%, from the six months ended June 30, 2015 to the six months ended June 30, 2016. This increase reflects the increase in costs related to our subsidiaries.

## 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 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. Adequate additional funding may not be available to us on acceptable terms or at all. If adequate funds are not available to us when needed, we may be required to delay, curtail or eliminate one or more of our research and development programs and, potentially, delay our growth strategy.

### Cash Flows for the Six Months June 30, 2016 and 2015

(\$ in thousands)	For the Six Months Ended June 30,	
	2016	2015
<b>Statement of cash flows data:</b>		
Total cash (used in)/provided by:		
Operating activities	\$ (19,019)	\$ (8,073)
Investing activities	(6,921)	(10,036)
Financing activities	(906)	9,387
Decrease in cash and cash equivalents	\$ (26,846)	\$ (8,722)

### **Operating Activities**

Net cash used in operating activities increased \$10.9 million from the six months ended June 30, 2015, compared to the six months ended June 30, 2016. The increase in net cash used in operating activities was primarily due to a \$33.0 million net loss, of which \$19.0 million relates to our subsidiaries. This increase is partially offset by \$2.1 million related to the acquired licenses, \$5.9 million of stock-based compensation expenses and \$1.8 million of change in fair value of investments.

### **Investing Activities**

Net cash used in investing activities decreased \$3.1 million from the six months ended June 30, 2015, compared to the six months ended June 30, 2016. The decrease is primarily due to a \$6.6 million decrease in licenses being acquired in 2016, offset by the build-out of the New York City office of \$4.3 million.

### **Financing Activities**

Net cash used in financing activities was \$0.9 million for the six months ended June 30, 2016, compared to \$9.4 million of net cash provided by financing activities for the six months ended June 30, 2015. During the first quarter of 2016, we paid-off \$2.8 million of the NSC Note, from which the proceeds of \$10.0 million were received in February of 2015. In the second quarter we received \$0.9 million in net proceeds from the Helocyte convertible debt.

### **Contractual Obligations and Commitments**

There have been no material changes to our contractual obligations and commitments outside of the ordinary course of business from those disclosed on our Annual Report on Form 10-K for the year ended December 31, 2015.

### **Off-Balance Sheet Arrangements**

None.

### **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, as of June 30, 2016, the effect of a 100+/- basis point change in interest rates on the value of our financial instruments and the resultant effect on our net loss are considered 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 June 30, 2016, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

### *Changes in Internal Control over Financial Reporting*

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

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

None.

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

Investing in our Common Stock 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 Quarterly Report on Form 10-Q, including the consolidated financial statements and the related notes, before deciding to invest in shares of our Common Stock. If any of the following risks 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 could decline and you could lose part of or all of your investment in our Common Stock.

#### **Risks Related to our Growth Strategy**

*If we acquire companies in the future, they could prove difficult to integrate, disrupt our business, dilute stockholder value, and adversely affect our operating results and the value of our Common Stock.*

As part of our growth strategy, we might acquire, enter into joint ventures with, or make investments in other companies. Acquisitions, such as our proposed acquisition of National Holdings Corporation ("NHL") and investments involve numerous risks, including:

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

If we fail to properly evaluate acquisitions or investments, we might not achieve the anticipated benefits of any such acquisitions or investments, 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 all or substantially all of the National Holdings Corporation stockholders tender their shares in connection with our proposed acquisition of National Holdings Corporation, our liquidity may be strained requiring us to seek additional sources of financing which might not be available on a timely or favorable basis and could, as a result, significantly curtail or delay certain aspects of our business and materially affect our financial condition and results of operations.*

On April 27, 2016, we entered into an Agreement and Plan of Merger with FBIO Acquisition, Inc., a wholly owned subsidiary of Fortress (“Acquisition Sub”), and NHLD providing for the acquisition of NHLD by Acquisition Sub (the “Merger Agreement”). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions described therein, we agreed to cause Acquisition Sub to commence a tender offer for all the issued and outstanding shares of NHLD’s common stock at a purchase price of \$3.25 per share. As of May 16, 2016, NHLD had 12,440,035 shares outstanding. If all or substantially all of the NHLD stockholders tender shares to Acquisition Sub, payment may strain our liquidity, which in turn could have material adverse effects on our business, including:

- requiring us to dedicate a substantial portion of our cash flow from operations to payments related to the Merger Agreement, thereby reducing the availability of our cash flow to fund working capital, capital expenditures, and other general corporate purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industries in which we operate;
- restricting us from making additional strategic acquisitions or exploiting business opportunities; and
- placing us at a disadvantage compared to our competitors that have more available cash.

As a result, we may need to raise additional capital through the issuance of debt or equity securities. We cannot guarantee that future capital will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity would dilute all of our stockholders. The incurrence of additional indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our or our subsidiaries’ product candidates or otherwise agree to terms unfavorable to us. If we are unable to obtain necessary debt or equity financing on a timely and favorable basis, we may be required to significantly curtail or delay certain aspects of our business, which could materially affect financial condition and results of operations.

*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 management, and administrative, operational and financial systems. In addition, we may need to hire, train and manage more employees, focusing on their integration with our Company 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.

*If certain of our subsidiaries cannot innovate, develop and continue to commercialize pharmaceutical and biotechnology products, we may not be able to generate revenue.*

Our revenue growth strategy also depends on our and our subsidiaries’ ability to generate revenue, including royalty-related fees. If we and our subsidiaries cannot innovate, develop and continue to commercialize our current and future pharmaceutical and biotechnology products, we may not be able to generate revenue growth as anticipated.

*We may not be able to generate returns for our investors if our subsidiaries, most of which have limited or no operating history and no commercialized revenue generating products, cannot obtain additional third-party financing and commercialize additional products.*

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 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 pharmaceutical and biotechnology products and/or companies in increasingly competitive and highly regulated markets. If our subsidiaries do not successfully obtain additional third-party financing and commercialize products or successfully acquire companies, the value of our investments and our business 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 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 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 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 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 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. 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.

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 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 our Company 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 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 significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, and on our ability to attract additional personnel for our Company and, in some cases, our subsidiaries as we continue to implement our growth strategy, develop products and acquire companies. 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 our Company 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 for any significant period of time 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 all of our and our subsidiaries' key personnel. We only maintain a limited amount of directors' and officers' liability insurance coverage to protect all of our directors and executive officers taken together (and those of our subsidiaries until they go public). There can be no assurance that this coverage will be sufficient to cover the costs of the events that may lead to its invocation, in which case, there could be a substantial impact on our and our subsidiaries' ability to continue operations.

## Risks Related to Our Business and Industry

*We are an early-stage company, with limited operating history upon which stockholders can base an investment decision.*

We remain 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 our subsidiaries have engaged primarily in R&D and investment activities and have not generated any revenues from product sales. We and our subsidiaries have incurred significant net losses since our inception. As of June 30, 2016, we had an accumulated deficit of approximately \$214.8 million. We and our subsidiaries have not demonstrated our ability to perform the functions necessary for the successful commercialization of any of our products. The successful commercialization of our products will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our Company (and in some cases our subsidiaries), 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.

*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 continue to generate product revenue.*

Neither we nor our 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 our subsidiaries must build and maintain this infrastructure or make arrangements with third parties to perform these functions in order to continue to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us, any of our subsidiaries or jointly with a partner, or the establishment of a contract sales force to market any products we or our subsidiaries may develop is expensive and time-consuming and could delay any product launch or compromise the successful commercialization of products. If we, certain of our subsidiaries, or our respective partners, are unable to establish and maintain sales and marketing capability or any other non-technical capabilities necessary to commercialize any products that may be successfully developed, we or our subsidiaries will need to contract with third parties to market and sell such products. We or our subsidiaries may not be able to establish arrangements with third parties on acceptable terms, or at all.

*If any of our or 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 our subsidiaries' product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our or 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 will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- 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;
- acceptance of the product by the target population;

- 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 indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of 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 our subsidiaries may not generate sufficient revenue from these products and in turn we may not become or remain profitable.

*Healthcare reform and restrictions on reimbursements may limit our financial returns.*

Our ability and the ability of certain of our subsidiaries and all of our respective collaborators to commercialize product candidates that are successfully developed may depend, in part, on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our or certain of our subsidiaries' product candidates, which would prevent those product candidates from selling at price levels sufficient to realize an appropriate return on investments in research and product development.

*Failure to be included in formularies developed by managed care organizations and coverage by other organizations may negatively impact the utilization of our and our subsidiaries' products, which could harm our and our subsidiaries' market share 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 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 existing product candidate 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 candidate, CNDO-109, 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 prior to commercialization. The development and regulatory approval process takes several years and it is not likely that CNDO-109 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 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 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.

*Product candidates 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 we or our subsidiaries advance into clinical trials may not receive regulatory approval.

*Any product candidates we or 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 candidate CNDO-109, and 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. Our development of CNDO-109, which is an individualized immunotherapy, may in particular be affected because to date the FDA has only approved one individualized immunotherapy treatment. Our subsidiaries' development of individualized immunotherapies, if any, will face similar challenges. 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 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 our subsidiaries;
- our or 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 our subsidiaries or our respective collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering the clinical data insufficient 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 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 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 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 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 our subsidiaries to withdraw such products from the market.

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

The commencement of clinical trials can be delayed for a variety of reasons, including 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 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 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 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:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

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

Changes in regulatory requirements and guidance also may occur and we or our subsidiaries may need to amend clinical trial protocols to reflect these changes. Amendments may require us or 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 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 our subsidiaries may develop and market may be later withdrawn from the market or subject to promotional limitations.*

Neither we nor our subsidiaries may be able to obtain the labeling claims necessary or desirable for the promotion of our product candidates if approved. We and 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 our subsidiaries currently rely on third parties to manufacture our preclinical and clinical pharmaceutical supplies and expect to continue to rely 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 depend 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 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, 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. 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 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 clinical trials, product testing and potential regulatory approval.

We do not expect to have the resources or capacity to commercially manufacture our and our subsidiaries' products, if approved, and will likely continue to be 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 on a timely basis or at all.

*We and 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 our subsidiaries have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We and 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 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.

*If our competitors develop treatments for any of the target indications of our or 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 our subsidiaries operate in highly competitive segments of the biotechnology and biopharmaceutical markets and face competition from many different sources, including commercial pharmaceutical and biotechnology 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 us. 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 cancer 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 our subsidiaries have entered into various agreements where 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 use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.*

We and 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 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' ability 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 by obtaining patents. These risks and uncertainties include the following:

- patent applications may not result in any patents being issued;
- 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;
- 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. Third parties are often responsible for maintaining patent protection for our product candidates and those of our subsidiaries. For example, UCLB is responsible for prosecuting and maintaining patent protection for CNDO-109, at our expense for our territories. If UCLB fails to appropriately prosecute and maintain patent protection for this product candidate, our ability to develop and commercialize CNDO-109 may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This 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. 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 PTO 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.

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 currently 12 years from the date of marketing approval, there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period, as 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, 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' ability and the ability 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.

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:

- 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. 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 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' consultants 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 pharmaceutical and biotechnology 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 biotechnology or 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 are 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. 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 such products, manufacturers or manufacturing processes;

- 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;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements to approved applications that we or our subsidiaries submit;
- 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.

#### **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 \$35.8 million, \$20.7 million and \$50.5 million for the years ended December 31, 2013, 2014 and 2015, respectively, and losses from operations of \$30.2 million for the six months ended June 30, 2016. At June 30, 2016, we had an accumulated deficit of approximately \$214.8 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 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 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 June 30, 2016, the amount of debt outstanding under our promissory note in favor of Israel Discount Bank of New York ("IDB") was \$14.0 million. The loan is collateralized by a security interest, a general lien upon, and right of set off against, our money market account of \$15.0 million. If we default on our obligations, IDB may declare the loan immediately payable together with accrued interest and exercise its right to set-off. 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, 2013, 2014 and 2015 we incurred R&D expenses of approximately \$25.7 million, \$10.2 million and \$29.8 million, respectively and research and development expenses of approximately \$14.1 million for the six months ended June 30, 2016. We expect to continue to spend significant amounts on our growth strategy, including on our proposed acquisition of NHLD. 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. In addition, in February 2015, we raised \$10.0 million in a private placement of a promissory note to NSC Biotech Venture Fund I LLC. However, 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 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 statements 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 June 30, 2016, Lindsay A. Rosenwald, M.D., our Chairman, President and Chief Executive Officer, beneficially owned 12.9% of our issued and outstanding capital stock. At June 30, 2016, 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:

- 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;
- 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;
- 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 48.7 million outstanding shares of our Common Stock as of June 30, 2016 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, in July 2013, we filed a shelf registration statement on Form S-3, which was declared effective on August 19, 2013. Under the 2013 Form S-3 and amended At-Market Issuance Sales Agreements entered into with MLV LLC in connection therewith (the "2013 ATM"), we may offer and sell shares of our Common Stock having an aggregate offering price of up to \$70.0 million. As of June 30, 2016, approximately \$53 million remains available for issuance under the 2013 ATM.

*We have never paid and do not intend to pay cash dividends. As a result, capital appreciation, if any, will be your sole source of gain.*

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

*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**

(b) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
31.1	Certification of Chairman, President and Chief Executive Officer (Principal Executive Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Executive Vice President and Chief Financial Officer (Principal Financial Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chairman, President and Chief Executive Officer (Principal Executive Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Executive Vice President and Chief Financial Officer (Principal Financial Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Documents
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.

FORTRESS BIOTECH, INC.

August 9, 2016

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

August 9, 2016

By: /s/ Lucy Lu, M.D.  
Lucy Lu, M.D., Executive Vice President and Chief  
Financial Officer (Principal Financial Officer)

## EXHIBIT INDEX

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**FORTRESS BIOTECH, INC.**  
**CERTIFICATION PURSUANT TO**  
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Lindsay A. Rosenwald, M.D., Chairman, President and Chief Executive Officer (Principal Executive Officer), 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.

August 9, 2016

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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**FORTRESS BIOTECH, INC.**  
**CERTIFICATION PURSUANT TO**  
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Lucy Lu, M.D., Executive Vice President and Chief Financial Officer (Principal Financial Officer), 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.

August 9, 2016

By: /s/ Lucy Lu, M.D.  
Lucy Lu, M.D.  
Executive Vice President and Chief Financial Officer  
(Principal Financial Officer)

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**FORTRESS BIOTECH, INC.**  
**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 of Fortress Biotech, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2016, 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, 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.

August 9, 2016

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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**FORTRESS BIOTECH, INC.**  
**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 of Fortress Biotech, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lucy Lu, Executive Vice President and Chief Financial Officer, 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.

August 9, 2016

By: /s/ Lucy Lu, M.D.  
Lucy Lu, M.D.  
Executive Vice President and Chief Financial Officer  
(Principal Financial Officer)

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