

ENNIS, INC.  
Form 4  
August 03, 2009

**FORM 4**

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

OMB APPROVAL

OMB Number: 3235-0287  
Expires: January 31, 2005  
Estimated average burden hours per response... 0.5

Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. See Instruction 1(b).

**STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES**

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person \*  
Bracken Frank

(Last) (First) (Middle)

85 KENNINGTON COURT

(Street)

DALLAS, TX 75248

(City) (State) (Zip)

2. Issuer Name and Ticker or Trading Symbol  
ENNIS, INC. [EBF]

3. Date of Earliest Transaction  
(Month/Day/Year)  
07/23/2009

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

Director  10% Owner  
 Officer (give title below)  Other (specify below)

6. Individual or Joint/Group Filing(Check Applicable Line)  
 Form filed by One Reporting Person  
 Form filed by More than One Reporting Person

**Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned**

1. Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)	4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)	5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Ownership (Instr. 4)
				Code V	Amount (A) or (D) Price		
Common Stock	07/23/2009	07/23/2009	A	500	A \$ 14.55	7,900	D
Common Stock	07/23/2009	07/23/2009	A	500	A \$ 14.77	8,400	D

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

**Persons who respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.**

SEC 1474 (9-02)

**Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned (e.g., puts, calls, warrants, options, convertible securities)**

Edgar Filing: ENNIS, INC. - Form 4

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)	5. Number of Derivative Securities Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amount of Underlying Securities (Instr. 3 and 4)	8. Price of Derivative Security (Instr. 5)	9. Number of Derivative Securities Owned Following Transaction (Instr. 5)
--	--	--------------------------------------	--	--------------------------------	---	--	---	--	---

## Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
Bracken Frank 85 KENNINGTON COURT DALLAS, TX 75248	X			

## Signatures

Richard L. Travis, Jr.,  
Attorney-in-Fact

08/03/2009

\_\_\_\_\_  
Signature of Reporting Person

\_\_\_\_\_  
Date

## Explanation of Responses:

\* If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

\*\* Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure. Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number.

FOR THE QUARTER ENDED JUNE 30, 2015

### TABLE OF CONTENTS

	Page
	No.
<u>PART I. FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements</u>	3

<u>Condensed Consolidated Balance Sheets as of June 30, 2015 and December 31, 2014</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2015 and 2014</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2015 and 2014</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2015 and 2014</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	22
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	35
Item 4. <u>Controls and Procedures</u>	35
<u>PART II. OTHER INFORMATION</u>	37
Item 1. <u>Legal Proceedings</u>	37
Item 1A. <u>Risk Factors</u>	37
Item 5. <u>Other Information</u>	56
Item 6. <u>Exhibits</u>	57
<u>Signatures</u>	58

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements.

## AVEO PHARMACEUTICALS, INC.

## Condensed Consolidated Balance Sheets

(In thousands, except par value amounts)

(Unaudited)

	June 30, 2015	December 31, 2014
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$26,766	\$52,306
Restricted cash	2,862	2,997
Accounts receivable	2,320	2,341
Prepaid expenses and other current assets	1,428	1,484
<b>Total current assets</b>	<b>33,376</b>	<b>59,128</b>
Property and equipment, net	131	11,295
Other assets	188	239
<b>Total assets</b>	<b>\$33,695</b>	<b>\$70,662</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$1,567	\$3,245
Accrued expenses	4,551	9,301
Loans payable, net of discount	7,985	11,722
Deferred revenue	384	537
Lease exit obligation	—	4,981
Deferred rent	—	10,569
<b>Total current liabilities</b>	<b>14,487</b>	<b>40,355</b>
Loans payable, net of current portion and discount	7,316	8,930
Other liabilities	656	771
<b>Stockholders' equity:</b>		
Preferred stock, \$.001 par value: 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$.001 par value: 200,000 shares authorized; 55,716 and 52,289 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	56	52
Additional paid-in capital	507,538	500,582
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(496,358)	(480,028)
<b>Total stockholders' equity</b>	<b>11,236</b>	<b>20,606</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$33,695</b>	<b>\$70,662</b>

Explanation of Responses:

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

3

---

## AVEO PHARMACEUTICALS, INC.

## Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
			June 30,	
	June 30, 2015	2014	2015	2014
Collaboration revenue	\$134	\$1,846	\$268	\$17,135
Operating expenses:				
Research and development	1,841	9,300	4,536	21,067
General and administrative	2,889	4,846	6,144	10,400
Restructuring and lease exit	25	5,165	4,358	9,025
	4,755	19,311	15,038	40,492
Loss from operations	(4,621 )	(17,465 )	(14,770 )	(23,357 )
Other income and expense:				
Other (expense) income, net	(209 )	(2 )	(223 )	5
Interest expense	(633 )	(502 )	(1,349 )	(1,083 )
Interest income	7	10	12	26
Other expense, net	(835 )	(494 )	(1,560 )	(1,052 )
Net loss	\$(5,456 )	\$(17,959 )	\$(16,330 )	\$(24,409 )
Net loss per share – basic and diluted	\$(0.10 )	\$(0.35 )	\$(0.30 )	\$(0.47 )
Weighted average number of common shares outstanding	55,164	51,663	53,908	51,649

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

## AVEO PHARMACEUTICALS, INC.

## Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Net loss	\$ (5,456)	\$ (17,959)	\$ (16,330)	\$ (24,409)
Other comprehensive (loss) income:				
Unrealized (loss) gain on available-for-sale securities		(4 )		4
Comprehensive loss	\$ (5,456)	\$ (17,963)	\$ (16,330)	\$ (24,405)

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

## AVEO PHARMACEUTICALS, INC.

## Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended	
	June 30, 2015	2014
Operating activities		
Net loss	\$ (16,330 )	\$ (24,409 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of property and equipment	232	7,600
Depreciation and amortization	9,464	1,690
Accretion	224	—
Loss on disposal of fixed assets	245	18
Stock-based compensation	838	1,366
Non-cash interest expense	244	100
Amortization of premium and discount on investments	33	197
Changes in operating assets and liabilities:		
Restricted cash	135	46
Accounts receivable	21	(251 )
Tenant improvement allowance receivable	—	(9,069 )
Prepaid expenses and other current assets	56	(672 )
Other noncurrent assets	51	192
Accounts payable	(1,678 )	(738 )
Accrued expenses	(4,743 )	3,763
Deferred revenue	(153 )	(17,136 )
Lease exit obligation	(5,205 )	7,646
Deferred rent	(10,569 )	(5,563 )
Other liabilities	(115 )	—

Explanation of Responses:

Edgar Filing: ENNIS, INC. - Form 4

Net cash used in operating activities	(27,250 )	(35,220 )
Investing activities		
Purchases of marketable securities	(8,808 )	(38,056 )
Proceeds from maturities and sales of marketable securities	8,775	83,967
Purchases of property and equipment	—	(11,833 )
Proceeds from sale of property and equipment	1,221	—
Net cash provided by investing activities	1,188	34,078
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	5,840	—
Proceeds from exercise of stock options and issuance of common and restricted stock	275	30
Principal payments on loans payable	(5,593 )	(6,352 )
Net cash provided by (used in) financing activities	522	(6,322 )
Net decrease in cash and cash equivalents	(25,540 )	(7,464 )
Cash and cash equivalents at beginning of period	52,306	50,826
Cash and cash equivalents at end of period	\$ 26,766	\$ 43,362
Supplemental cash flow information		
Cash paid for interest	\$ 1,162	\$ 1,040

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



AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

## (1) Organization

AVEO Pharmaceuticals, Inc. (the “Company”) is a biopharmaceutical company committed to developing targeted therapies through biomarker-driven insights to provide substantial improvements in patient outcomes where significant unmet medical needs exist. The Company’s proprietary platform has delivered unique insights into cancer and related diseases. The Company’s development programs, which seek to advance its clinical stage assets, are as follows:

- (i) **Tivozanib:** A potent, selective, long half-life vascular endothelial growth factor (“VEGF”) tyrosine kinase inhibitor (“TKI”) of VEGF receptors 1, 2 and 3. The Company is evaluating several paths for the development of tivozanib, including a second phase 3 trial of tivozanib in refractory renal cell carcinoma, or RCC, to support an application for U.S. regulatory approval; the filing of a Marketing Authorization Application to seek European regulatory approval for tivozanib in RCC on the basis of existing trial data; and a phase 2 study for tivozanib in the first line treatment of metastatic colorectal cancer, or CRC, in a subgroup of patients with low serum neuropilin-1 (below the median, representing 50% of the population), a cell surface protein that modulates blood vessel development. Furthermore, the Company has entered into agreements to allow it to monetize tivozanib in areas outside of the Company’s core strategic focus. The Company has granted Ophthotech Corporation an option to develop and commercialize tivozanib for use in non-oncologic ocular conditions, and the Company has sublicensed to a subsidiary of Pharmstandard OJCE exclusive rights to develop and commercialize tivozanib for all conditions (excluding non-oncologic ocular conditions) in Russia, Ukraine and the Commonwealth of Independent States (CIS).
- (ii) **Ficlatuzumab:** A potent Hepatocyte Growth Factor inhibitory antibody. The Company has entered into a partnership with Biodesix, Inc. (“Biodesix”) to develop and commercialize ficlatuzumab with BDX004, a serum based diagnostic test. Pursuant to the Biodesix agreement, the Company has initiated a phase 2 confirmatory study of ficlatuzumab (the “FOCAL” study) in combination with erlotinib, an epidermal growth factor receptor (“EGFR”) TKI, in first line advanced non-small cell lung cancer patients who have an EGFR mutation and who are identified by the BDX004 test as being most likely to benefit from the addition of ficlatuzumab to erlotinib.
- (iii) **AV-203:** A potent anti-ErbB3 (also known as HER3) specific monoclonal antibody with high ErbB3 affinity. The Company has observed potent anti-tumor activity in mouse models. AV-203 selectively inhibits the activity of the ErbB3 receptor, and the Company’s preclinical studies suggest that neuregulin-1 (also known as heregulin), levels predict AV-203 anti-tumor activity in preclinical models. The Company has completed a phase 1 dose escalation study of AV-203. The Company is seeking to pursue further clinical development of AV-203 with a strategic partner.
- (iv) **AV-380:** A potent humanized IgG1 inhibitory monoclonal antibody targeting growth differentiating factor-15, (“GDF15”), a divergent member of the TGF- $\beta$  family, for the potential treatment or prevention of cachexia, a serious and common complication of advanced cancer and a number of chronic diseases including chronic kidney disease, congestive heart failure and chronic obstructive pulmonary disease. The Company has established preclinical proof of concept for GDF15 as a key driver of cachexia. The Company is evaluating partnership opportunities to continue the development of AV-380.

As used throughout these condensed consolidated financial statements, the terms “AVEO,” and the “Company” refer to the business of AVEO Pharmaceuticals, Inc. and its subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation, both of which are wholly-owned.

The Company has devoted substantially all of its resources to its drug discovery efforts, comprising research and development, conducting clinical trials for its product candidates, protecting its intellectual property and the general and administrative functions relating to these operations.

The Company has an accumulated deficit as of June 30, 2015 of approximately \$496.4 million, and will require substantial additional capital for research and product development.

(2) Basis of Presentation

These condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation. The Company has eliminated all significant intercompany accounts and transactions in consolidation.

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with 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 generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the condensed consolidated financial statements have been included. Interim results for the three and six months ended June 30, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015 or any other future period.

The information presented in the condensed consolidated financial statements and related footnotes at June 30, 2015, and for the three and six months ended June 30, 2015 and 2014, is unaudited and the condensed consolidated balance sheet amounts and related footnotes as of December 31, 2014 have been derived from the Company's audited financial statements. For further information, refer to the consolidated financial statements and accompanying footnotes included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2014, which was filed with the U.S. Securities and Exchange Commission ("SEC") on March 6, 2015.

### (3) Significant Accounting Policies

#### Revenue Recognition

The Company's revenues are generated primarily through collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses, or options to obtain licenses, to the Company's technology, (ii) research and development activities to be performed on behalf of the collaborative partner, and (iii) in certain cases, services in connection with the manufacturing of pre-clinical and clinical material. Payments to the Company under these arrangements typically include one or more of the following: non-refundable, up-front license fees; option exercise fees; funding of research and/or development efforts; milestone payments; and royalties on future product sales.

When evaluating multiple element arrangements, the Company considers whether the deliverables under the arrangement represent separate units of accounting. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the relevant facts and circumstances for each arrangement. The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units.

The Company determines the estimated selling price for deliverables within each agreement using vendor-specific objective evidence ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE is not available, or best estimate of selling price if neither VSOE nor TPE is available. Determining the best estimate of selling price for a deliverable requires significant judgment. The Company typically uses best estimate of selling price to estimate the selling price for licenses to the Company's proprietary technology, since the Company often does not have VSOE or TPE of selling price for these deliverables. In those circumstances where the Company utilizes best estimate of selling price to determine the estimated selling price of a license to the Company's proprietary technology, the Company considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements and internally developed models that include assumptions related to the market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating the Company's best estimate of selling price, the Company evaluates

whether changes in the key assumptions used to determine the best estimate of selling price will have a significant effect on the allocation of arrangement consideration among multiple deliverables.

The Company typically receives non-refundable, up-front payments when licensing its intellectual property in conjunction with a research and development agreement. When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, the Company generally recognizes revenue attributed to the license on a straight-line basis over the Company's contractual or estimated performance period, which is typically the term of the Company's research and development obligations. If management cannot reasonably estimate when the Company's performance obligation ends, then revenue is deferred until management can reasonably estimate when the performance obligation ends. When management believes the license to its intellectual property has stand-alone value, the Company generally recognizes revenue attributed to the license upon delivery. The periods over which revenue should be recognized are subject to estimates by management and may change over the course of the research and development agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Payments or reimbursements resulting from the Company's research and development efforts for those arrangements where such efforts are considered as deliverables are recognized as the services are performed and are presented on a gross basis so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is reasonably assured. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance, and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

The Company aggregates its milestones into four categories: (i) clinical and development milestones, (ii) regulatory milestones, (iii) commercial milestones, and (iv) patent-related milestones. Clinical and development milestones are typically achieved when a product candidate advances into a defined phase of clinical research or completes such phase. For example, a milestone payment may be due to the Company upon the initiation of a phase 3 clinical trial for a new indication, which is the last phase of clinical development and could eventually contribute to marketing approval by the U.S. Food and Drug Administration ("FDA") or other global regulatory authorities. Regulatory milestones are typically achieved upon acceptance of the submission for marketing approval of a product candidate or upon approval to market the product candidate by the FDA or other global regulatory authorities. For example, a milestone payment may be due to the Company upon the FDA's acceptance of a New Drug Application ("NDA"). Commercial milestones are typically achieved when an approved pharmaceutical product reaches certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. Patent-related milestones are typically achieved when a patent application is filed or a patent is issued with respect to certain intellectual property related to the applicable collaboration.

Revenues from clinical and development, regulatory, and patent-related milestone payments, if the milestones are deemed substantive and the milestone payments are nonrefundable, are recognized upon successful accomplishment of the milestones. The Company has concluded that the clinical and development, regulatory and patent-related milestones pursuant to its current research and development arrangements are substantive. Milestones that are not considered substantive are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance. Revenues from commercial milestone payments are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

#### Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including personnel-related costs such as salaries and stock-based compensation, facilities, research-related overhead, clinical trial costs, manufacturing costs and costs of other contracted services, license fees, and other external costs. Nonrefundable 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.

#### 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 equivalents at June 30, 2015 consisted of money market funds, U.S. government agency securities, and corporate debt securities, including commercial paper, maintained by an investment manager totaling \$17.6 million. Cash equivalents at December 31, 2014 consisted of money market funds, U.S. government agency securities and corporate debt securities, including commercial paper, maintained by an investment manager totaling \$36.6 million. The carrying values of our cash equivalent securities approximate fair value due to their short term maturities.

#### Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits.

Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

#### Fair Value Measurements

The Company records cash equivalents at fair value. The accounting standards for fair value measurements establish a hierarchy that distinguishes between fair value measurements based on market data (observable inputs) and those based on the Company's own assumptions (unobservable inputs). The hierarchy consists of three levels:

- Level 1—Quoted market prices in active markets for identical assets or liabilities. Assets that are valued utilizing only Level 1 inputs include money market funds.
- Level 2—Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves. Assets that are valued utilizing Level 2 inputs include U.S. government agency securities, and corporate bonds, including commercial paper. These investments have been initially valued at the transaction price and are subsequently valued, at the end of each reporting period, utilizing third party pricing services or other observable market data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates, and other industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by pricing services as of June 30, 2015.
- Level 3—Unobservable inputs developed using estimates and assumptions developed by the Company, which reflect those that a market participant would use. The Company currently has no assets or liabilities measured at fair value on a recurring basis that utilize Level 3 inputs.

The following tables summarize the cash equivalents measured at fair value on a recurring basis in the accompanying condensed consolidated balance sheets as of June 30, 2015 and December 31, 2014.

Fair Value Measurements of Cash Equivalents as of June 30, 2015				
	Level	Level		
	1	2	3	Total
	(in thousands)			
Cash equivalents	\$ 14,299	\$ 3,252	\$ —	\$ 17,551

  

Fair Value Measurements of Cash Equivalents as of December 31, 2014				
	Level	Level		
	1	2	3	Total
	(in thousands)			
Cash equivalents	\$ 28,777	\$ 7,834	\$ —	\$ 36,611

The fair value of the Company's loans payable at June 30, 2015, computed pursuant to a discounted cash flow technique using a market interest rate, is \$15.9 million and is considered a Level 3 fair value measurement. The effective interest rate, which reflects the current market rate, considers the fair value of the warrant issued in connection with the loan, loan issuance costs and the deferred financing charge.

#### Explanation of Responses:

## Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repair costs are charged to expense as incurred. During the quarter ended June 30, 2015, the Company transitioned to new office space and, as a result, revised the estimated useful life of its office furniture, resulting in an increase in depreciation expense of approximately \$0.4 million during the three months and six months ended June 30, 2015, respectively.

## Long-lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever changes in business circumstances indicate that the carrying amount of the asset may not be fully recoverable. No impairment charges were recognized during the three months ended June 30, 2015. The Company recognized \$0.2 million of impairment losses for the six months ended June 30, 2015 related to leasehold improvements. The Company recognized \$5.1 million and \$7.6 of impairment losses for the three and six months ended June 30, 2014 related to leasehold improvements.

## Basic and Diluted Loss per Common Share

Basic (loss) earnings per share is computed by dividing net (loss) income available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted (loss) earnings per share is computed by dividing net (loss) income available to common stockholders by the weighted-average number of common shares and dilutive common share equivalents then outstanding which exclude unvested restricted stock. Potential common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants. Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per common share is the same.

The following table sets forth for the periods presented the potential common shares excluded from the calculation of net loss per common share because their inclusion would have been anti-dilutive:

	Outstanding at	
	June 30, 2015	2014
Options outstanding	6,420	6,243
Warrants outstanding	609	—
	7,029	6,243

## Stock-Based Compensation

Under the Company's stock-based compensation programs, the Company periodically grants stock options and restricted stock to employees, directors and nonemployee consultants. The Company also issues shares under an employee stock purchase plan. The fair value of all awards is recognized in the Company's statements of operations over the requisite service period for each award. Awards that vest as the recipient provides service are expensed on a straight-line basis over the requisite service period. Other awards, such as performance-based awards that vest upon the achievement of specified goals, are expensed using the accelerated attribution method if achievement of the specified goals is considered probable. The Company has also granted awards that vest upon the achievement of market conditions. Per ASC 718 Share-Based Payments, market conditions must be considered in determining the estimated grant-date fair value of share-based payments and the market conditions must be considered in determining the requisite service period over which compensation cost is recognized. The Company estimates the fair value of the awards with market conditions using a Monte Carlo simulation, which utilizes several assumptions including the risk-free interest rate, the volatility of the Company's stock and the exercise behavior of award recipients. The grant-date fair value of the awards is then recognized over the requisite service period, which represents the derived service period for the awards as determined by the Monte Carlo simulation.

The fair value of equity-classified awards to employees and directors are measured at fair value on the date the awards are granted. Awards to nonemployee consultants are recorded at their fair values and are re-measured as of each balance sheet date until the recipient's services are complete. During the three and six months ended June 30, 2015 and June 30, 2014, the Company recorded the following stock-based compensation expense:

	Three Months Ended	Six Months Ended

Explanation of Responses:

Edgar Filing: ENNIS, INC. - Form 4

	June 30,		June 30,	
	2015	2014	2015	2014
	(in thousands)			
Research and development	\$63	\$197	\$188	\$515
General and administrative	348	459	581	851
Restructuring			69	
	\$411	\$656	\$838	\$1,366

Stock-based compensation expense is allocated to research and development and general and administrative expense based upon the department of the employee to whom each award was granted. Expenses recognized in connection with the modification of awards in connection with the Company's strategic restructurings are allocated to restructuring expense. No related tax benefits of the stock-based compensation expense have been recognized.

#### Income Taxes

The Company provides for income taxes using the asset-liability method. Under this method, deferred tax assets and liabilities are recognized based on differences between financial reporting and tax bases of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Uncertain tax positions are recognized if the position is more-likely-than-not to be sustained upon examination by a tax authority. Unrecognized tax benefits represent tax positions for which reserves have been established. The Company maintains a full valuation allowance on all deferred tax assets.

## Segment and Geographic Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment principally in the United States. As of June 30, 2015, the Company has \$1.0 million of net assets located in the United Kingdom.

## Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (“GAAP”) requires the Company’s management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

## Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements adopted by the Company, please refer to Note 2, “Significant Accounting Policies,” included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 6, 2015. The Company did not adopt any new accounting pronouncements during the six months ended June 30, 2015 that had a material effect on the Company’s condensed consolidated financial statements.

In May 2014, the FASB issued a comprehensive new revenue recognition standard that will supersede nearly all existing revenue recognition guidance under US GAAP. The standard was originally scheduled to be effective for public entities for annual and interim periods beginning after December 15, 2016. In July 2015, the standard was deferred and will now be effective for annual and interim periods beginning after December 15, 2017. Early adoption is not permitted. The Company is currently evaluating what effect, if any, this standard will have on its revenue recognition policies and its financial statements, including how the standard will be adopted.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. This ASU is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern within one year of the date of issuance of the entity’s financial statements and to provide related footnote disclosures. This guidance is effective for fiscal years beginning after December 15, 2016, with early application permitted. The Company is currently evaluating what effect, if any, the adoption of this guidance will have on the disclosures included in its condensed consolidated financial statements.

In April 2015, the FASB issued a standard that will require that debt issuance costs be presented in the balance sheet as a reduction of the carrying amount of the associated liability, consistent with debt discounts. The standard is effective for public entities for annual and interim periods beginning after December 15, 2015. The Company does not believe the adoption of this standard will have a material effect on its financial statements.

## (4) Collaborations and License Agreements

Ophthotech Corporation

In November 2014 the Company entered into a Research and Exclusive Option Agreement (the “Option Agreement”) with Ophthotech Corporation (“Ophthotech”). Under the Option Agreement, the Company granted Ophthotech an option to exclusively license the right to develop and commercialize tivozanib in all territories outside of Asia for the potential diagnosis, prevention and treatment of non-oncologic diseases or conditions of the eye in humans.

Pursuant to this Option Agreement, the Company granted to Ophthotech an exclusive, royalty free license or sublicense, as applicable, under intellectual property rights controlled by the Company solely to perform the research and development activities related to the use of tivozanib for the specific purposes outlined in the agreement during the option period (as defined below). These activities include formulation work for ocular administration, preclinical research and the conduct of a phase 1/2a, proof of concept clinical trial of a product containing tivozanib in patients with wet age-related macular degeneration (the “POC Study”).

Ophthotech paid the Company \$500,000 in consideration for the grant of the option. Such amount is non-refundable and not creditable against any other amounts due under the agreement. The Company is obligated to make available to Ophthotech, at no cost to Ophthotech, certain quantities of tivozanib hydrochloride solely for conducting its option period research including manufacturing additional quantities of tivozanib in the event stability data indicates that the current supply will expire prior to the end of February 2017.

During the option period, if Ophthotech elects to continue the development of tivozanib for non-oncologic diseases of the eye, the Company is entitled to receive a one-time milestone payment of \$2.0 million upon acceptance of the first Investigational New Drug application for the purpose of conducting a human clinical study of tivozanib in ocular diseases (the “IND Submission Milestone Payment”). The Company is also entitled to receive a one-time milestone payment of \$6.0 million (the “Clinical Efficacy Milestone Payment”) on the earlier of (a) December 31, 2016 and (b) the later to occur of: (i) the achievement of a clinical milestone in the POC Study (the “Clinical Efficacy Milestone”) and (ii) the earlier of (A) the date twelve (12) months after the Company and Ophthotech’s agreement as to the form and substance of the KHK Amendment (as defined below) or (B) the date ninety (90) days after the entry into the KHK Amendment, subject to the Company’s right to terminate the Option Agreement on 90 days’ written notice (the date on which such payment is due, referred to as the “Clinical Efficacy Milestone Payment Trigger Date”).

If the option is exercised, the resulting license agreement would entitle the Company to receive (i) \$10.0 million assuming certain efficacy and safety endpoints in phase 2 clinical trials that would enable the commencement of a phase 3 clinical trial are met, (ii) \$20.0 million upon marketing approval in the United States, (iii) \$20.0 million upon marketing approval in the UK, Germany, Spain, Italy and France and (iv) up to \$45.0 million in sales-based milestone payments. Ophthotech would also be required to pay tiered, double digit royalties, up to the mid-teens, on net sales of tivozanib or products containing tivozanib.

Activities under the agreement with Ophthotech were evaluated under ASC 605-25 Revenue Recognition—Multiple Element Arrangements, or ASC 605-25, to determine whether such activities represented a multiple element revenue arrangement. The agreement with Ophthotech includes the following non-contingent deliverables: the Company’s obligation to grant an exclusive option to Ophthotech to enter into a license agreement to develop and commercialize products incorporating tivozanib for treatment of AMD and other diseases of the eye outside of Asia during the option period; the Company’s obligation to enter into an amendment with KHK to modify the terms of the existing KHK agreement to negotiate a mutually acceptable form of license agreement; and the Company’s obligation to transfer research-grade tivozanib API for Ophthotech to conduct the option period research.

The Company determined that the delivered Option Grant Deliverable, or the Company’s obligation to grant an exclusive option to Ophthotech to enter into a license agreement to develop and commercialize products incorporating tivozanib for treatment of AMD and other diseases of the eye outside of Asia during the option period, did not have stand-alone value from the remaining deliverables since Ophthotech could not obtain the intended benefit of the option without the remaining deliverables. Similarly, the remaining deliverables have no stand-alone value without the Option Grant Deliverable. The Company is accounting for the deliverables as one unit of accounting.

Under the agreement, the Company received a cash payment of \$0.5 million during the year ended December 31, 2014. The Company deferred the payment and is recording the deferred revenue over the Company’s period of performance, which is estimated to be through December 2016. The Company recorded approximately \$58,000 and \$0.1 million of revenue during the three and six months ended June 30, 2015, respectively.

## Biodesix

In April 2014, the Company entered into a worldwide agreement with Biodesix to develop and commercialize its hepatocyte growth factor (“HGF”) inhibitory antibody ficlatuzumab, with BDX004, a proprietary companion diagnostic test developed by Biodesix and derived from VeriStrat<sup>®</sup>, a serum protein test that is commercially available to help physicians guide treatment decisions for patients with advanced non-small cell lung cancer (“NSCLC”). Under the agreement, the Company granted Biodesix perpetual, non-exclusive rights to certain intellectual property, including all clinical and biomarker data related to ficlatuzumab, to develop and commercialize BDX004. Biodesix granted the Company perpetual, non-exclusive rights to certain intellectual property, including diagnostic data related to BDX004, with respect to the development and commercialization of ficlatuzumab; each license includes the right to sublicense, subject to certain exceptions. Pursuant to a joint development plan to be agreed upon by a joint steering committee, the Company retains primary responsibility for clinical development of ficlatuzumab in a proof of concept (“POC”)

clinical study of ficlatuzumab for NSCLC, in which VeriStrat will be used to select clinical trial subjects, referred to as the NSCLC POC Trial. The NSCLC POC Trial will be fully funded by Biodesix up to a maximum of \$15.0 million, referred to as the “Cap”. After the Cap is reached, the Company and Biodesix will share equally in the costs of the NSCLC trial, and the Company and Biodesix will each be responsible for 50% of development and regulatory costs associated with all future clinical trials agreed-upon by Biodesix and the Company, including all milestone payments and royalties payable to third parties, if any.

Pending marketing approval of ficlatuzumab and subject to a commercialization agreement to be entered into after receipt of results from the NSCLC POC Trial, each party would share equally in commercialization profits and losses, subject to the Company’s right to be the lead commercialization party.

Biodesix is solely responsible for the BDX004 development costs, as well as BDX004 sales and marketing costs. Subject to and following the approval of the BDX004 test as a companion diagnostic for ficlatuzumab, Biodesix has agreed to make the BDX004 test

available and use commercially reasonable efforts to seek reimbursement in all geographies where ficlatuzumab is approved. The Company has agreed to reimburse Biodesix a pre-specified amount, under certain circumstances for BDX004 tests performed.

Prior to the first commercial sale of ficlatuzumab and after the earlier of (i) the Cap being reached or (ii) the completion of the NSCLC POC Trial, each party has the right to elect to discontinue participating in further development or commercialization efforts with respect to ficlatuzumab, which is referred to as an “Opt-Out”. If either AVEO or Biodesix elects to Opt-Out, with such party referred to as the “Opting-Out Party”, then the Opting-Out Party shall not be responsible for any future costs associated with developing and commercializing ficlatuzumab other than any ongoing clinical trials. After election of an Opt-Out, the non-opting out party shall have sole decision-making authority with respect to further development and commercialization of ficlatuzumab. Additionally, the Opting-Out Party shall be entitled to receive, if ficlatuzumab is successfully developed and commercialized, a royalty equal to 10% of net sales of ficlatuzumab throughout the world, if any, subject to offsets under certain circumstances.

If Biodesix elects to Opt-Out, it will continue to be responsible for its development and commercialization obligations with respect to BDX004. If AVEO elects to Opt-Out, it will continue to make the existing supply of ficlatuzumab available to Biodesix for the purposes of enabling Biodesix to complete the development of ficlatuzumab, and Biodesix will have the right to commercialize ficlatuzumab.

Prior to any Opt-Out, the parties shall share equally in any payments received from a third party licensee; provided, however, after any Opt-Out, the Opting-Out Party shall be entitled to receive only a reduced portion of such third party payments. The agreement will remain in effect until the expiration of all payment obligations between the parties related to development and commercialization of ficlatuzumab, unless earlier terminated.

Activities under the agreement with Biodesix were evaluated under ASC 605-25 Revenue Recognition—Multiple Element Arrangements, or ASC 605-25, to determine whether such activities represented a multiple element revenue arrangement. The agreement with Biodesix includes the following non-contingent deliverables: perpetual, non-exclusive rights to certain intellectual property including clinical and biomarker data related to ficlatuzumab for use in developing and commercializing BDX004; the Company’s obligation to deliver technology improvements and data developed during the NSCLC POC Trial to Biodesix; the Company’s obligation to participate in the joint steering committee during the NSCLC POC Trial; the Company’s obligation to perform certain development activities associated with the NSCLC POC Trial; and the Company’s obligation to supply clinical material for use in conducting the NSCLC POC Trial; and the Company’s obligation to deliver clinical specimens and data during the NSCLC POC Trial. The Company concluded that any deliverables that would be delivered after the NSCLC POC Trial is complete are contingent deliverables because these services are contingent upon the results of the NSCLC POC Trial. As these deliverables are contingent, and are not at an incremental discount, they are not evaluated as deliverables at the inception of the arrangement. These contingent deliverables will be evaluated and accounted for separately as each related contingency is resolved. As of June 30, 2015, no contingent deliverables had been provided by the Company.

The Company determined that the delivered item, or the perpetual, non-exclusive rights to certain intellectual property for use in developing and commercializing BDX004 did not have stand-alone value from the remaining deliverables since Biodesix could not obtain the intended benefit of the license without the remaining deliverables. Since the remaining deliverables will be performed over the same period of performance there is no difference in accounting for the deliverables as one unit or multiple units of accounting, and therefore, the Company is accounting for the deliverables as one unit of accounting.

The Company records the consideration earned while conducting the NSCLC POC Trial, which consists of reimbursements from Biodesix for expenses related to the trial under the Cap, as a reduction to research and development expense using the proportional performance method over the respective period of performance. As a result of the cost sharing provisions in the agreement, the Company reduced research and development expenses by approximately \$1.0 million and \$1.9 million during the three and six months ended June 30, 2015, respectively. The

Company reduced research and development expenses by approximately \$0.2 million during the three and six months ended June 30, 2014. The amount due to the Company from Biodesix pursuant to the cost-sharing provision was \$1.9 million at June 30, 2015. The Company received cash payments related to cost reimbursements of \$1.8 million during the six months ended June 30, 2015.

#### Biogen Idec International GmbH

In March 2009, the Company entered into an exclusive option and license agreement with Biogen Idec International GmbH, a subsidiary of Biogen Idec Inc., (collectively “Biogen Idec”) regarding the development and commercialization of the Company’s discovery-stage ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases outside of North America. Under the agreement, the Company is responsible for developing ErbB3 antibodies through completion of the first phase 2 clinical trial designed in a manner that, if successful, will generate data sufficient to support advancement to a phase 3 clinical trial.

In March 2014, the Company and Biogen Idec amended the exclusive option and license agreement (the “Amendment”). Pursuant to the Amendment, Biogen agreed to the termination of its rights and obligations under the agreement, including Biogen’s option to (i) obtain a co-exclusive (with AVEO) worldwide license to develop and manufacture ErbB3 targeted antibodies and (ii) obtain exclusive commercialization rights to ErbB3 products in countries in the world other than North America. As a result, AVEO has worldwide rights to AV-203. Pursuant to the Amendment, AVEO is obligated to use reasonable efforts to seek a collaboration partner for the purpose of funding further development and commercialization of ErbB3 targeted antibodies. AVEO is also obligated to pay Biogen a percentage of milestone payments received by AVEO from future partnerships after March 28, 2016 and single digit royalty payments on net sales related to the sale of ErbB3 products, if any, up to cumulative maximum amount of \$50 million.

Under the terms of the original agreement, Biogen Idec made up-front and milestone-based cash payments totaling \$20.0 million. Of the \$20.0 million received, \$10.0 million was associated with milestones that were considered substantive and these amounts were included in revenue when they were earned. The remaining \$10.0 million was amortized as additional license revenue over the Company’s period of substantial involvement.

The Company concluded that the Amendment materially modified the terms of the agreement and, as a result, required application of ASC 605-25. Based upon the terms of the Amendment, the remaining deliverables included the Company’s obligation to seek a collaboration partner to fund further development of the program and the Company’s obligation to continue development and commercialization of the licensed products if a collaboration partner is secured (“Development Deliverable”). The Company concluded that its obligation to use best efforts to seek a collaboration partner does not have stand-alone value from the Development Deliverable upon delivery and thus the deliverables should be treated as a single unit of accounting.

Upon modifying the arrangement, the Company had \$14.7 million of deferred revenue remaining to be amortized. The Company is not entitled to receive any further consideration from Biogen Idec under the amended arrangement. The Company allocated a portion of the remaining deferred revenue to the undelivered unit of accounting based upon the Company’s best estimate of the selling price, as the Company determined that neither VSOE or TPE were available. The Company determined the best estimate of selling price to be approximately \$0.6 million and recognized the remaining \$14.1 million as collaboration revenue in March 2014. The deferred revenue associated with the undelivered unit of accounting is being recognized on a straight-line basis over the expected period of performance, or through December 2015, based upon the Company’s historical experience with marketing its product candidates to potential partners.

The best estimate of selling price was based upon a cost approach pursuant to which the Company estimated the costs expected to be incurred in executing a partnership agreement and then applied a reasonable markup. The Company estimated future cash outflows for several possible outcomes, including the execution of a partnership at different times within a reasonable range and partnerships of differing complexity. The Company estimated its cash outflows for each scenario based upon the expected costs associated with the relevant employees and the expected level of effort to be expended to seek and execute a partnership. The Company’s analysis also considered the legal charges that it anticipates it will incur. Changes to the Company’s assumptions within the reasonable range of possible values would not have a material impact on the amounts recorded in current or future periods.

Under the agreement, the Company recorded revenue of \$0.1 million and \$0.2 million during the three and six months ended June 30, 2015, respectively. The Company also recorded \$0.1 million and \$14.4 million of revenue during the three and six month periods ended June 30, 2014, respectively.

#### Astellas Pharma

In February 2011, the Company, together with its wholly-owned subsidiary AVEO Pharma Limited, entered into a Collaboration and License Agreement with Astellas (the “Astellas Agreement”), pursuant to which the Company and Astellas intended to develop and commercialize tivozanib for the treatment of a broad range of cancers. Astellas

elected to terminate the Astellas Agreement effective on August 11, 2014, at which time the tivozanib rights were returned to the Company. In accordance with the Astellas Agreement, committed development costs, including the costs of completing certain tivozanib clinical development activities, are shared equally. There are no refund provisions in the Astellas Agreement.

The Company accounted for the joint development and commercialization activities in North America and Europe as a joint risk-sharing collaboration in accordance with ASC 808, Collaborative Arrangements. In addition, these activities were not deemed to be separate deliverables under the Astellas Agreement.

Payments from Astellas with respect to Astellas' share of tivozanib development and commercialization costs incurred by the Company pursuant to the joint development plan are recorded as a reduction to research and development expense and general and administrative expense in the accompanying condensed consolidated financial statements due to the joint risk-sharing nature of the activities in North America and Europe. Similarly, payments from the Company to Astellas with respect to the Company's share of

tivozanib development and commercialization costs incurred by Astellas pursuant to the joint development plan are recorded as a component of research and development expense and general and administrative expense in the accompanying condensed consolidated financial statements. As a result of the cost-sharing provisions in the Astellas Agreement, the Company decreased research and development expense by \$0.4 million and \$1.1 million during the three months ended June 30, 2015 and 2014, respectively, and by \$0.2 million and \$2.3 million during the six months ended June 30, 2015 and 2014, respectively. The net amount due to the Company from Astellas pursuant to the cost-sharing provisions was \$0.4 million and \$1.0 million at June 30, 2015 and 2014, respectively.

Under the agreement, the Company received cash payments related to cost reimbursements of \$34,000 and \$1.2 million during each of the three months ended June 30, 2015 and 2014, respectively, and \$0.6 million and \$2.2 million during each of the six months ended June 30, 2015 and 2014, respectively.

#### (5) Accrued Expenses

Accrued expenses consisted of the following as of June 30, 2015 and December 31, 2014:

	June 30, 2015	December 31, 2014
	(in thousands)	
Clinical expenses	\$ 1,255	\$ 2,312
Salaries and benefits	910	1,744
Restructuring	904	—
Professional fees	378	685
Manufacturing and distribution	90	3,216
Other	1,014	1,344
	\$4,551	\$ 9,301

#### (6) Loans Payable

On May 28, 2010, the Company entered into a loan and security agreement (the “Loan Agreement”) with Hercules Technology II, L.P. and Hercules Technology III, L.P., affiliates of Hercules Technology Growth (collectively, “Hercules”), pursuant to which the Company received a loan in the aggregate principal amount of \$25.0 million. The Company was required to repay the aggregate principal balance under the Loan Agreement in 30 equal monthly installments of principal starting on January 1, 2012. On March 31, 2012, the Company entered into an amendment to the Loan Agreement, pursuant to which the Company increased the principal amount under the Loan Agreement to \$26.5 million. Under the amendment to the Loan Agreement, the date on which the Company was required to begin repaying the aggregate principal balance was extended to April 1, 2013, at which point the Company began repaying such balance in 30 equal monthly installments.

On September 24, 2014, the Company further amended the Loan Agreement with Hercules (the “Amended Loan Agreement”). Pursuant to the Amended Loan Agreement, the Company received a new loan in the aggregate principal amount of \$10.0 million and amended the terms of the Loan Agreement with an outstanding principal balance of \$11.6 million.

Pursuant to the Amended Loan Agreement, the Company is not required to pay principal on the new loan of \$10.0 million for a period of time until November 1, 2015, provided, that such date may be extended if the Company achieves certain performance milestones, after which time, the Company is required to make monthly principal and interest payments with the entire loan due and payable on January 1, 2018. With respect to the Loan Agreement, the Company is not required to pay principal until January 1, 2015, at which time the Company is required to commence making 12 principal and interest payments. The Amended Loan Agreement has an end-of-term payment of approximately \$0.5 million due on January 1, 2018 or on such earlier date as the new loan is prepaid. The Company accounted for the Amended Loan Agreement as a loan modification in accordance with ASC 470-50, Debt—Modifications and Extinguishments.

The Company must make interest payments on both loans each month they remain outstanding. Per annum interest is payable on the principal balance of both loans at the greater of 11.9% and an amount equal to 11.9% plus the prime rate of interest minus 4.75% as determined daily, provided however, that the per annum interest shall not exceed 15.0% (currently 11.9%). With respect to the new loan of \$10.0 million, the unpaid principal balance and all accrued but unpaid interest will be due and payable on January 1, 2018, and with respect to the original loan with a principal balance of \$11.6 million, the unpaid principal balance and all accrued but unpaid interest will be due and payable on January 1, 2016.

In addition to the obligations and covenants currently existing under the Loan Agreement, the Amended Loan Agreement contains a financial covenant, whereby the Company has agreed to maintain, with respect to the new loan of \$10.0 million, a liquidity ratio equal to or greater than 1.25 to 1.00 or the equivalent of \$12.5 million in unrestricted and unencumbered cash and cash equivalents. The financial covenant shall not apply after such time that the Company receives favorable data both with respect to its phase 2 clinical trial of ficlatuzumab and a phase 1 clinical trial of AV-380. The Company was in compliance with this and all other financial covenants at June 30, 2015 that are included in the Amended Loan Agreement.

The Loan Agreement required a deferred financing charge of \$1.3 million which was paid in May 2012 related to the amendment of the Loan Agreement. The Loan Agreement also included an additional deferred financing charge of \$1.2 million which was paid in June 2014, and was recorded as a loan discount and is being amortized to interest expense over the term of the loan borrowed under the Loan Agreement using the effective interest rate method. The Company had recorded a liability for the full amount of the charge since the payment of such amount was not contingent on any future event. The Company incurred approximately \$0.2 million in loan issuance costs paid directly to Hercules under the Loan Agreement, which were offset against the loan proceeds and are accounted for as a loan discount.

As part of the Loan Agreement, on June 2, 2010, the Company issued warrants to the lenders to purchase up to 156,641 shares of the Company's common stock at an exercise price equal to \$7.98 per share. The Company recorded the relative fair value of the warrants of approximately \$0.8 million as stockholders' equity and as a discount to the related loan outstanding and is amortizing the value of the discount to interest expense over the term of the loan using the effective interest method. On July 21, 2011, Hercules exercised these warrants and they are no longer outstanding.

As part of the Amended Loan Agreement, on September 24, 2014, the Company issued warrants to the lenders to purchase up to 608,696 shares of the Company's common stock at an exercise price equal to \$1.15 per share. The Company recorded the relative fair value of the warrants of approximately \$0.4 million as stockholders' equity and as a discount to the related loan outstanding and is amortizing the value of the discount to interest expense over the term of the loan using the effective interest method.

As part of the Loan Agreement, Hercules also received an option, subject to the Company's written consent, not to be unreasonably withheld, to purchase, either with cash or through conversion of outstanding principal under the loan, up to \$2.0 million of equity of the Company sold in any sale by the Company to third parties of equity securities resulting in at least \$10.0 million in net cash proceeds to the Company, subject to certain exceptions. The Company has evaluated the embedded conversion option, and has concluded that it does not need to be bifurcated and separately accounted for. No amount will be recognized for the conversion feature until such time as the conversion feature is exercised and it can be determined whether a beneficial conversion feature exists. As of June 30, 2015, the aggregate principal balance outstanding was \$16.0 million.

The Amended Loan Agreement defines events of default, including the occurrence of an event that results in a material adverse effect upon the Company's business operations, properties, assets or condition (financial or otherwise), its ability to perform its obligations under and in accordance with the terms of the Amended Loan Agreement, or upon the ability of the lenders to enforce any of their rights or remedies with respect to such obligations, or upon the collateral under the Loan Agreement, the related liens or the priority thereof. The Company has determined that the risk of subjective acceleration under the material adverse events clause is remote and therefore has classified the outstanding principal in current and long-term liabilities based on the timing of scheduled principal payments.

Future minimum payments under the loans payable outstanding as of June 30, 2015 are as follows (amounts in thousands):

Edgar Filing: ENNIS, INC. - Form 4

Years Ending December 31:	
2015 (6 months remaining)	\$7,411
2016	4,644
2017	4,644
2018	2,096
	18,795
Less amount representing interest	(2,238 )
Less discount	(716 )
Less deferred charges	(540 )
Less current portion	(7,985 )
Loans payable, net of current portion and discount	\$7,316

(7) Common Stock

In February 2015, the Company entered into an at-the-market issuance sales agreement with MLV & Co. LLC (“MLV”), pursuant to which the Company could issue and sell shares of its common stock from time to time up to an aggregate amount of \$17.9 million, at the Company’s option, through MLV as its sales agent. Sales of common stock through MLV may be made by any method that is deemed an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including by means of ordinary brokers’ transactions at market prices, in block transactions or as otherwise agreed by the Company and MLV. Subject to the terms and conditions of the sales agreement between the Company and MLV (the “Sales Agreement”), MLV will use commercially reasonable efforts to sell the common stock based upon the Company’s instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company is not obligated to make any sales of its common stock under the Sales Agreement. Any shares sold will be sold pursuant to an effective shelf registration statement on Form S-3. The Company will pay MLV a commission of up to 3% of the gross proceeds. The Sales Agreement may be terminated by the Company at any time.

On May 7, 2015, the Company filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale by the Company of up to \$100.0 million of its common stock, preferred stock, debt securities, warrants and/or units (the “2015 Shelf”). The 2015 Shelf was filed to replace the Company’s existing \$250.0 million shelf registration statement (the “2012 Shelf”). On May 7, 2015, the Company amended its Sales Agreement with MLV (the “Amended Sales Agreement”) to provide for the offering, issuance and sale by the Company of up to \$15.0 million of its common stock under the 2015 Shelf, which replaced the Company’s existing \$17.9 million offering that expired along with the expired 2012 Shelf. As of June 30, 2015, the Company has sold approximately 3.4 million shares pursuant to the Sales Agreement and the Amended Sales Agreement, resulting in proceeds of approximately \$5.8 million, net of commissions and issuance costs.

Approximately \$13.5 million remains available for sale under the amended Sales Agreement.

(8) Stock-based Compensation

Stock Plans

The Company issued stock options and restricted stock awards during the six months ended June 30, 2015. A summary of the status of the Company’s stock option activity at June 30, 2015 and changes during the six months then ended is presented in the table and narrative below.

	Options	Exercise Price	Weighted-Average Remaining Contractual Term	Weighted-Average Aggregate Intrinsic Value
Outstanding at December 31, 2014	5,817,313	\$ 4.45		

Edgar Filing: ENNIS, INC. - Form 4

Granted	3,104,834	\$ 1.11		
Exercised	(163,305 )	\$ 1.46		
Forfeited	(2,338,733)	\$ 2.13		
Outstanding at June 30, 2015	6,420,109	\$ 3.75	7.48	\$1,797,511
Vested or expected to vest at June 30, 2015	3,311,468	\$ 5.97	5.75	\$551,581
Exercisable at June 30, 2015	2,313,241	\$ 7.71	4.25	\$133,884

Stock options to purchase 1,303,500 shares of common stock contain market conditions which were not deemed probable of vesting at June 30, 2015.

The fair value of stock options subject only to service or performance conditions that are granted to employees is estimated on the date of grant using the Black-Scholes option-pricing model using the assumptions noted in the following table:

	Three Months Ended	
	June 30,	
	2015	2014
Volatility factor	73.04%	<del>72.30%</del> 73.98%
Expected term (in years)	5.50-6.25	5.50-6.25
Risk-free interest rates	1.85%	1.88%
Dividend yield	—	—
	Six Months Ended	
	June 30,	
	2015	2014
Volatility factor	73.04%	<del>72.70%</del> 73.98%
Expected term (in years)	5.50-6.25	5.50-6.25
Risk-free interest rates	1.54-1.85%	1.88-2.02%
Dividend yield	—	—

The risk-free interest rate is determined based upon the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the options being valued. The Company does not expect to pay dividends in the foreseeable future.

The Company does not have sufficient history to support a calculation of volatility and expected term using only its historical data. As such, the Company has used a weighted-average volatility considering the Company's own volatility since March 2010, and the volatilities of several peer companies. For purposes of identifying similar entities, the Company considered characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. Due to lack of available option activity data, the Company elected to use the "simplified" method for "plain vanilla" options to estimate the expected term of the stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. Based upon these assumptions, the weighted-average grant date fair value of stock options granted to employees during the six months ended June 30, 2015 and 2014 was \$1.13 per share and \$0.83 per share, respectively.

The Company is required to include an estimate of the value of the awards that will be forfeited in calculating compensation costs, which the Company estimates based upon actual historical forfeitures. The forfeiture estimates are recognized over the requisite service period of the awards on a straight-line basis. The Company estimated its forfeiture rate to be approximately 71% and 57% as of June 30, 2015 and 2014, respectively.

As of June 30, 2015, there was \$1.2 million of total unrecognized stock-based compensation expense related to stock options granted to employees under the Company's 2002 Stock Incentive Plan and 2010 Stock Incentive Plan (collectively, the "Plans"). The expense is expected to be recognized over a weighted-average period of 3.2 years. The intrinsic value of options exercised during the three and six months ended June 30, 2015 was \$44,000 and \$57,000, respectively. No options were exercised during the three and six months ended June 30, 2014.

The restricted stock activity for the six months ended June 30, 2015 is as follows:

Explanation of Responses:

		Weighted-
		Average
	Number of Shares	Fair-Value
Unvested at December 31, 2014	477,600	\$ 1.81
Granted	—	—
Cancelled	(196,680 )	1.88
Expired	—	—
Vested/Released	(233,670 )	1.80
Unvested at June 30, 2015	47,250	\$ 1.61

As of June 30, 2015, there was approximately \$32,000 of total unrecognized stock-based compensation expense related to restricted stock awards granted under the Plans. The expense is expected to be recognized over a weighted-average period of 0.6 years.

## (9) Strategic Restructuring

On January 6, 2015, the Board of the Company approved a strategic restructuring of the Company that eliminated the Company's internal research function and aligned the Company's resources with the Company's future strategic plans. As part of this restructuring, the Company eliminated approximately two-thirds of the Company's workforce, or 40 positions across the organization. The Company substantially completed the restructuring during the quarter-ended March 31, 2015.

The following table summarizes the components of the Company's restructuring activity recorded in operating expenses and in current liabilities:

	Restructuring expense	Restructuring amounts paid	Restructuring amounts accrued at
	amounts during the six months ended December 31,	amounts during the six months ended June 30,	amounts accrued at June 30,
	2014	2015	2015
	(in thousands)		
Employee severance, benefits and related costs	\$— 3,560	\$ (2,656 )	904

The table above excludes non-cash stock-based compensation costs of approximately \$0.1 million incurred as part of the restructuring during the six months ended June 30, 2015.

## (10) Facility Lease Exit

In September 2014, the Company entered into the Lease Termination Agreement pursuant to which the Company immediately surrendered leased space that it had previously ceased using earlier in 2014. In connection with the Lease Termination Agreement, the Company agreed to pay the landlord a termination fee totaling \$15.6 million of which approximately \$5.0 remained due as of December 31, 2014. The Company also agreed to surrender its remaining leased space upon 90 days written notice prior to September 24, 2015. In February 2015, the Company provided notice that it would surrender the remaining space on May 29, 2015. Accordingly, the Company revised the estimated useful life of its leasehold improvements related to this office space and amortized such assets through May 2015, resulting in an additional \$2.9 million of depreciation expense during the six months ended June 30, 2015. Similarly, the Company accelerated the amortization of its deferred rent and leasehold improvement allowance associated with this office space through May 2015, resulting in an additional \$3.5 million of amortization during the six months ended June 30, 2015. Upon the surrender of the remaining space, the Company had no further rights or obligations

with respect to the lease. The Company has secured office space appropriate for its current needs under a cancellable arrangement that began in May 2015.

The following table summarizes the components of the Company's lease exit activity recorded in current liabilities:

	Accretion		Expense		Amounts
			incurred	paid	
			during the six	during the six	
			months ended	months ended	Additional expense incurred
Amounts accrued at			June 30,	June 30,	during the six months
December			2014	2015	ended June 30, 2015
31, 2014	2015				June
(in thousands)					30, 2015
Lease exit costs	\$4,981	\$ 224	\$ (5,477	) \$ 272	\$ -

In addition to the \$0.5 million of expense for the six months ended June 30, 2015 included in the table above, lease exit expenses also include the write-off of \$0.2 million of leasehold improvements.

#### (11) Legal Proceedings

Two purported shareholder class action lawsuits have been filed in the United States District Court for the District of Massachusetts against AVEO and certain of the Company's former officers and present and former directors (Tuan Ha-Ngoc, David N. Johnston, William Slichenmyer and Ronald DePinho). The cases were consolidated as *In re AVEO Pharmaceuticals, Inc. Securities Litigation*, No. 1:13-cv-11157-DJC, and in an amended complaint filed on February 3, 2014 the lead plaintiffs alleged that the Company made false and/or misleading statements concerning the development of the drug tivozanib and its prospects for FDA approval. The amended complaint sought unspecified damages, interest, attorneys' fees, and other costs. The Company moved to dismiss the amended complaint, and after briefing and oral argument, on March 20, 2015, the Court granted the Company's motion and dismissed the case without prejudice. The lead plaintiffs were allowed to amend and refile their complaint, and they filed a second

amended complaint bringing similar allegations. The Company filed a new motion to dismiss this second amended complaint on July 17, 2015, and the plaintiffs filed an opposition to that motion on July 31, 2015. The Company intends to continue to deny any allegations of wrongdoing and to vigorously defend against this lawsuit. However, there is no assurance that the Company will be successful in its defense or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of the action. Moreover, the Company is unable to predict the outcome or reasonably estimate a range of possible loss at this time.

On April 4, 2014, a different purported purchaser of AVEO stock filed a derivative complaint allegedly on behalf of AVEO in the United States District Court for the District of Massachusetts, captioned Van Ingen v. Ha-Ngoc, et al., No. 1:14-cv-11672-DJC. The suit named AVEO as a nominal defendant and also named as defendants present and former members of our board of directors, including Tuan Ha-Ngoc, Henri A. Termeer, Kenneth M. Bate, Anthony B. Evnin, Robert Epstein, Raju Kucherlapati, Robert C. Young, and Kenneth E. Weg. The complaint alleges breaches of fiduciary duty and abuse of control on the part of those directors. The complaint seeks, among other relief, unspecified damages, costs and expenses, including attorneys' fees, an order requiring us to implement certain corporate governance reforms, restitution from the defendants and such other relief as the court might find just and proper. The Company filed a motion to dismiss the derivative complaint, and after briefing and oral argument, on March 18, 2015 the Court ruled in our favor and dismissed the case with prejudice. The plaintiff then filed a motion seeking to vacate the Court's order of dismissal and permit filing of an amended complaint, which the Company opposed, and which the Court denied on June 30, 2015. The Plaintiff has appealed the Court's decision to the United States Court of Appeals for the First Circuit. The Company intends to continue to deny any allegations of wrongdoing and to vigorously defend against this lawsuit. However, there is no assurance that the Company will be successful in our defense or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of this action. Moreover, the Company is unable to predict the outcome or reasonably estimate a range of possible loss at this time.

On July 3, 2013, the Company received a subpoena from the SEC, requesting documents and information concerning tivozanib, including related communications with the FDA, investors and others. The Company is fully cooperating with the SEC regarding this fact-finding inquiry. The SEC has informed us that this inquiry should not be construed as an indication that any violations of law have occurred or that the SEC has any negative opinion of any person, entity or security.

## (12) Subsequent Events

### Pharmstandard Group

On August 4, 2015, the Company entered into an exclusive license agreement with JSC "Pharmstandard-Ufimskiy Vitamin Plant", or Pharmstandard, a subsidiary of Pharmstandard OJSC. Under the License Agreement, the Company granted to Pharmstandard the exclusive right to develop, manufacture and commercialize tivozanib in the territories of Russia, Ukraine and the Commonwealth of Independent States for all conditions excluding non-oncologic ocular conditions. Under this agreement, Pharmstandard is responsible for all activities and costs associated with the further development, regulatory filings, health services and commercialization of tivozanib in the specified territories. Pharmstandard is obligated under the agreement to make an upfront payment to the Company of \$1.5 million. The Company is also eligible to receive \$7.5 million in connection with the first marketing authorization of tivozanib in Russia. If Russian regulatory authorities require additional studies to be conducted prior to approval, this amount would be reduced to \$3.0 million. In addition, the Company is eligible to receive \$3.0 million for each additional approved indication of tivozanib, if Pharmstandard elects to seek any such approvals, as well as a high single-digit royalty on net sales in the sublicensed territories. A percentage of all upfront, milestone and royalty payments received by the Company are due to KHK as a sublicensing fee. The Company is currently evaluating the

accounting for this arrangement.

21

---

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

### Forward-Looking Information

This report contains forward-looking statements regarding, among other things, our future discovery and development efforts, our collaborations, our future operating results and financial position, our business strategy, and other objectives for our operations. You can identify these forward-looking statements by their use of words such as “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “plan,” “project,” “target,” “will” and other words and terms having similar meaning. You also can identify them by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery, preclinical trials and clinical development activities, our ability to obtain any necessary financing to conduct our planned activities, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our drug candidates, our ability to obtain, maintain and enforce intellectual property rights for our drug candidates, our dependence on our existing and future strategic partners, and other risk factors. Please refer to the section entitled “Risk Factors” in Item 1A of Part II and elsewhere in this report for a description of these risks and uncertainties. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.

### Company Overview

We are a biopharmaceutical company committed to developing targeted therapies through biomarker-driven insights to provide substantial improvements in patient outcomes where significant unmet medical needs exist. Our proprietary platform has delivered unique insights into cancer and related diseases. Our strategy is to leverage these biomarker insights and partner resources to advance the development of our clinical pipeline. As further described below, we currently are exploring partnership opportunities to fund the further development of three of our four development programs, including our lead program for tivozanib. Our development programs, which seek to advance our clinical stage assets, are as follows:

· **Tivozanib:** Tivozanib is a potent, selective, long half-life vascular endothelial growth factor (“VEGF”) tyrosine kinase inhibitor (“TKI”), of VEGF receptors 1, 2 and 3. In 2006, we acquired the exclusive rights to develop and commercialize tivozanib in all countries outside of Asia under a license from Kyowa Hakko Kirin (formerly Kirin Brewery Co. Ltd.), or KHK. We have programs to evaluate tivozanib in several tumor types, including renal cell, colorectal and breast cancer.

**Initial RCC Phase 3 Trial (TIVO-1):** We conducted a global phase 3 clinical trial comparing the efficacy and safety of tivozanib with Nexavar<sup>®</sup> (sorafenib), an approved therapy, for first-line treatment of renal cell carcinoma, or RCC. The trial met its primary endpoint for progression-free survival, or PFS, but showed a non-statistically significant trend favoring the sorafenib arm in overall survival, OS. In June 2013, the U.S. Food and Drug Administration, or FDA, issued a complete response letter informing us that it would not approve tivozanib for the treatment of first line advanced RCC based on the study data from this trial, and recommended that we perform an additional study that is adequately sized to reassure the FDA that there is no adverse effect on OS.

**TIVO-1 Extension Study Results (One-way crossover from sorafenib to tivozanib):** We have completed a TIVO-1 extension study, known as Study 902, in which patients with advanced RCC received tivozanib as second-line treatment subsequent to disease progression on sorafenib in the Company's phase 3 TIVO-1 first-line RCC study, and presented the final results at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting on June 1, 2015. The final results show a median PFS in this setting of 11.0 months and median OS of 21.6 months, demonstrating the efficacy of tivozanib in a VEGF treatment refractory population. We believe that the significant OS results demonstrated for tivozanib in Study 902 contributed to the discordance in the results between the OS and PFS in the TIVO-1 phase 3 trial.

### Explanation of Responses:

Additional RCC Phase 3 Trial: We are evaluating the opportunity to conduct an additional phase 3 trial of tivozanib in the refractory RCC setting using PFS as the primary endpoint and OS as a secondary endpoint, in order to address the overall survival concerns presented in the June 2013 complete response letter from the FDA. Our proposed study design, which we have shared with the FDA, contemplates a randomized, controlled, multi-center, open-label Phase 3 study of approximately 314 subjects randomized 1:1 to receive either tivozanib or sorafenib. Subjects enrolled in the study may include those who have received prior immunotherapy, including immune checkpoint (PD-1) inhibitors, reflecting a potentially evolving treatment landscape. The primary objective of the study would be to show improved PFS. Secondary endpoints would include OS and objective response rate (ORR), as well as safety and pharmacokinetic endpoints. On May 14, 2015, we received a written response from the FDA stating that the phase 3 study design we outlined, in patients with RCC who have failed at least two prior regimens, including VEGF therapy, “may support AVEO’s proposed indication for tivozanib in the 3rd line setting.” In response to whether the study, together with the TIVO-1 study, would be sufficient to support licensure of tivozanib as a treatment for advanced RCC, the FDA stated: “whether the results from this [third line] study can support AVEO’s proposal for tivozanib in the first line setting is a review issue.” We are evaluating all options for funding, including partnerships, for the clinical and regulatory advancement of tivozanib in RCC as well as colorectal cancer, or CRC.

**European MAA Filing:** We are also evaluating the clinical, regulatory and economic feasibility of seeking regulatory approval for tivozanib in Europe. In November 2014, we filed a letter of intent with the European Medicines Agency, or EMA, allowing us to begin exploring the submission of a Marketing Authorization Application, or MAA, for tivozanib for the treatment of RCC based on clinical trials conducted to date. In late April 2015, we met with our assigned Rapporteur and co-Rapporteur from the EMA in pre-submission advisory meetings to discuss the potential for filing an MAA. On June 3, 2015, the Rapporteur and co-Rapporteur delivered their confirmation of support for the filing of an MAA. The Rapporteur (from Portugal) and Co-Rapporteur (from the United Kingdom) are the two appointed members of the Committee for Medicinal Products for Human Use (CHMP) who would lead the evaluation of the MAA, if submitted. The application would be based on our existing dataset, which includes the results from the TIVO-1 study of tivozanib in the first-line treatment of RCC in which tivozanib demonstrated a significant improvement over sorafenib in the study's primary endpoint of PFS. At the advisory meetings, we provided data that we believe demonstrates that the discordance in OS, the secondary endpoint of the study, was attributable to the one-way crossover design of the study. The final meeting minutes reflect that the Rapporteurs "did not see a 'blocking issue' with the OS trend" and that we "clearly presented a credible story for the Rapporteurs to assess but one which would need to be supported with very careful reasoning." The Rapporteurs also noted that they "cannot advise on [the] final outcome of the review." Based on our assessment of the economic and infrastructure requirements associated with filing an MAA and subsequently launching tivozanib in Europe, we are evaluating partnership opportunities for the European market in parallel with our continued preparation for a potential filing.

**CRC Phase 2 Results:** We recently announced results from a predefined biomarker analysis of our BATON-CRC study, a randomized phase 2 clinical trial of modified FOLFOX6, a commonly used chemotherapy, combined with tivozanib or Avastin® (bevacizumab), which both target angiogenesis signaling pathways, in first line treatment of metastatic CRC. In this study, among prospectively defined biomarkers, a subgroup of patients with low serum neuropilin-1, or NRP-1, a cell surface protein that modulates blood vessel development, showed an improved PFS versus patients with high serum NRP-1 in both treatment arms, supporting the value of serum NRP-1 as a potential prognostic marker for angiogenesis inhibitors. Further, in the subgroup with samples available at the interim analysis, patients identified using a research-use assay to have low serum NRP-1 (below the median, representing 50% of the population) demonstrated longer PFS when treated with tivozanib compared to bevacizumab, which suggests that first line colorectal cancer patients with low NRP-1 levels may benefit from treatment with tivozanib over bevacizumab, a standard of care in this disease. In April 2015, we contracted with Myriad RBM, Inc., or Myriad, pursuant to which Myriad will assist us to identify a NRP-1 antibody which could produce comparable outcomes and be suitable for the development of a commercializable companion diagnostic assay for tivozanib in CRC. We have presented the results from the phase 2 BATON-CRC study and the Company's ongoing assay development efforts to the FDA in connection with our evaluation of a proposed pivotal phase 3 trial of tivozanib in CRC. In response to questions we posed to the FDA regarding this proposed trial, the FDA suggested that we continue work on the development of our biomarker assay to address variability between assays presented, and that, at present, "insufficient data exists to determine the appropriateness of this [NRP-1 low] subgroup" for the proposed phase 3 study. This feedback is consistent with the Company's current clinical strategy and discussions with cancer research cooperative groups. As such, we hope to identify a commercially viable assay, which will enable a prospectively defined, randomized Phase 2 study.

**Monetizing Assets in Areas Outside of Our Core Strategic Focus:**

**Ophthotech Option for Ocular Conditions (Non-Oncologic):** In November 2014, we entered into a research and exclusive option agreement with Ophthotech Corporation, or Ophthotech, under which we granted Ophthotech an option to develop and commercialize tivozanib for the potential diagnosis, prevention and treatment of non-oncologic diseases or conditions of the eye in humans.

**Pharmstandard License Agreement for Russia, Ukraine and the CIS:** On August 4, 2015, we entered into a license agreement under which we granted to a subsidiary of Pharmstandard OJCE the exclusive right to develop, manufacture and commercialize tivozanib in the territories of Russia, Ukraine and the Commonwealth of Independent States for all conditions excluding non-oncologic ocular conditions. Under this agreement, Pharmstandard is be

**Explanation of Responses:**

responsible for all activities and costs associated with the further development, regulatory filings, health services and commercialization of tivozanib in the specified territories.

·Ficlatuzumab: Ficlatuzumab is a potent Hepatocyte Growth Factor (“HGF”) inhibitory antibody. HGF is the sole known ligand of the c-Met receptor which is believed to trigger many activities that are involved in cancer development and metastasis. We have completed two phase 1 clinical studies of ficlatuzumab administered as a single agent and in combination with erlotinib, a TKI, of the epidermal growth factor receptor (“EGFR”), and a phase 2 clinical study evaluating ficlatuzumab in combination with gefitinib, an EGFR TKI, in first line non-small cell lung cancer, or NSCLC. The phase 2 trial failed to demonstrate a statistically significant benefit in the intent-to-treat population. However, an exploratory analysis using a serum-based molecular diagnostic test, known as VeriStrat®, identified a sub-population of

patients who experienced a progression free survival and overall survival benefit from the addition of ficlatuzumab to gefitinib. VeriStrat is commercially available to help physicians guide treatment decisions for patients with second line advanced NSCLC. Data from the exploratory analyses with VeriStrat prompted the development of a separate investigational companion diagnostic test called BDX004. Based upon the exploratory analyses, BDX004 may be indicative of a predictive biomarker for the combination of ficlatuzumab and EGFR TKI over EGFR TKI alone in the first line EGFR mutation patients who have been previously identified to not respond well to the current standard of care.

In April 2014, we entered into a worldwide agreement with Biodesix, Inc. to develop and commercialize ficlatuzumab with BDX004, a serum based diagnostic test which has been derived from the VeriStrat test, employing the same methodology and data processing algorithms as VeriStrat, for use in a confirmatory clinical trial. Pursuant to the Biodesix agreement, in December 2014 we initiated a phase 2 confirmatory study of ficlatuzumab, which we refer to as the FOCAL study, in combination with erlotinib in first line advanced NSCLC patients who have an EGFR mutation and who are identified by the BDX004 test as being most likely to benefit from the addition of ficlatuzumab to the EGFR TKI. We hope to begin patient enrollment this year. Biodesix will fund up to \$15 million of the cost of this study, as well as all of the costs associated with development and registration of BDX004, and any additional development, regulatory and commercial costs for ficlatuzumab will be shared equally. Under the Biodesix agreement, subject to regulatory approval, AVEO would lead worldwide commercialization of ficlatuzumab.

·AV-203: AV-203 is a potent anti-ErbB3 (also known as HER3) specific monoclonal antibody with high ErbB3 affinity. We have observed potent anti-tumor activity in mouse models. AV-203 selectively inhibits the activity of the ErbB3 receptor, and our preclinical studies suggest that neuregulin-1, or NRG1 (also known as heregulin), levels predict AV-203 anti-tumor activity in preclinical models. We have completed a phase 1 dose escalation study of AV-203, which established a recommended phase 2 dose of AV-203 at 20mg/kg intravenously every 2 weeks, demonstrated good tolerability and promising early signs of activity, and reached the maximum planned dose of AV-203 monotherapy. No anti-drug antibodies were detected, and pharmacokinetic results indicated a dose-proportional increase in levels of AV-203.

The expansion cohort of this study among patients with a specific biomarker has been discontinued. We are seeking to pursue further clinical development of AV-203 with a strategic partner.

·AV-380: AV-380 is a potent humanized IgG1 inhibitory monoclonal antibody targeting growth differentiating factor-15, or GDF15, a divergent member of the TGF- $\beta$  family, for the potential treatment or prevention of cachexia. Cachexia is defined as a multi-factorial syndrome of involuntary weight loss characterized by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. Cachexia is associated with various cancers as well as diseases outside of cancer including chronic kidney disease, congestive heart failure, and chronic obstructive pulmonary disease (COPD). We believe that AV-380 represents a unique approach to treating cachexia because it addresses key underlying mechanisms of the syndrome and focuses on a significant area of patient need. It is estimated that approximately 30% of all cancer patients die due to cachexia and over half of cancer patients who die do so with cachexia present. (J Cachexia Sarcopenia Muscle 2010). In the United States alone, the estimated prevalence of cancer cachexia alone is over 400,000 patients (Am J Clin Nutr 2006).

In September 2014, we presented the results from four preclinical studies of AV-380 in various in vivo cachexia models and in vitro assays at the 2<sup>nd</sup> Cancer Cachexia Conference held in Montreal Canada. Our research was also selected for presentation in an oral session at the conference. In April 2015, we also presented the results from a preclinical study of AV-380 in a cachectic human tumor xenograft model at the Annual Meeting of the American Association of Cancer Research. The Company has established preclinical proof of concept for GDF15 as a key driver of cachexia by demonstrating, in animal models, that the administration of GDF15 induces cachexia, and that inhibition of GDF15 reverses cachexia and provides a potential indication of an overall survival benefit.

In connection with the AV-380 program, we have in-licensed certain patents and patent applications from St. Vincent's Hospital in Sydney, Australia. We have demonstrated preclinical proof-of-concept for AV-380 in multiple cancer cachexia models and have completed cell line development and manufacturing of our first cGMP batch, in preparation

for potential future clinical development. We are evaluating partnership opportunities to continue the development of AV-380.

We have devoted substantially all of our resources to our drug discovery efforts, comprising research and development, conducting clinical trials for our product candidates, protecting our intellectual property and the general and administrative functions relating to these operations. We have generated no revenue from product sales through June 30, 2015, and through such date have principally funded our operations through the proceeds from our strategic partnerships, sales of stock to investors and loan agreements with Hercules Technology II, L.P. and Hercules Technology III, L.P.

We do not have a history of being profitable and, as of June 30, 2015, we had an accumulated deficit of \$496.4 million. We anticipate that we will continue to incur significant operating costs over the next several years as we continue our planned development activities for our preclinical and clinical products. We will need additional financing to support our operating activities.

#### Strategic Partnerships

##### Pharmstandard Group

On August 4, 2015, we entered into an exclusive license agreement with JSC “Pharmstandard-Ufimskiy Vitamin Plant”, or Pharmstandard, a subsidiary of Pharmstandard OJSC, under which we granted Pharmstandard the exclusive right to develop, manufacture and commercialize tivozanib in the territories of Russia, Ukraine and the Commonwealth of Independent States for all conditions excluding non-oncologic ocular conditions.

Pharmstandard is obligated to use commercially reasonable efforts to develop and commercialize tivozanib throughout the licensed territories, and Pharmstandard has responsibility for all activities and costs associated with the further development, manufacture, regulatory filings and commercialization of tivozanib in the licensed territories. Pharmstandard is obligated to file an application for marketing authorization in Russia for tivozanib for the treatment of renal cell carcinoma no later than the first anniversary of the license agreement, unless Russian regulatory authorities require Pharmstandard to conduct an additional clinical trial prior to approval and Pharmstandard is actively performing such trial.

Pharmstandard is obligated under the agreement to make an upfront payment to us of \$1.5 million. We are also eligible to receive \$7.5 million in connection with the first marketing authorization of tivozanib in Russia. If Russian regulatory authorities require additional studies to be conducted prior to approval, this amount would be reduced to \$3.0 million. In addition, we are eligible to receive \$3.0 million for each additional approved indication of tivozanib, if Pharmstandard elects to seek any such approvals, as well as a high single-digit royalty on net sales in the sublicensed territories. A percentage of all upfront, milestone and royalty payments we receive under the agreement are due to KHK as a sublicensing fee.

##### Ophthotech Corporation

In November 2014 we entered into a research and exclusive option agreement with Ophthotech Corporation. Under this agreement, we granted Ophthotech an option to exclusively license the right to develop and commercialize tivozanib in all territories outside of Asia for the potential diagnosis, prevention and treatment of non-oncologic diseases or conditions of the eye in humans.

Pursuant to this option agreement, we granted to Ophthotech an exclusive, royalty free license or sublicense, as applicable, under intellectual property rights controlled by us solely to perform the research and development activities related to the use of tivozanib for the specific purposes outlined in the agreement during the option period. These activities include formulation work for ocular administration, preclinical research and the conduct of a phase 1/2a, proof of concept clinical trial of a product containing tivozanib in patients with wet age-related macular degeneration (the “POC Study”).

Ophthotech paid us \$500,000 in consideration for the grant of the option. Such amount is non-refundable and not creditable against any other amounts due under the agreement. We are obligated to make available to Ophthotech, at no cost to Ophthotech, certain quantities of tivozanib hydrochloride solely for conducting its option period research.

##### Biodesix

In April 2014, we entered into a worldwide agreement with Biodesix to develop and commercialize our HGF inhibitory antibody ficlatuzumab, with BDX004, a proprietary companion diagnostic test developed by Biodesix and based upon an exploratory analyses with VeriStrat<sup>®</sup>, a serum protein test that is commercially available to help physicians guide treatment decisions for patients with advanced NSCLC.

Under the agreement, we granted Biodesix perpetual, non-exclusive rights to certain intellectual property, including all clinical and biomarker data related to ficlatuzumab, to develop and commercialize BDX004. Biodesix granted us perpetual, non-exclusive rights to certain intellectual property, including diagnostic data related to BDX004, with respect to the development and commercialization of ficlatuzumab; each license includes the right to sublicense, subject to certain exceptions. Pursuant to a joint development plan, as monitored by a joint steering committee, we retain primary responsibility for clinical development of ficlatuzumab in a phase 2 proof of concept, or POC, clinical study of ficlatuzumab for non-small cell lung cancer, in which BDX004, a diagnostic test derived from VeriStrat will be used to select clinical trial subjects, referred to as the FOCAL study. The FOCAL study will be fully funded by Biodesix up to a maximum of \$15 million, referred to as the Cap. Biodesix will also be responsible for all of the costs associated with development and registration of BDX004. After the Cap is reached, we and Biodesix will share equally in the costs of the FOCAL study, and we and

Biodesix will each be responsible for 50% of development and regulatory costs associated with all future ficlatuzumab clinical development trials agreed-upon by Biodesix and us, including all milestone payments and royalties payable to third parties, if any.

#### St. Vincent's Hospital

In July 2012, we entered into a license agreement with St. Vincent's Hospital Sydney Limited, which we refer to as St. Vincent's, under which we obtained an exclusive, worldwide license to research, develop, manufacture and commercialize products for therapeutic applications that benefit from inhibition or decreased expression or activity of MIC-1, which is also known as GDF15. We believe GDF15 is a novel target for cachexia and we are exploiting this license in our AV-380 program for cachexia. Under the agreement, we have the right to grant sublicenses subject to certain restrictions. We have a right of first negotiation to obtain an exclusive license to certain improvements that St. Vincent's or third parties may make to licensed therapeutic products. Under the license agreement, St. Vincent's also granted us non-exclusive rights for certain related diagnostic products and research tools.

#### Biogen Idec

In March 2009, we entered into an exclusive option and license agreement with Biogen Idec International GmbH, or Biogen Idec, regarding the development and commercialization of our discovery-stage ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases in humans outside of North America. Under the agreement, we were responsible for developing ErbB3 antibodies through completion of the first phase 2 clinical trial designed in a manner that, if successful, will generate data sufficient to support advancement to a phase 3 clinical trial. In March 2014, we amended our agreement with Biogen Idec, whereby Biogen Idec agreed to the termination of its rights and obligations under the agreement, including Biogen Idec's option to (i) obtain a co-exclusive (with us) license to develop and manufacture ErbB3 targeted antibodies and (ii) obtain exclusive commercialization rights to ErbB3 products in countries in the world other than North America. As a result, we retain worldwide rights to AV-203, a clinical stage ErbB3-targeted antibody. Pursuant to the amendment, we are obligated to in good faith use reasonable efforts to seek a collaboration partner for the purpose of funding further development and commercialization of ErbB3-targeted antibodies. Pursuant to the amendment, we are obligated to pay Biogen Idec a percentage of milestone payments received by us from future partnerships after March 28, 2016 and single digit royalty payments on net sales related to the sale of ErbB3 products, up to a cumulative maximum amount of \$50.0 million.

#### Astellas Pharma

In February 2011, we entered into a collaboration and license agreement with Astellas and certain of its indirect wholly-owned subsidiaries pursuant to which we and Astellas made plans to develop and seek to commercialize tivozanib for the treatment of a broad range of cancers. On February 12, 2014, Astellas exercised its right to terminate the agreement. The termination of the agreement became effective August 11, 2014, at which time all rights to tivozanib that had been sublicensed to Astellas returned to us. In accordance with the collaboration and license agreement, we and Astellas agreed to equally share committed development costs, including the costs of completing certain tivozanib clinical development activities that were initiated as part of our partnership with Astellas.

#### Kyowa Hakko Kirin

In December 2006, we entered into a license agreement with KHK under which we obtained an exclusive license, with the right to grant sublicenses subject to certain restrictions, to research, develop, manufacture and commercialize tivozanib, pharmaceutical compositions thereof and associated biomarkers. Our exclusive license covers all territories in the world, except for Asia. KHK has retained rights to tivozanib in Asia. Under the license agreement, we obtained exclusive rights in our territory under certain KHK patents, patent applications and know-how related to tivozanib, to research, develop, make, have made, use, import, offer for sale, and sell tivozanib for the diagnosis, prevention and treatment of any and all human diseases and conditions. We and KHK each have access to and can benefit from the

other party's clinical data and regulatory filings with respect to tivozanib and biomarkers identified in the conduct of activities under the license agreement.

Under the license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize tivozanib in our territory. Prior to the first anniversary of the first post-marketing approval sale of tivozanib in our territory, neither we nor any of our subsidiaries has the right to conduct certain clinical trials of, seek marketing approval for or commercialize any other cancer product that also works by inhibiting the activity of the VEGF receptor.

Upon entering into the license agreement with KHK, we made a one-time cash payment in the amount of \$5.0 million. In March 2010, we made a \$10.0 million milestone payment to KHK in connection with the dosing of the first patient in our phase 3 clinical trial of tivozanib. In December 2012, we made a \$12.0 million milestone payment to KHK in connection with the acceptance by the FDA of our NDA filing for tivozanib. The total remaining maximum payments for clinical and US and EU regulatory milestones under our license agreement with KHK are \$38.0 million, in the aggregate.

We also made a \$22.5 million payment to KHK during the year ended December 31, 2011 related to the up-front license payment received under the collaboration and license agreement with Astellas which we entered into in February 2011. We are also required to pay tiered royalty payments on net sales we make of tivozanib in our territory, which range from the low to mid-teens as a percentage of net sales. The royalty rate escalates within this range based on increasing tivozanib sales. Our royalty payment obligations in a particular country in our territory begin on the date of the first commercial sale of tivozanib in that country, and end on the later of 12 years after the date of first commercial sale of tivozanib in that country or the date of the last to expire of the patents covering tivozanib that have been issued in that country. In the event we sublicense the rights licensed to us under the license agreement with KHK, we are required to pay KHK a specified percentage of any amounts we receive from any third party sublicensees other than amounts we receive in respect of research and development funding or equity investments in lieu of making milestone payments, subject to certain limitations.

## Financial Overview

### Revenue

To date, we have not generated any revenue from product sales. All of our revenue to date has been derived from license fees, milestone payments, premium over the fair value of convertible preferred shares sold to our strategic partners, and research and development payments received from our strategic partners.

In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and research and development payments in connection with strategic partnerships, and royalties resulting from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestone and other payments received under our strategic partnerships, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales in the near term. If we or our strategic partners fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

### Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of:

- employee-related expenses, which include salaries, benefits and stock-based compensation expense;
  - expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
  - the cost of acquiring and manufacturing clinical trial materials, as well as commercial materials prior to our anticipated launch of tivozanib;
  - the cost of completing certain tivozanib clinical development activities that were initiated as part of our partnership with Astellas;
  - facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets;
  - license fees for, and milestone payments related to, in-licensed products and technology;
  - and
  - costs associated with outsourced development activities, regulatory approvals and medical affairs.
- We expense research and development costs as incurred. Nonrefundable 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.

Research and development expenses are net of amounts reimbursed under our agreements with Astellas and Biodesix for their share of development costs incurred by us under our respective agreements.

In January 2015, as part of a strategic restructuring, we eliminated our internal research function to better align our resources with our future clinically focused strategic plans. As part of this restructuring, we eliminated approximately two-thirds of our workforce, or 40 positions, across the organization. The restructuring was substantially completed as of March 31, 2015.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success, if any, of each product candidate, as well as ongoing assessment of each product candidate's commercial potential. We will need to raise substantial additional capital in the future in order to fund the development of our preclinical and clinical product candidates.

We track external development expenses and personnel expense on a program-by-program basis and allocate common expenses, such as scientific consultants and laboratory supplies, to each program based on the personnel resources allocated to such program. Facilities, depreciation, stock-based compensation, research and development management and research and development support services are not allocated among programs and are considered overhead. We expect our overhead expenses to continue to decrease in future periods as a result our January 2015 restructuring and move to a smaller facility in May 2015. Below is a summary of our research and development expenses for the three and six months ended June 30, 2015 and 2014:

	Three Months Ended		Six Months Ended	
	June 30, 2015 (in thousands)	2014	June 30, 2015 (in thousands)	2014
Tivozanib	\$993	\$3,551	\$2,438	\$6,418
AV-380 Program in Cachexia	282	1,898	757	4,162
Ficlatuzumab		852		1,532
AV-203	79	726	366	1,199
Other pipeline programs		25	11	25
Other research and development		26	10	42
Overhead	487	2,222	954	7,689
Total research and development expenses	\$1,841	\$9,300	\$4,536	\$21,067

#### Tivozanib

With the termination of our partnership with Astellas and the return of our tivozanib rights, we plan on pursuing partnering options to fund further tivozanib development in appropriate clinical settings. We continue to share the costs of development activities to which we and Astellas were committed at the time the partnership was terminated.

#### AV-380 Program in Cachexia

Following our restructuring in January 2015 which eliminated our internal research function, we expect our costs associated with this program to decrease in 2015 in comparison to 2014. We are exploring partnerships and collaborations to further the development of AV-380. Due to the unpredictable nature of preclinical and clinical development and given the early stage of this program, we are unable to estimate with any certainty the costs we will incur in the future development of AV-380.

#### Ficlatuzumab

In April 2014, we entered into a worldwide agreement with Biodesix to develop and commercialize AVEO's potent HGF inhibitory antibody ficlatuzumab, with BDX004, Biodesix's proprietary companion diagnostic test, developed by Biodesix and based upon an exploratory analyses with VeriStrat<sup>®</sup>, a serum protein test that is commercially available to help physicians guide treatment decisions for patients with advanced NSCLC. In September 2014, at the 2014 Congress of the European Society for Medical Oncology, we presented detailed data from our phase 2 clinical trial comparing the combination of ficlatuzumab and gefitinib to gefitinib monotherapy in previously untreated Asian subjects with first line non-small cell lung cancer. In the intent-to-treat population, the addition of ficlatuzumab to gefitinib did not result in statistically significant improved overall response rate. However, an exploratory analysis in the phase 2 using a serum-based molecular diagnostic test, known as VeriStrat<sup>®</sup>, identified a sub-population of patients who showed a progression free survival and overall survival benefit from the addition of ficlatuzumab to the EGFR TKI. Pursuant to the agreement with Biodesix, Biodesix will provide up to \$15 million for a phase 2 trial of ficlatuzumab in combination with erlotinib in first line advanced NSCLC patients selected using BDX004, a diagnostic test derived from VeriStrat and fund the further development and registration of BDX004 as a companion diagnostic. After the completion of the phase 2 trial, any additional development, regulatory or commercial expenses for ficlatuzumab will be equally shared, as well as profits, if any. Due to the unpredictable nature of preclinical and clinical development, we are unable to estimate with any certainty the costs we will incur in the future development of ficlatuzumab.

AV-203

In March 2014, we regained our worldwide rights from Biogen Idec to develop, manufacture and commercialize AV-203, and we are actively pursuing partnerships or collaborations to further advance the development of AV-203. Because obtaining a partnership and collaborations may be complex and unpredictable in timing and nature of terms, we are unable to estimate with any certainty the costs we will incur in the future development of AV-203.

#### Uncertainties of Estimates Related to Research and Development Expenses

The process of conducting preclinical studies and clinical trials necessary to obtain FDA approval for each of our product candidates is costly and time-consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability.

At this time, we cannot reasonably estimate or know the nature, specific timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates, or the period, if any, in which material net cash inflows may commence from sales of any approved products. This uncertainty is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- our ability to establish and maintain strategic partnerships, the terms of those strategic partnerships and the success of those strategic partnerships, if any, including the timing and amount of payments that we might receive from strategic partners;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for any product candidate;
- the progress and results of our clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the emergence of competing technologies and products and other adverse market developments; and
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims.

As a result of the uncertainties associated with developing drugs, including those discussed above, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates, or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success, if any, of each product candidate, as well as ongoing assessment of each product candidate's commercial potential. We will need to raise substantial additional capital in the future in order to fund the development of our preclinical and clinical product candidates.

#### General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, corporate development, information technology, legal and human resource functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, prosecution and defense costs and professional fees for legal, consulting, pre-commercialization activities, auditing and tax services.

We anticipate that our general and administrative expenses will decrease in 2015 as compared to 2014 due to the January 2015 restructuring and our relocation to a smaller facility during the second quarter of 2015. This decrease may be partially offset by an increase in legal costs associated with the ongoing shareholder litigation and U.S. Securities and Exchange Commission, or SEC, investigation described in this report under the heading "Legal Proceedings" below in Part II—Item 1.

Explanation of Responses:

Interest Income and Interest Expense

Interest income consists of interest earned on our cash, cash equivalents and marketable securities. The primary objective of our investment policy is capital preservation.

Interest expense consists of interest, amortization of debt discount, and amortization of deferred financing costs associated with our loans payable.

## Income Taxes

We calculate our provision for income taxes on ordinary income based on our projected annual tax rate for the year. As of June 30, 2015, we are forecasting a net loss for the year ended December 31, 2015, and since we maintain a full valuation allowance on all of our deferred tax assets, we have recorded no income tax provision or benefit in the current quarter.

## Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued clinical expenses, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we and our management believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in the notes to our condensed consolidated financial statements appearing elsewhere in this report. There have been no material changes to our critical accounting policies during the six month period ended June 30, 2015. Please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", of our annual report on Form 10-K for the fiscal year ended December 31, 2014 for further discussion of our critical accounting policies and significant judgments and estimates.

## Results of Operations

## Comparison of Three Months Ended June 30, 2015 and 2014

The following table summarizes the results of our operations for each of the three months ended June 30, 2015 and 2014, together with the changes in those items in dollars and as a percentage:

	Three Months Ended			
	June 30, 2015 (in thousands)	2014	Increase/ (decrease)	%
Revenue	\$134	\$1,846	\$(1,712)	(93)%
Operating expenses:				
Research and development	1,841	9,300	(7,459)	(80)%
General and administrative	2,889	4,846	(1,957)	(40)%
Restructuring and lease exit	25	5,165	(5,140)	(100)%
Total operating expenses	4,755	19,311	(14,556)	(75)%
Loss from operations	(4,621)	(17,465)	12,844	74%
Other expense, net	(209)	(2)	(207)	10,350%
Interest expense	(633)	(502)	(131)	26%
Interest income	7	10	(3)	(30)%

Net loss \$(5,456) \$(17,959) \$(12,503 ) (70 )%

The following table sets forth revenue for the three months ended June 30, 2015 and 2014:

Revenue	Three Months Ended		Increase/ (decrease)	%
	June 30, 2015	2014		
(in thousands)				
Strategic Partner:				
Biogen Idec	\$76	\$77	(1 )	(1 )%
Ophthotech	58	—	58	—
Astellas	—	1,769	(1,769 )	(100)%
	\$134	\$1,846	\$ (1,712 )	(93 )%

**Revenue.** Revenue for the three months ended June 30, 2015 was \$0.1 million compared to \$1.8 million for the three months ended June 30, 2014, a decrease of approximately \$1.7 million. The decrease was primarily due to an additional \$1.8 million in revenue recognized in the second quarter of 2014 in connection with our agreement with Astellas, which concluded in August 2014.

**Research and development.** Research and development, or R&D, expenses for the three months ended June 30, 2015 were \$1.8 million compared to \$9.3 million for the three months ended June 30, 2014, a decrease of \$7.5 million or 80%. The decrease is primarily attributable to a \$1.5 million decrease in employee compensation and travel costs and a decrease of \$1.8 million in facilities, IT, and other costs following our January 2015 restructuring and the reduction of our utilized facility space as well as a \$4.2 million decrease in external clinical trial and consulting costs primarily associated with the decreased tivozanib clinical development activity and AV-380 preclinical development activity.

**General and administrative.** General and administrative expenses for the three months ended June 30, 2015 were \$2.9 million compared to \$4.8 million for the three months ended June 30, 2014, a decrease of \$1.9 million or 40%. The decrease is primarily the result of a \$0.3 million decrease in external legal costs associated with various ongoing legal matters and a \$1.6 million decrease in employee compensation, facilities and IT costs following our January 2015 restructuring and the reduction of our utilized facility space.

**Restructuring and lease exit.** Restructuring and lease exit expenses for the three months ended June 30, 2015 were \$25,000 compared to \$5.2 million for the three months ended June 30, 2014. The expenses incurred during the three months ended June 30, 2015 relate to accretion expense associated with our lease termination liability for the 650 E. Kendall Street facility. The expenses incurred during the three months ended June 30, 2014 relate to expenses associated with the portion of the 650 E. Kendall Street facility that we ceased using during that quarter.

**Interest expense.** Interest expense for the three months ended June 30, 2015 was \$0.6 million compared to \$0.5 million for the three months ended June 30, 2014, an increase of \$0.1 million or 26%. The increase is primarily attributable to the increase in the outstanding balance on our loan with Hercules Technology Growth.

**Interest income.** Interest income for the three months ended June 30, 2015 was \$7,000 compared to \$10,000 for the three months ended June 30, 2014, a decrease of \$3,000 or 30%. The decrease in interest income is primarily due to a lower average cash balance during the three months ended June 30, 2015 compared to the three months ended June 30, 2014.

#### Comparison of Six Months Ended June 30, 2015 and 2014

The following table summarizes the results of our operations for each of the six months ended June 30, 2015 and 2014, together with the changes in those items in dollars and as a percentage:

	Six Months Ended			
	June 30, 2015 (in thousands)	2014	Increase/ (decrease)	%
Revenue	\$268	\$17,135	\$(16,867)	(98)%
Operating expenses:				
Research and development	4,536	21,067	(16,531)	(78)%
General and administrative	6,144	10,400	(4,256)	(41)%
Restructuring and lease exit	4,358	9,025	(4,667)	(52)%
Total operating expenses	15,038	40,492	(25,454)	(63)%

Edgar Filing: ENNIS, INC. - Form 4

Loss from operations	(14,770)	(23,357)	8,587	(37 )%
Other (expense) income, net	(223 )	5	(228 )	(4,560)%
Interest expense	(1,349 )	(1,083 )	(266 )	25 %
Interest income	12	26	(14 )	(54 )%
Net loss	\$(16,330)	\$(24,409)	\$ 8,079	(33 )%

31

---

The following table sets forth revenue for the six months ended June 30, 2015 and 2014:

Revenue	Six Months Ended		Increase/	
	June 30, 2015	2014	(decrease)	%
(in thousands)				
<b>Strategic Partner:</b>				
Biogen Idec	\$ 152	\$14,367	(14,215 )	(99 )%
Ophthotech	116	—	116	—
Astellas	—	2,768	(2,768 )	(100)%
	\$268	\$17,135	\$(16,867 )	(98 )%

Revenue. Revenue for the six months ended June 30, 2015 was \$0.3 million compared to \$17.1 million for the six months ended June 30, 2014, a decrease of approximately \$16.8 million. The decrease was primarily due to an additional \$14.3 million in revenue recognized in connection with modification of our agreement with Biogen in March 2014 and the termination of our agreement with Astellas in August 2014.

Research and development. Research and development, or R&D, expenses for the six months ended June 30, 2015 were \$4.5 million compared to \$21.1 million for the six months ended June 30, 2014, a decrease of \$16.6 million or 78%. The decrease is primarily attributable to a \$3.5 million decrease in employee compensation and travel costs and a decrease of \$5.1 million in facilities, IT, and other costs following our January 2015 restructuring and the reduction of our utilized facility space as well as a \$8.0 million decrease in external clinical trial and consulting costs associated with the decreased clinical and preclinical development activity.

General and administrative. General and administrative expenses for the six months ended June 30, 2015 were \$6.1 million compared to \$10.4 million for the six months ended June 30, 2014, a decrease of \$4.3 million or 41%. The decrease is primarily the result of a \$0.9 million decrease in external legal costs associated with various ongoing legal matters and a \$3.4 million decrease in employee compensation, facilities and IT costs following our January 2015 restructuring and the reduction of our utilized facility space.

Restructuring and lease exit. Restructuring and lease exit expenses for the six months ended June 30, 2015 were \$4.4 million compared to \$9.0 million for the six months ended June 30, 2014. The expenses incurred during the six months ended June 30, 2015 primarily relate to the January 2015 restructuring, which was substantially completed in March 2015. As part of this restructuring, we eliminated our internal research function, reducing our headcount by approximately 40 positions. The expenses incurred during the six months ended June 30, 2014 relate to expenses associated with the portion of our former 650 E. Kendall Street facility that we ceased using.

Interest expense. Interest expense for the six months ended June 30, 2015 was \$1.3 million compared to \$1.1 million for the six months ended June 30, 2014, an increase of 25%. The increase is primarily attributable to the increase in the outstanding balance on our loan with Hercules Technology Growth.

Interest income. Interest income for the six months ended June 30, 2015 was \$12,000 compared to \$26,000 for the six months ended June 30, 2014, a decrease of \$14,000 or 54%. The decrease in interest income is primarily due to a lower average cash balance during the six months ended June 30, 2015 compared to the six months ended June 30, 2014.

## Liquidity and Capital Resources

We have funded our operations principally through the sale of equity securities sold in private placements and underwritten public offerings, revenue and expense reimbursements from strategic partnerships, debt financing and interest income. As of June 30, 2015, we had cash and cash equivalents of approximately \$26.8 million. Currently, our funds are invested in money market funds, U.S. government agency securities, and corporate debt securities, including commercial paper. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Six Months Ended	
	June 30, 2015	2014
	(in thousands)	
Net cash used in operating activities	\$(27,250)	\$(35,220)
Net cash provided by investing activities	1,188	34,078
Net cash provided by (used in) financing activities	522	(6,322)
Net decrease in cash and cash equivalents	\$(25,540)	\$(7,464)

For the six months ended June 30, 2015 and 2014, our operating activities used cash of \$27.3 million and \$35.2 million, respectively. Cash used by operations for the six months ended June 30, 2015 and 2014 was due primarily to our net loss adjusted for non-cash items and changes in working capital.

For the six months ended June 30, 2015 and 2014, our investing activities provided cash of \$1.2 million and \$34.1 million, respectively. Cash provided by investing activities for the six months ended June 30, 2015 was primarily the net result of the proceeds from the maturity of marketable securities and the sale of equipment. Cash provided by investing activities for the six months ended June 30, 2014 was primarily the net result of maturities and sales of marketable securities partially offset by purchases of marketable securities, in addition to purchases of property and equipment of \$11.8 million, which were primarily associated with the build-out of our leased facilities, all of which for 2014 was reimbursed to us by our landlord via tenant improvement allowances under our leases.

For the six months ended June 30, 2015 and 2014, our financing activities provided (used) cash of \$0.5 million and (\$6.3) million, respectively. The increase in cash provided by financing activities is primarily the result of the receipt of proceeds from the sale of common stock during the six months ended June 30, 2015.

#### At-The-Market Issuance Sales Agreements with MLV

In February 2015, we entered into an at-the-market issuance sales agreement, which we refer to as the Sales Agreement, with MLV & Co. LLC, or MLV, pursuant to which we could issue and sell shares of our common stock from time to time up to an aggregate amount of \$17.9 million, at our option, through MLV as our sales agent.

On May 7, 2015, we filed a shelf registration statement on Form S-3 with the SEC, which we refer to as the 2015 Shelf. The 2015 Shelf covers the offering, issuance and sale of up to \$100 million of our common stock, preferred stock, debt securities, warrants and/or units. The 2015 Shelf was filed to replace our existing \$250 million shelf registration statement, which expired at the end of May 2015, and which we refer to as the 2012 Shelf. On May 7, 2015, we also amended the Sales Agreement to provide for the offering, issuance and sale of up to \$15 million of our common stock under the 2015 Shelf. The prior offering initiated under the Sales Agreement expired along with the 2012 Shelf. As of June 30, 2015, we have sold approximately 3.4 million shares pursuant to the Sales Agreement and the amended Sales Agreement, resulting in proceeds of approximately \$5.8 million, net of commissions and issuance costs. Approximately \$13.5 million remains available for sale under the amended Sales Agreement.

Sales of common stock through MLV may be made by any method that is deemed an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including by means of ordinary brokers’ transactions at market prices, in block transactions or as otherwise agreed by the Company and MLV. Subject to the terms and conditions of the amended Sales Agreement, MLV will use commercially reasonable efforts to sell our common stock based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are not obligated to make any sales of common stock under the amended Sales Agreement. Any shares sold will be sold pursuant to an effective shelf registration statement on Form S-3. We are required to pay MLV a commission of up to 3% of the gross proceeds. The amended Sales Agreement may be terminated by us at any time.

Credit Facilities. On September 24, 2014, we amended our loan and security agreement, which we refer to as the Amended Loan Agreement, with Hercules Technology II, L.P. and Hercules Technology III, L.P., affiliates of Hercules Technology Growth, which we originally entered into on May 28, 2010 and previously amended on December 21, 2011 and March 31, 2012. Pursuant to the Amended Loan Agreement, we received a new loan in an aggregate principal amount of \$10.0 million and amended the terms of our original loan with Hercules, which had an outstanding principal balance of \$11.6 million at the date of the amendment. We are not required to make any principal payments on the new loan of \$10.0 million until November 1, 2015, which date may be extended if we achieve certain performance milestones, and after which time we will be required to make monthly principal and interest payments with the entire loan due and payable on January 1, 2018. With respect to the original loan, we were

not required to pay principal until January 1, 2015, at which time we were required to commence making twelve (12) principal and interest payments. The original loan agreement also included an obligation to pay a deferred financing charge of \$1.2 million which we paid on June 1, 2014, and which has been recorded as a loan discount and is being amortized to interest expense over the term of the original loan using the effective interest rate method. We recorded a liability for the full amount of the charge because the payment of such amount was not contingent on any future event.

The Amended Loan Agreement has an end-of-term payment of approximately \$0.5 million due on January 1, 2018 or on such earlier date as the new loan is prepaid. The Amended Loan Agreement also has a financial covenant with respect to the new loan, whereby we have agreed to maintain a liquidity ratio equal to or greater than 1.25 to 1.00 or the equivalent of \$12.5 million in unrestricted and unencumbered cash and cash equivalents. This financial covenant will not apply after such time as we receive favorable data both with respect to our phase 2 clinical study of ficlatuzumab and a phase 1 clinical study of AV-380. We continued to be in compliance with all financial covenants under the Amended Loan Agreement at June 30, 2015. We must make interest payments on both loans each month the loans remains outstanding. Per annum interest is payable on each loan at the greater of 11.9% and an amount equal to 11.9% plus the prime rate minus 4.75%, provided, however, that the per annum interest shall not exceed 15.0%. Our annual interest rate as of June 30, 2015 is 11.9%.

We have determined that the risk of subjective acceleration under the material adverse events clause included in this loan and security agreement is remote and, therefore, have classified the outstanding principal amount in current and long-term liabilities based on the timing of scheduled principal payments.

The loan is secured by a lien on all of our personal property (other than intellectual property). As of June 30, 2015, the principal balance outstanding was \$16.0 million.

**Operating Capital Requirements.** We anticipate that we will continue to incur significant operating losses for the next several years as we incur expenses to continue to execute on our clinical development strategy to advance our clinical stage assets.

We believe that our cash resources will allow us to fund our current operations at least through the third quarter of 2016. This estimate does not include our payment of potential licensing milestones or the costs of conducting any contemplated clinical trials and assumes no milestone payments from our partners, additional funding from new partnership agreements, equity financings, debt financings or accelerated repayment thereof or further sales under our ATM. The timing and nature of activities contemplated for 2015 and 2016 will be conducted subject to the availability of sufficient financial resources.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;