AVEO PHARMACEUTICALS INC
Form 10-Q
November 09, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission file number 001-34655

AVEO PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	04-3581650
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

One Broadway, 14th Floor, Cambridge, Massachusetts 02142

(Address of Principal Executive Offices) (Zip Code)

(617) 588-1960

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

Number of shares of the registrant's Common Stock, $0.001 par value, outstanding on November 2, 2015: 58,179,121

AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2015

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except par value amounts)

(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$34,739	$52,306
Marketable securities	2,500	—
Restricted cash	2,863	2,997
Accounts receivable	2,334	2,341
Prepaid expenses and other current assets	1,364	1,484
Total current assets	43,800	59,128
Property and equipment, net	52	11,295
Other assets	164	239
Total assets	$44,016	$70,662
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$290	$3,245
Accrued expenses	5,453	9,301
Loans payable, net of discount	4,217	11,722
Deferred revenue	457	537
Lease exit obligation	—	4,981
Deferred rent	—	10,569
Total current liabilities	10,417	40,355
Loans payable, net of current portion and discount	8,260	8,930
Deferred revenue	884	231
Other liabilities	577	540
Stockholders' equity:		
Preferred stock, $.001 par value: 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $.001 par value: 200,000 shares authorized; 58,177 and 52,289 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	58	52
Additional paid-in capital	512,259	500,582
Accumulated other comprehensive income (loss)	1	—
Accumulated deficit	(488,440)	(480,028)

Total stockholders' equity	23,878	20,606
Total liabilities and stockholders' equity	$44,016	$70,662

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

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Collaboration and licensing revenue	$15,158	$873	$15,426	$18,007
Operating expenses:				
Research and development	4,466	8,485	9,002	29,552
General and administrative	2,225	5,084	8,367	15,485
Restructuring and lease exit	—	1,403	4,358	10,426
	6,691	14,972	21,727	55,463
Income (loss) from operations	8,467	(14,099)	(6,301)	(37,456)
Other income and expense:				
Other (expense) income, net	(22)	98	(245)	103
Interest expense	(533)	(439)	(1,880)	(1,522)
Interest income	2	4	14	30
Other expense, net	(553)	(337)	(2,111)	(1,389)
Net income (loss)	$7,914	$(14,436)	$(8,412)	$(38,845)
Basic net income (loss) per share				
Net income (loss) per share	$0.14	$(0.28)	$(0.15)	$(0.75)
Weighted average number of common shares outstanding	56,794	51,771	54,880	51,690
Dilutive net income (loss) per share				
Net income (loss) per share	$0.14	$(0.28)	$(0.15)	$(0.75)
Weighted average number of common shares and dilutive common share equivalents outstanding	57,016	51,771	54,880	51,690

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

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(In thousands)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net income (loss)	$7,914	$(14,436)	$(8,412)	$(38,845)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	1	(2)	1	2
Comprehensive income (loss)	$7,915	$(14,438)	$(8,411)	$(38,843)

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)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$(8,412)	$(38,845)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of property and equipment	232	7,600
Depreciation and amortization	9,561	2,764
Accretion	224	—
Loss (gain) on disposal of fixed assets	230	(122)
Stock-based compensation	1,180	2,578
Non-cash interest expense	344	139
Amortization of premium and discount on investments	33	218
Changes in operating assets and liabilities:		
Restricted cash	135	598
Accounts receivable	7	(674)
Tenant improvement allowance receivable	—	5,637
Prepaid expenses and other current assets	120	(270)
Other noncurrent assets	75	244
Accounts payable	(2,958)	(2,585)
Accrued expenses	(3,848)	(4,263)
Deferred revenue	573	(18,007)
Lease exit obligation	(5,205)	7,798
Deferred rent	(10,569)	(6,033)
Other liabilities	37	—
Net cash used in operating activities	(18,241)	(43,223)
Investing activities		
Purchases of marketable securities	(11,581)	(38,056)
Proceeds from maturities and sales of marketable securities	9,050	102,107
Purchases of property and equipment	(14)	(12,875)
Proceeds from sale of property and equipment	1,241	183
Net cash (used in) provided by investing activities	(1,304)	51,359
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	10,217	—
Proceeds from exercise of stock options and issuance of common and restricted stock	278	191
Loan proceeds	—	10,000
Loan issuance cost	—	(1,388)
Principal payments on loans payable	(8,517)	(7,785)
Net cash provided by financing activities	1,978	1,018
Net decrease in cash and cash equivalents	(17,567)	9,154

Cash and cash equivalents at beginning of period	52,306	50,826
Cash and cash equivalents at end of period	$34,739	$59,980
Supplemental cash flow information		
Cash paid for interest	$1,619	$1,447
Non-cash financing activity		
Fair value of warrants issued in connection with loan payable	—	$413

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 potential 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-ß 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. In August 2015, the Company granted Novartis International Pharmaceuticals Ltd. ("Novartis") an exclusive worldwide license to develop and commercialize AV-380 and related AVEO antibodies that bind to GDF15. Novartis is responsible for all further activities and costs to develop and commercialize 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 September 30, 2015 of approximately $488.4 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 nine months ended September 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 September 30, 2015, and for the three and nine months ended September 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 September 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 $27.7 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.

Marketable Securities

Marketable securities at September 30, 2015 consisted of corporate debt securities maintained by an investment manager. The Company did not maintain any marketable securities at December 31, 2014. Credit risk is reduced as a result of the Company’s policy to limit the amount invested in any one issuance. Marketable securities consist primarily of investments which have expected average maturity dates in excess of three months, but not longer than 24 months. The Company classifies these investments as available-for-

sale. Unrealized gains and losses are included in other comprehensive income (loss) until realized. The cost of securities sold is based on the specific identification method. There were no realized gains or losses recognized on the sale or maturity of marketable securities during the three months ended September 30, 2015 and 2014.

Available-for-sale securities at September 30, 2015 consist of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
September 30, 2015:				
Corporate debt securities (Due within 1 year)	$2,499	1	—	$2,500

There were no securities that were in an unrealized loss position at September 30, 2015.

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. The Company’s credit risk related to marketable securities is reduced as a result of the Company’s policy to limit the amount invested in any one issuance.

Fair Value Measurements

The Company records cash equivalents and marketable securities 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 September 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 and marketable securities measured at fair value on a recurring basis in the accompanying condensed consolidated balance sheets as of September 30, 2015 and December 31, 2014.

	Fair Value Measurements of Cash Equivalents and Marketable Securities as of September 30, 2015			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents	$15,202	$12,488	$ —	$27,691
Marketable securities	—	2,500	—	2,500
	15,202	14,988	—	30,191

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

The fair value of the Company's loans payable at September 30, 2015, computed pursuant to a discounted cash flow technique using a market interest rate, was $13.0 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.

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 nine months ended September 30, 2015.

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 September 30, 2015 and September 30, 2014. The Company recognized $0.2 million and $7.6 million of impairment losses for the nine months ended September 30, 2015 and 2014, respectively, related to leasehold improvements.

Basic and Diluted Earnings (Loss) per Common Share

Basic earnings (loss) per share is computed by dividing net income (loss) available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed by dividing net income (loss) 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. After applying the treasury stock method for those instruments that were “in-the-money,” the dilutive effect of stock options and warrants resulted in an increase in the weighted-average number of dilutive common share equivalents outstanding of 222,000 used in calculating diluted earnings per common share for the three months ending September 30, 2015. For periods presented during which the Company had a net loss, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per common share is the same for those periods.

The following table sets forth the potential common shares excluded from the calculation of net loss per common share-diluted for the nine months ended September 30, 2015 and 2014 because their inclusion would have been anti-dilutive:

	Outstanding at September 30,	
	2015	2014
	(in thousands)	
Options outstanding	5,826	5,825
Warrants outstanding	609	609
	6,435	6,434

The following table sets forth the potential common shares excluded from the calculation of net income per common share—diluted for the three months ended September 30, 2015 and the calculation of net loss per common share—diluted for the three months ended September 30, 2014 because their inclusion would have been anti-dilutive:

	Outstanding at September 30,	
	2015	2014
	(in thousands)	
Options outstanding	4,096	5,825
Warrants outstanding		609
	4,096	6,434

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 Accounting Standards Codification ("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 nine months ended September 30, 2015 and September 30, 2014, the Company recorded the following stock-based compensation expense:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	(in thousands)			
Research and development	$50	$406	$238	$921
General and administrative	294	769	873	1,657
Restructuring			69	
	$344	$1,175	$1,180	$2,578

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. The Company calculates its provision for income taxes on ordinary income based on its projected annual tax rate for the year. 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. As of September 30, 2015, the Company is forecasting a net loss for the year ended December 31, 2015. The Company maintains a full valuation allowance on all deferred tax assets and has recorded no income tax provision or benefit in the current quarter.

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 September 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 nine months ended September 30, 2015 that had a material effect on the Company's condensed consolidated financial statements.

In May 2014, the Financial Accounting Standards Board ("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 permitted for annual and interim periods beginning after December 15, 2016. 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 Accounting Standards Update ("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

Novartis

In August 2015, the Company entered into a license agreement with Novartis. Under the license agreement, the Company has granted to Novartis the exclusive right to develop and commercialize worldwide the Company's proprietary antibody AV-380 and related AVEO antibodies that bind to Growth Differentiation Factor 15 ("GDF15") for the treatment and prevention of diseases and other conditions in all indications in humans (the "Product").

Pursuant to the license agreement, Novartis made an upfront payment to the Company of $15.0 million within fifteen days of the effective date. Novartis also has the right for 90 days after the effective date to acquire the Company's inventory of clinical quality, AV-380 biological drug substance. If Novartis exercises such right, it will reimburse the Company up to approximately $3.5 million for such existing inventory. The Company will also be eligible to receive (a) up to $53.0 million in potential clinical and development milestone payments and up to $105.0 million in potential regulatory milestone payments tied to the commencement of clinical trials and to regulatory approvals of products developed under the license agreement in the United States, the European Union and Japan; and (b) up to $150.0 million in potential commercial milestone payments based on annual net sales of such products. Upon commercialization, the Company is eligible to receive tiered royalties on net sales of approved products ranging from the high single digits to the low double digits. Novartis has responsibility under the license agreement for the development, manufacture and commercialization of the Company's antibodies and any resulting approved therapeutic products.

The term of the license agreement commenced in August 2015 and will continue on a country-by-country basis until the later to occur of the 10th anniversary of the first commercial sale of a product in such country or the expiration of the last valid patent claim for a product in that country. Either party may terminate the license agreement in the event of a material breach of the license agreement by the other party that remains uncured for a period of sixty days, which period may be extended an additional thirty days under certain circumstances. Novartis may terminate the license agreement, either in its entirety or with respect to any individual products or countries, at any time upon sixty days' prior written notice. In addition, the Company may terminate the license agreement upon thirty days' prior written notice if Novartis challenges certain patents controlled by the Company related to the Company's antibodies.

The Company has agreed that it will not directly or indirectly develop, manufacture or commercialize any GDF15 modulator as a human therapeutic during the term of the license agreement.

Activities under the agreement with Novartis 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 Novartis includes the following non-contingent deliverables: (i) the Company's grant of an exclusive, worldwide license to develop and commercialize the Product; (ii) the Company's obligation to transfer all technical knowledge and data useful in the development and manufacture of the Product; and (iii) the Company's obligation to cooperate with Novartis' requests for transition assistance during a 90 day period. The Company determined that the option to purchase the Company's existing inventory was a contingent deliverable.

The Company determined the delivered license and obligation to transfer technical knowledge and data have standalone value from the undelivered cooperation. The Company allocated up-front consideration of $15.0 million to the delivered license and technical knowledge. The relative selling price of the undelivered cooperation had de minimis value.

The Company received cash payments of $15.0 million and recorded this $15.0 million upfront payment allocated to the delivered license and technical knowledge deliverables as revenue during the three months ended September 30, 2015.

Pharmstandard

In August 2015, the Company entered into a license agreement with JSC "Pharmstandard- Ufimskiy Vitamin Plant," a company registered under the laws of the Russian Federation ("Pharmstandard"). Pharmstandard is a subsidiary of Pharmstandard OJSC. Under the license agreement, the Company has granted to Pharmstandard the exclusive, sublicensable right to develop, manufacture and commercialize tivozanib in the territories of Russia, Ukraine and the Commonwealth of Independent States (the "Licensed Territories") for all diseases and conditions in humans, excluding non-oncologic ocular conditions.

Under the license agreement, Pharmstandard is required to make an upfront payment to AVEO of $1.5 million, of which $1.0 million was paid during the three months ended September 30, 2015 and $0.5 million is payable within fifteen business days of the date the license agreement is registered with the Federal Service for Intellectual Property of the Russian Federation. 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 by Pharmstandard 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 Licensed Territories.

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 effective date, unless Russian regulatory authorities require Pharmstandard to conduct an additional clinical trial prior to approval and Pharmstandard is actively performing such trial.

The term of the license agreement commenced in August 2015 and will continue on a product-by-product and country-by-country basis until the later to occur of (a) the expiration of the last valid patent claim for such product in such country, (b) the expiration of the last marketing authorization for such product in such country or (c) the 10th anniversary of the first commercial sale of such product in such country. Either party may terminate the license agreement in the event of a material breach by the other party that remains uncured, following receipt of written notice of such breach, for a period of (a) thirty days, in the case of breach for nonpayment of any amount due under the license agreement, and (b) ninety days, in the case of any other material breach. After the first anniversary of the effective date, Pharmstandard may terminate the license agreement at any time upon ninety days' prior written notice. In addition, the Company may terminate the license agreement upon thirty days' prior written notice if Pharmstandard challenges certain patents controlled by the Company or the Company's licensor, Kyowa Hakko Kirin (formerly Kirin Brewery Co. Ltd.) ("KHK"), related to tivozanib.

Activities under the agreement with Pharmstandard were evaluated under ASC 605-25 to determine whether such activities represented a multiple element revenue arrangement. The agreement with Pharmstandard includes the following non-contingent deliverables: (i) the Company's grant of an exclusive license to develop and commercialize tivozanib in the Licensed Territories, (ii) the Company's obligation to provide access, upon request, to all clinical data, regulatory filings, safety data and manufacturing data to Pharmstandard for use in the development and commercialization of tivozanib in the Licensed Territories, (iii) the Company's obligation to participate in certain development and commercialization planning meetings and (iv) the Company's obligation to provide support for certain development, regulatory or manufacturing activities if requested by Pharmstandard.

The Company determined the delivered license does not have standalone value from the undelivered items and that the arrangement should be treated as a single unit of accounting. The Company allocated the upfront payment of $1.0 million to the bundled unit of accounting and is amortizing it over the Company's performance period through April 2022, the remaining patent life of tivozanib. The Company recognized approximately $23,000 as revenue during the three and nine months ended September 30, 2015.

The Company believes the regulatory milestones that may be achieved under the Pharmstandard agreement are consistent with the definition of a milestone included in ASU 2010-17, Revenue Recognition—Milestone Method, and, accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when such milestone is achieved. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve each milestone, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone.

A percentage of all upfront, milestone and royalty payments received by AVEO are due to KHK as a sublicensing fee under the License Agreement between AVEO and KHK dated as of December 21, 2006. The Company incurred $0.3 million of R&D expense associated with sublicensing fees payable to KHK during the three months ended September 30, 2015.

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 to determine whether such activities represented a multiple element revenue arrangement. The agreement with Ophthotech includes the following non-contingent

deliverables: (i) 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 "Option Grant Deliverable"); (ii) 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 (iii) the Company's obligation to transfer research-grade tivozanib active pharmaceutical ingredient ("API") for Ophthotech to conduct the option period research.

The Company determined that the delivered Option Grant Deliverable 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 $0.2 million of revenue during the three and nine months ended September 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®, 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, to determine whether such activities represented a multiple element revenue arrangement. The agreement with Biodesix includes the following non-contingent deliverables: (i) perpetual, non-exclusive rights to certain intellectual property including clinical and biomarker data related to ficlatuzumab for use in developing and commercializing BDX004; (ii) the Company's obligation to deliver technology improvements and data developed during the NSCLC POC Trial to Biodesix; (iii) the Company's obligation to participate in the joint steering committee during the NSCLC POC Trial; (iv) the Company's obligation to perform certain development activities associated with the NSCLC POC Trial; (v) the Company's obligation to supply clinical material for use in conducting the NSCLC POC Trial; (vi) 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 September 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 $0.8 million and $2.7 million during the three and nine months ended September 30, 2015, respectively. The Company reduced research and development expenses by approximately $0.6 million and $0.9 million during the three and nine months ended September 30, 2014, respectively. The amount due to the Company from Biodesix pursuant to the cost-sharing provision was $1.8 million at September 30, 2015. The Company received cash payments related to cost reimbursements of $2.7 million during the nine months ended September 30, 2015.

St. Vincent's

In July 2012, the Company entered into a license agreement with St. Vincent's Hospital Sydney Limited ("St. Vincent's"), under which the Company obtained an exclusive, worldwide license to research, develop, manufacture and commercialize products for human therapeutic, preventative and palliative applications that benefit from inhibition or decreased expression or activity of MIC-1, which is also referred to as GDF15. Under the agreement, the Company has the right to grant sublicenses subject to certain restrictions. Under the license agreement, St. Vincent's also granted the Company non-exclusive rights for certain related diagnostic products and research tools.

In order to sublicense certain necessary intellectual property rights to Novartis in August 2015, the Company entered into an amendment (the "Amended St. Vincent's Agreement") to the license agreement with St. Vincent's. Under the Amended St. Vincent's Agreement, the Company was required to make an upfront payment to St. Vincent's of $1.5 million. This payment was recorded as R&D expense during the three months ended September 30, 2015. St. Vincent's is also eligible to receive up to approximately $18.9 million in connection with development and regulatory milestones under the Amended St. Vincent's Agreement. Royalties for approved products resulting from the Amended St. Vincent's Agreement will also be payable to St. Vincent's, and the Company and Novartis will share that obligation equally. Under the license agreement with Novartis, the Company is required to maintain the Amended St. Vincent's Agreement in effect, and not enter into any amendment that would adversely affect Novartis' rights during the term of the license agreement with Novartis.

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 nine months ended September 30, 2015, respectively. The Company also recorded revenue of $0.1 million and $14.4 million of revenue during the three and nine month periods ended September 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 Pharma Inc. and certain of its indirect wholly-owned subsidiaries (collectively, "Astellas"), pursuant to which the Company and Astellas intended to develop and commercialize tivozanib for the treatment of a broad range of cancers (the "Astellas Agreement"). 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 $0.5 million and $0.9 million during the three months ended September 30, 2015 and 2014,

respectively, and by $0.7 million and $3.0 million during the nine months ended September 30, 2015 and 2014, respectively. The net amount due to the Company from Astellas pursuant to the cost-sharing provisions was $0.5 million and $0.9 million at September 30, 2015 and 2014, respectively.

Under the agreement, the Company received cash payments related to cost reimbursements of $0.4 million and $1.0 million during each of the three months ended September 30, 2015 and 2014, respectively, and $1.0 million and $3.2 million during each of the nine months ended September 30, 2015 and 2014, respectively.

(5) Accrued Expenses

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

	September 30, 2015	December 31, 2014
	(in thousands)	
Clinical expenses	$2,378	$ 2,312
Salaries and benefits	922	1,744
Restructuring	605	—
Professional fees	440	685
Manufacturing and distribution	136	3,216
Other	972	1,344
	$5,453	$ 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. The Company is not required to pay principal on the original loan until January 1, 2015, at which time the Company is required to commence making 12 principal and interest payments ending December 1, 2015.

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 May 1, 2016. The period during which the Company is not required to pay principal was extended six months from November 1, 2015 to May 1, 2016 upon executing the Company's license agreement with Novartis and may be further extended if the Company continues to achieve 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. 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% (11.9% as of September 30, 2015). 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 September 30, 2015 that are included in the Loan Agreement and 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 September 30, 2015, the aggregate principal balance outstanding was $13.0 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 September 30, 2015 are as follows (amounts in thousands):

Years Ending December 31:	
2015 (3 months remaining)	$3,458

2016	3,499
2017	4,644
2018	4,269
	15,870
Less amount representing interest	(2,236)
Less discount	(617)
Less deferred charges	(540)
Less current portion	(4,217)
Loans payable, net of current portion and discount	$8,260

(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 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 September 30, 2015, the Company has sold approximately 5.9 million shares pursuant to the Sales Agreement, resulting in proceeds of approximately $10.2 million, net of commissions and issuance costs.

Approximately $9.1 million remains available for sale under the Sales Agreement.

(8) Stock-based Compensation

Stock Plans

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

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2014	5,817,313	$ 4.45		
Granted	3,159,134	$ 1.11		
Exercised	(163,305)	$ 1.46		
Forfeited	(2,987,202)	$ 3.02		
Outstanding at September 30, 2015	5,825,940	$ 3.45	7.91	$ 511,535
Vested or expected to vest at September 30, 2015	3,018,136	$ 5.37	6.84	$ 236,889
Exercisable at September 30, 2015	2,079,625	$ 7.06	5.75	$ 74,899

Stock options to purchase 1,281,500 shares of common stock contain market conditions which were not deemed probable of vesting at September 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	
	September 30,	
	2015	2014
Volatility factor	74.53%-76.38%	69.38%-72.16%
Expected term (in years)	6.25	5.50-6.25
Risk-free interest rates	1.56%	2.00%
Dividend yield	—	—

	Nine Months Ended	
	September 30,	
	2015	2014
Volatility factor	73.04%-76.38%	69.38%-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 nine months ended September 30, 2015 and 2014 was $0.75 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 70% and 52% as of September 30, 2015 and 2014, respectively.

As of September 30, 2015, there was $1.0 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 3.0 years. The intrinsic value of options exercised during the nine months ended September 30, 2015 was $57,000. No options were exercised during the three months ended September 30, 2015, and three and nine months ended September 30, 2014.

The restricted stock activity for the nine months ended September 30, 2015 is as follows:

	Number of Shares	Weighted-Average Fair-Value
Unvested at December 31, 2014	477,600	$ 1.81
Granted	—	—
Cancelled	(201,180)	1.87
Vested/Released	(233,670)	1.80
Unvested at September 30, 2015	42,750	$ 1.61

As of September 30, 2015, there was approximately $19,000 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 0.4 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 amounts accrued at December 31, 2014	Restructuring expense incurred during the nine months ended September 30, 2015	Restructuring amounts paid during the nine months ended September 30, 2015	Restructuring amounts accrued at September 30, 2015
	(in thousands)			
Employee severance, benefits and related costs	$—	3,560	$ (2,955)	605

The Company is obligated to continue to pay the remaining amounts accrued through the first quarter of 2016. The table above excludes non-cash stock-based compensation costs of approximately $0.1 million incurred as part of the restructuring during the nine months ended September 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 nine months ended September 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 nine months ended September 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:

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

In addition to the $0.5 million of expense for the nine months ended September 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 the Company and certain of its former officers and 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 lawsuit seeks 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 its 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 new complaint on July 17, 2015, the plaintiffs filed an opposition to that motion on July 31, 2015, and the Company filed a reply brief on August 14, 2015. The Court heard oral argument on this latest motion to dismiss on September 24, 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 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 the Company's stock filed a derivative complaint allegedly on behalf of the Company 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 the Company as a nominal defendant and also named as defendants present and former members of its 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 with respect to the same statements at issue in the securities litigation. 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 its 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 its 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 staff ("SEC Staff") of the United States Securities and Exchange Commission ("Commission") served a subpoena on the Company for documents and information concerning tivozanib, including related communications with the FDA, investors and others. The Company has fully cooperated with the inquiry, which the Company believes is nearly complete. In September 2015, the SEC Staff invited the Company to discuss the settlement of potential claims that the SEC Staff may recommend that the Commission bring against the Company asserting that the Company violated federal securities laws by omitting to disclose to investors the recommendation made to the Company by the staff of the U.S. Food and Drug Administration, on May 11, 2012, that the Company conduct an additional clinical trial with respect to tivozanib. The Company has commenced such discussions, but there can be no assurance that a settlement on terms agreeable to the Company will be achieved. If settlement discussions conclude without a settlement proposal that is acceptable to the SEC Staff, the SEC Staff may request that the Commission authorize the SEC Staff to bring claims against the Company. In the ordinary course, before the Commission makes a decision about such a request, the Company would be permitted to make a submission to the Commission explaining why no claim should be brought against the Company, or why the Commission should enter into a settlement on terms acceptable to the Company. If settlement discussions with the SEC Staff do not result in a settlement, the Company intends to make such a submission. The Company cannot predict the outcome of its discussions with the SEC Staff or reasonably estimate a range of possible loss at this time, and there can be no assurance that the Company will be able to resolve any potential claims of the Commission or that any settlement will not have a material adverse impact on its ability to execute on its proposed plans or on its financial position or results of operations. The Company intends to defend any claim brought against it by the Commission.

The SEC Staff has also invited three of the Company's former officers to discuss the settlement of potential claims that the SEC Staff may recommend that the Commission bring against them. The Company is not a party to any discussions between the Staff and the former officers.

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 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® (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, or 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 assure 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. We 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.

Additional RCC Phase 3 Trial: We are evaluating the opportunity to conduct an additional phase 3 trial of tivozanib in the third-line treatment of patients with refractory RCC setting using PFS as the primary endpoint and OS as a secondary endpoint, in order to support the approval of tivozanib as a third-line treatment and 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: In March 2015, we 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.

PD-1 Combination Trial: We are evaluating the opportunity to conduct a phase 1 combination study of tivozanib combined with a PD-1 inhibitor for the treatment of patients with RCC. We are evaluating all options for funding, including partnerships, for the clinical and regulatory advancement of tivozanib in combination with PD-1 inhibitors in RCC.

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: In August 2015, we entered into a license agreement under which we granted to one of Pharmstandard OJSC's subsidiaries ("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.

- 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 began enrolling patients during the second half of 2015. 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-ß 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 2nd 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 August 2015, we entered into a license agreement under which we granted Novartis International Pharmaceutical Ltd. the exclusive right to develop and commercialize AV-380 and related AVEO antibodies. Under this agreement, Novartis is responsible for all activities and costs associated with the further development, regulatory filing and commercialization of AV-380 worldwide.

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 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 September 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 September 30, 2015, we had an accumulated deficit of $488.4 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, and the timing and nature of activities contemplated for 2015 and thereafter will be conducted subject to the availability of sufficient financial resources.

Strategic Partnerships

Novartis

In August 2015, we entered into a license agreement with Novartis International Pharmaceutical Ltd., which we refer to as Novartis, under which we granted Novartis the exclusive right to develop and commercialize AV-380 and related AVEO antibodies that bind to Growth Differentiation Factor 15 worldwide. Under this agreement, Novartis is responsible for all activities and costs associated with the further development, regulatory filing and commercialization of AV-380 worldwide.

Novartis made an upfront payment to us of $15.0 million during September 2015. We will also be eligible to receive (a) up to $53 million in potential clinical milestone payments and up to $105 million in potential regulatory milestone payments tied to the commencement of clinical trials and to regulatory approvals of products developed under the license agreement in the United States, the European Union and Japan; and (b) up to $150 million in potential sales based milestone payments based on annual net sales of such products. Upon commercialization, we are eligible to receive tiered royalties on net sales of approved products ranging from the high single digits to the low double digits. Novartis has responsibility under the license agreement for the development, manufacture and commercialization of the licensed antibodies and any resulting approved therapeutic products.

Novartis also has the right for 90 days following the effective date of the agreement to acquire our inventory of clinical quality drug substance. If Novartis exercises such right, it will reimburse us up to approximately $3.5 million for such existing inventory.

Pharmstandard Group

In August 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 made an upfront payment to us of $1.0 million and will be obligated to pay an additional $0.5 million upon registration of the license agreement with a Russian regulatory agency. 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 paid 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.

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®, 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 ficlatuzuamab 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.

In August 2015, in connection with the execution of our license agreement with Novartis, we entered into an amended agreement with St. Vincent's, pursuant to which we made an upfront payment to St. Vincent's of $1.5 million. St. Vincent's is also eligible to receive up to approximately $18.9 million in connection with development and regulatory milestones. Royalties for approved products resulting from the license agreement will also be payable to St. Vincent's, and we and Novartis will share that obligation equally.

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, would 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 nine months ended September 30, 2015 and 2014:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	(in thousands)		(in thousands)	
Tivozanib	$2,612	$1,947	$5,050	$8,365
AV-380 Program in Cachexia	1,573	2,354	2,330	6,517
Ficlatuzumab		312		1,844
AV-203	89	343	455	1,542
Other pipeline programs		13	11	38
Other research and development		13	10	55
Overhead	192	3,503	1,146	11,191
Total research and development expenses	$4,466	$8,485	$9,002	$29,552

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. We are also evaluating the opportunity to conduct an additional phase 3 trial of tivozanib vs. sorafenib in approximately 314 patients in the refractory RCC setting using PFS as the primary endpoint and OS as a secondary endpoint, in order to support the approval of tivozanib as a third-line treatment and to address the overall survival concerns presented in the June 2013 complete response letter from the FDA. We expect this trial to cost between $34.0 and $38.0 million through completion.

AV-380 Program in Cachexia

In August 2015, we entered into a license agreement with Novartis, under which we granted Novartis the exclusive right to develop and commercialize AV-380 and related AVEO antibodies that bind to Growth Differentiation Factor 15 worldwide. Under this agreement, Novartis is responsible for all activities and costs associated with the further development, regulatory filing and commercialization of AV-380 worldwide. We do not expect to incur any significant costs related to AV-380 in future periods beyond any milestone fees and royalties payable to St. Vincent’s pursuant to our in-licensing agreement.

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®, 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®, 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. As a result of the cost sharing provisions in our arrangement with Biodesix, we reduced research and development expenses by approximately $0.8 million and $2.7 million during the three and nine months ended September 30, 2015, respectively. Biodesix is committed to provide up to $9.3 million to fund the remaining costs of the phase 2 trial. 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.

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 September 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 nine month period ended September 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 September 30, 2015 and 2014

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

	Three Months Ended			
	September 30,		Increase/	
	2015	2014	(decrease)	%
	(in thousands)			
Revenue	$15,158	$873	$ 14,285	1,636%
Operating expenses:				
Research and development	4,466	8,485	(4,019)	(47)%
General and administrative	2,225	5,084	(2,859)	(56)%
Restructuring and lease exit	—	1,403	(1,403)	(100)%
Total operating income (expenses)	6,691	14,972	(8,281)	(55)%
Income (loss) from operations	8,467	(14,099)	22,566	160%
Other (expense) income, net	(22)	98	(120)	(122)%
Interest expense	(533)	(439)	(94)	21%
Interest income	2	4	(2)	(50)%

Net income (loss)	$7,914	$(14,436)	$ 22,350	155	%

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

Revenue	Three Months Ended September 30, 2015	2014	Increase/ (decrease)	%	
	(in thousands)				
Strategic Partner:					
Novartis	$15,000	$—	$ 15,000	100	%
Biogen Idec	77	77	—	—	
Pharmstandard	23	—	23	—	
Ophthotech	58	—	58	—	
Astellas	—	796	(796)	(100)	%
	$15,158	$873	$ 14,285	1,636	%

Revenue. Revenue for the three months ended September 30, 2015 was $15.2 million compared to $0.9 million for the three months ended September 30, 2014, an increase of approximately $14.3 million. The increase was primarily due to an additional $15.0 million in revenue recognized in the third quarter of 2015 in connection with our out-licensing agreement with Novartis, which was executed in August 2015, and an additional $0.8 million in revenue recognized in the third 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 September 30, 2015 were $4.5 million compared to $8.5 million for the three months ended September 30, 2014, a decrease of $4.0 million or 47%. The decrease was primarily attributable to a $1.5 million decrease in employee compensation and travel costs and a decrease of $2.4 million in facilities, IT, and other costs following our January 2015 restructuring and the reduction of our utilized facility space as well as a $1.6 million decrease in external clinical trial and consulting costs primarily associated with the decreased ficlatuzumab manufacturing activity and AV-380 preclinical development activity. This decrease was offset by a $1.8 million increase in in-licensing expense associated with the sub-licensing payments to KHK and St. Vincent's as a result of the license agreements signed in August 2015 with Novartis and Pharmstandard.

General and administrative. General and administrative expenses for the three months ended September 30, 2015 were $2.2 million compared to $5.1 million for the three months ended September 30, 2014, a decrease of $2.9 million or 56%. The decrease was primarily the result of a $0.7 million decrease in external legal costs associated with various ongoing legal matters and a $2.2 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 expense for the three months ended September 30, 2015 and 2014 were $0 and $1.4 million, respectively. The expenses incurred during the three months ended September 30, 2014 relate to the partial termination of our lease for space that we ceased using at our 650 E Kendall Street facility, which occurred in September 2014.

Interest expense. Interest expense for the three months ended September 30, 2015 was $0.5 million compared to $0.4 million for the three months ended September 30, 2014. The increase was 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 September 30, 2015 was $2,000 compared to $4,000 for the three months ended September 30, 2014, a decrease of $2,000 or 50%. The decrease in interest income was primarily due to a lower average cash balance during the three months ended September 30, 2015 compared to the three months ended September 30, 2014.

Comparison of Nine Months Ended September 30, 2015 and 2014

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

	Nine Months Ended September 30,		Increase/ (decrease)	%
	2015	2014		
	(in thousands)			
Revenue	$15,426	$18,007	$(2,581)	(14)%
Operating expenses:				

Research and development	9,002	29,552	(20,550)	(70)%
General and administrative	8,367	15,485	(7,118)	(46)%
Restructuring and lease exit	4,358	10,426	(6,068)	(58)%
Total operating expenses	21,727	55,463	(33,736)	(61)%
Loss from operations	(6,301)	(37,456)	31,155	(83)%
Other (expense) income, net	(245)	103	(348)	(338)%
Interest expense	(1,880)	(1,522)	(358)	24 %
Interest income	14	30	(16)	(53)%
Net loss	$(8,412)	$(38,845)	$30,433	(78)%

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

Revenue	Nine Months Ended September 30, 2015	2014	Increase/ (decrease)	%
	(in thousands)			
Strategic Partner:				
Novartis	$15,000	$—	$15,000	100 %
Biogen Idec	230	14,443	(14,213)	(98)%
Pharmstandard	23	—	23	100 %
Ophthotech	173	—	173	100 %
Astellas	—	3,564	(3,564)	(100)%
	$15,426	$18,007	$(2,581)	(14)%

Revenue. Revenue for the nine months ended September 30, 2015 was $15.4 million compared to $18.0 million for the nine months ended September 30, 2014, a decrease of approximately $2.6 million. The decrease was primarily due to due to $3.6 million in revenue recognized in the third quarter of 2014 in connection with our agreement with Astellas, which concluded in August 2014, and an additional $14.1 million of deferred revenue recognized as a result of the amendment to our agreement with Biogen in March 2014, offset by an additional $15.0 million in revenue recognized in the third quarter of 2015 in connection with our out-licensing agreement with Novartis, which was executed in August 2015.

Research and development. Research and development, or R&D, expenses for the nine months ended September 30, 2015 were $9.0 million compared to $29.6 million for the nine months ended September 30, 2014, a decrease of $20.6 million or 70%. The decrease was primarily attributable to a $5.0 million decrease in employee compensation and travel costs, a decrease of $7.5 million in facilities, IT, and other costs following our January 2015 restructuring and the reduction of our utilized facility space as well as a $9.6 million decrease in external clinical trial and consulting costs associated with the decreased clinical and preclinical development activity. This was offset by a $1.8 million increase in in-licensing expense associated with the sub-licensing payments to KHK and St. Vincent’s as a result of the license agreements signed in August 2015 with Novartis and Pharmstandard.

General and administrative. General and administrative expenses for the nine months ended September 30, 2015 were $8.4 million compared to $15.5 million for the nine months ended September 30, 2014, a decrease of $7.1 million or 46%. The decrease was primarily the result of a $1.6 million decrease in external legal costs associated with various ongoing legal matters and a $5.5 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 nine months ended September 30, 2015 were $4.4 million compared to $10.4 million for the nine months ended September 30, 2014. The expenses incurred during the nine months ended September 30, 2015 primarily related 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 nine months ended September 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 nine months ended September 30, 2015 was $1.9 million compared to $1.5 million for the nine months ended September 30, 2014, an increase of 24%. The increase was primarily attributable to the increase in the outstanding balance on our loan with Hercules Technology Growth.

Interest income. Interest income for the nine months ended September 30, 2015 was $14,000 compared to $30,000 for the nine months ended September 30, 2014, a decrease of $16,000 or 53%. The decrease in interest income was primarily due to a lower average cash balance during the nine months ended September 30, 2015 compared to the nine months ended September 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 September 30, 2015, we had cash, cash equivalents and marketable securities of approximately $37.2 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:

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Net cash used in operating activities	$(18,241)	$(43,223)
Net cash (used in) provided by investing activities	(1,304)	51,359
Net cash provided by financing activities	1,978	1,018
Net (decrease) increase in cash and cash equivalents	$(17,567)	$9,154

For the nine months ended September 30, 2015 and 2014, our operating activities used cash of $18.2 million and $43.2 million, respectively. Cash used by operations for the nine months ended September 30, 2015 and 2014 was due primarily to our net loss adjusted for non-cash items and changes in working capital.

For the nine months ended September 30, 2015 and 2014, our investing activities used cash of $1.3 million and provided cash of $51.4 million, respectively. Cash used by investing activities for the nine months ended September 30, 2015 was primarily the net result of the purchase of marketable securities, partially offset by the proceeds from the maturity of marketable securities and the sale of equipment. Cash provided by investing activities for the nine months ended September 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 $12.9 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 nine months ended September 30, 2015 and 2014, our financing activities provided cash of $2.0 million and $1.0 million, respectively. The increase in cash provided by financing activities is primarily the result of the receipt of proceeds from sales of common stock during the nine months ended September 30, 2015, partially offset by principal payments on our loan with Hercules.

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 September 30, 2015, we have sold approximately 5.9 million shares pursuant to the Sales Agreement, resulting in proceeds of approximately $10.2 million, net of commissions and issuance costs. Approximately $9.1 million remains available for sale under the 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 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 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 May 1, 2016. The date on which we will be required to begin making principal payments was extended in August 2015 and may be further extended if we continue to achieve performance milestones, 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 September 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 September 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 September 30, 2015, the principal balance outstanding was $13.1 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 would allow us to fund our current operations through the fourth quarter of 2017. 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 of equity under our ATM. In addition, we cannot estimate the impact on our cash resources of a settlement of claims with the SEC. A Phase 3 trial for RCC such as the one contemplated by us could cost in the range of $34-38 million through 2019. The timing and nature of activities contemplated for 2015 and thereafter 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;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the absence of any breach, acceleration event or event of default under our loan agreement with Hercules or under any other agreements with third parties;
- the outcome of lawsuits and SEC proceedings against us, including the current lawsuits and SEC proceedings described below under “Part II, Item 1A—Legal Proceedings;” and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we identify additional opportunities to do so, we may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate our clinical trials or other development activities for one or more of our product candidates; and/or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, if approved.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on March 6, 2015.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2015, we had cash, cash equivalents and marketable securities of $37.2 million, consisting of cash on deposit with banks, money market funds, U.S. government agency securities and corporate debt, including commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

Our long-term debt bears interest at variable rates. In May 2010, we entered into a loan agreement with affiliates of Hercules Technology Growth Capital pursuant to which we received a loan in the aggregate principal amount of $25.0 million. In March 2012, we entered into an amendment to the loan agreement, pursuant to which we increased the principal amount to $26.5 million. In September 2014, we entered into a further amendment to the loan agreement, pursuant to which we borrowed a new loan of $10.0 million, which is in addition to the existing loan which had an outstanding principal balance of $11.6 million. As of September 30, 2015 our aggregate principal balance outstanding on our loans was $13.1 million. Per annum interest is payable at the greater of 11.9% and 11.9% plus the prime rate of interest minus 4.75%, not to exceed 15%. As a result of the 15% maximum per annum interest rate under the amended loan agreement, we have limited exposure to changes in interest rates on borrowings under this loan agreement. For every 1% increase in the prime rate over 4.75%, given the amount of debt outstanding under the loan agreement as of September 30, 2015, and expected loan payments during 2015, we would have a decrease in future annual cash flows

of approximately $0.1 million over the next twelve month period as a result of such 1% increase.

We are also exposed to market risk related to change in foreign currency exchange rates. We contract with contract research organizations and investigational sites that are located around the world. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign currency exchange rate risk.

Item 4. Controls and Procedures.

Our management, with the participation of our President and Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our President and Chief Executive Officer (our principal executive officer) and our Chief Financial Officer

(our principal financial officer) concluded that as of September 30, 2015, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our management including our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. 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 our former officers and 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 AVEO made false and/or misleading statements concerning the development of the drug tivozanib and its prospects for FDA approval. The lawsuit seeks unspecified damages, interest, attorneys' fees, and other costs. We moved to dismiss the amended complaint, and after briefing and oral argument, on March 20, 2015, the Court granted our 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. We filed a new motion to dismiss this new complaint on July 17, 2015, the plaintiffs filed an opposition to that motion on July 31, 2015, and we filed a reply brief on August 14, 2015. The Court heard oral argument on this latest motion to dismiss on September 24, 2015. We intend to continue to deny any allegations of wrongdoing and to vigorously defend against this lawsuit. However, there is no assurance that we 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 the action. Moreover, we are 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 with respect to the same statements at issue in the securities litigation. 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. We 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 we 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. We intend to continue to deny any allegations of wrongdoing and to vigorously defend against this lawsuit. However, there is no assurance that we 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, we are unable to predict the outcome or reasonably estimate a range of possible loss at this time.

On July 3, 2013, the staff (the "SEC Staff") of the United States Securities and Exchange Commission (the "Commission") served a subpoena on us for documents and information concerning tivozanib, including related communications with the FDA, investors and others. We have fully cooperated with the inquiry, which we believe is nearly complete. In September 2015, the SEC Staff invited us to discuss the settlement of potential claims that the SEC Staff may recommend that the Commission bring against us asserting that we violated federal securities laws by omitting to disclose to investors the recommendation made to us by the staff of the U.S. Food and Drug Administration, on May 11, 2012, that we conduct an additional clinical trial with respect to tivozanib. We have commenced such discussions, but there can be no assurance that a settlement on terms agreeable to us will be achieved. If settlement discussions conclude without a settlement proposal that is acceptable to the SEC Staff, the SEC Staff may request that the Commission authorize the SEC Staff to bring claims against us. In the ordinary course, before the Commission makes a decision about such a request, we would be permitted to make a submission to the

Commission explaining why no claim should be brought against us, or why the Commission should enter into a settlement on terms acceptable to us. If settlement discussions with the SEC Staff do not result in a settlement, we intend to make such a submission. We cannot predict the outcome of our discussions with the SEC Staff or reasonably estimate a range of possible loss at this time, and there can be no assurance that we will be able to resolve any potential claims of the Commission or that any settlement will not have a material adverse impact on our ability to execute on our proposed plans or on our financial position or results of operations. We intend to defend any claim brought against us by the Commission.

The SEC Staff has also invited three of our former officers to discuss the settlement of potential claims that the SEC Staff may recommend that the Commission bring against them. The Company is not a party to any discussions between the Staff and the former officers.

Item 1A. Risk Factors

Our business is subject to numerous risks. We caution you that the following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in this Quarterly Report on Form 10-Q and other filings with the SEC, press releases, communications with investors and oral statements. Any or all of our forward-looking statements in this Quarterly Report on Form 10-Q and in any other public statements we make may turn out to be

wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in the discussion below will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may differ materially from those anticipated in our forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosure we make in our reports filed with the SEC.

Risks Related to Our Financial Position and Capital Requirements

We may not be successful in establishing and maintaining strategic partnerships to further the development of each of our therapeutic programs. A failure to obtain such partnerships in the near future will have a material adverse effect on our operations and business.

We currently are exploring partnership opportunities to fund the further development of a majority of our development programs, including our lead program for tivozanib as well as AV-203. Accordingly, our success will depend in significant part on our ability to attract and maintain strategic partners and strategic relationships with major biotechnology or pharmaceutical companies to support the development and commercialization of these product candidates. In these partnerships, we would expect our strategic partner to provide substantial funding, as well as significant capabilities in research, development, marketing and sales.

We face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any product candidates and programs because our development pipeline may be deemed insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy.

Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic partnership agreements related to our product candidates could have an adverse effect on our business or our operating plan, including delaying the development and commercialization of our product candidates.

Moreover, if we fail to establish and maintain additional strategic partnerships related to our product candidates:

- we will have limited resources with which to continue to operate our business and we may not be able to successfully complete any other strategic transactions;
- the development of certain of our product candidates may be terminated or delayed; and
- our cash expenditures related to development of our product candidates would increase significantly, and we do not have the cash resources to develop our product candidates on our own.

We will require substantial additional financing, and a failure to obtain this necessary capital when needed would force us to delay, limit, reduce or terminate our research, product development or commercialization efforts.

We will require substantial funds to continue our development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for substantial working capital to support our development activities for tivozanib, ficlatuzumab and AV-203. Moreover, we have future payment obligations and cost-sharing arrangements under certain of our collaboration and license agreements. For example, under our agreements with KHK and St. Vincent’s, we are required to make certain clinical and regulatory milestone payments, have royalty obligations with respect to product sales and are required to pay a specified percentage of sublicense revenue in certain instances. Moreover, under our agreement with Biodesix, we are obligated to share any costs for the phase 2 FOCAL study that exceed $15 million. Accordingly, we will need substantial additional funding

in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, or if we are unable to procure partnership arrangements to advance our programs, we would be forced to delay, reduce or eliminate our research and development programs and any future commercialization efforts.

We believe that our cash resources would allow us to fund our current operations through the fourth quarter of 2017. 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 of equity under our ATM. In addition, we cannot estimate the impact on our cash resources of a settlement of claims with the SEC. A Phase 3 trial for RCC such as the one contemplated by us could cost in the range of $34-38 million through 2019. The timing and nature of activities contemplated for 2015 and thereafter will be conducted subject to the availability of sufficient financial resources.

However, because of the numerous risks and uncertainties associated with the development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future capital requirements depend on many factors, including:

- 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 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;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the absence of any breach, acceleration event or event of default under our loan agreement with Hercules or under any other agreements with third parties;
- the outcome of lawsuits and SEC proceedings against us, including the current lawsuits and SEC proceedings described under “Part II, Item 1—Legal Proceedings;”
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize, and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all.

We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all.

We anticipate that we will require additional funding. If we are unable to obtain such additional funding on a timely basis, whether through payments under existing or future collaborations or license agreement or sales of debt or equity, we may be required to delay, limit, reduce or terminate our clinical trials or development activities for one or more of our product candidates.

We anticipate that we will continue to incur significant operating losses for the foreseeable future. It is uncertain if we will ever attain profitability, which would depress the market price of our common stock.

We have incurred net losses in all prior annual reporting periods, other than for the year ended December 31, 2011, including a net loss of $8.4 million during the nine months ended September 30, 2015. As of September 30, 2015, we had an accumulated deficit of $488.4 million. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, we may never attain profitability. Our losses have resulted principally from costs incurred in our discovery and development activities. We anticipate that we will continue to incur significant operating costs over the next several years as we seek to develop our product candidates.

If we do not successfully develop and obtain regulatory approval for our existing and future pipeline of product candidates, and effectively manufacture, market and sell any product candidates that are approved, we may never generate product sales. Even if we do generate product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We and certain of our former officers and present and former directors have been named as defendants in multiple lawsuits that could result in substantial costs and divert management's attention.

We, and certain of our former officers and present and former directors, were named as defendants in a consolidated class action lawsuit initiated in 2013 that generally alleges that we and those individuals violated federal securities laws by making allegedly false and/or misleading statements concerning the development of our drug tivozanib and its prospects for FDA approval. The lawsuit seeks unspecified damages, interest, attorneys' fees, and other costs. The consolidated amended complaint was dismissed without prejudice on March 20, 2015, but the lead plaintiffs have filed a second amended complaint bringing similar allegations. We filed a new motion to dismiss this new complaint on July 17, 2015, the plaintiffs filed an opposition to that motion on July 31, 2015, and we filed a reply brief on August 14, 2015. The Court heard oral argument on this latest motion to dismiss on September 24, 2015. Another plaintiff has also filed a derivative complaint, allegedly on our behalf, naming us as a nominal defendant and also naming as defendants present and former members of our board of directors, alleging breach of fiduciary duty and abuse of control on the part of those directors with respect to the same statements at issue in the securities litigation. The derivative 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 derivative complaint was dismissed with prejudice on March 18, 2015. The plaintiff has appealed the court's decision to the United States Court of Appeals for the First Circuit.

We intend to continue to deny these allegations and to engage in a vigorous defense of these lawsuits. However, we are unable to predict the outcome of these matters at this time. Moreover, any conclusion of these matters in a manner adverse to us could have a material adverse effect on our financial condition and business. For example, we could incur substantial costs not covered by our liability insurance, suffer a significant adverse impact on our reputation and divert management's attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. In addition, any of these matters could require payments that are not covered by, or exceed the limits of, our available liability insurance, which could have a material adverse effect on our operating results or financial condition.

We are in settlement discussions with the SEC. If such discussions do not result in a settlement, the SEC may bring a claim against us.

The SEC Staff has invited us, and three of our former officers, to discuss the settlement of potential claims that the SEC Staff may recommend that the Commission bring, asserting that we violated federal securities laws by omitting to disclose the recommendation of the staff of the U.S. Food and Drug Administration, on May 11, 2012, that we conduct an additional clinical trial with respect to Tivozanib. We have commenced such discussions with the SEC Staff. If settlement discussions conclude without a settlement proposal that is acceptable to the SEC Staff, they may seek permission from the Commission to bring claims against us. In the ordinary course, before the Commission makes a decision about such a request, we would be permitted to make a submission to the Commission explaining why no claim should be brought against us, or why the Commission should enter into a settlement on terms acceptable to us. If settlement discussions with the SEC Staff do not result in a settlement, we intend to make such a submission. We cannot predict the outcome of our discussions with the SEC Staff, and there can be no assurance that we will be able to resolve any potential claim of the Commission. The terms of any settlement with the Commission, the filing of any claims by the Commission, or the outcome of any claims that the Commission may bring against us, could have a material adverse impact on our business, cash position and prospects, and could significantly harm our reputation. Moreover, these ongoing matters with the Commission may adversely affect our ability to raise additional needed capital to fund our business, could divert our management's attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, and may

adversely affect the trading price of our common stock. If the Commission makes claims against our former officers, they may seek advancement of legal expenses or indemnification for any losses, either of which could be material to the extent not covered by our director and officer liability insurance.

Our business is in early stage of development, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

All of our product candidates are in early stages of development. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop one new medicine from the time it is discovered to when it is available for treating patients. Preclinical studies and clinical trials may involve highly uncertain results and a high risk of failure. Moreover, positive data from preclinical studies and clinical trials of our product candidates may not be predictive of results in ongoing or subsequent preclinical studies and clinical trials. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as an early stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To be profitable, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Drug Candidates

All of our product candidates are still in preclinical and clinical development. Preclinical testing and clinical trials of our product candidates may not be successful, or may not result in approval by the FDA. If we are unable to obtain marketing approval or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Development of our product candidates, all of which are still in preclinical and clinical development, is at an early stage and we may not successfully develop a drug candidate that becomes a commercially viable drug. Our ability to generate product revenues, which we do not expect for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. This process can take many years to complete, requiring the expenditure of substantial resources with highly uncertain results and a high risk of failure. Moreover, positive data from preclinical studies and clinical trials of our product candidates may not be predictive of results in ongoing or subsequent preclinical studies and clinical trials and may not be predictive of success in gaining any regulatory or marketing approvals necessary for commercialization.

The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. If any of our product candidates are not shown to be safe and effective in humans through clinical trials, we and/or our strategic partners will not be able to obtain regulatory approval for such product candidate, and the resulting delays in developing other product candidates and conducting related preclinical studies and clinical trials would have a material adverse effect on our business, financial condition and results of operations.

The success of our product candidates will depend on several factors, many of which are beyond our control, including the following:

- our ability to maintain collaborations with our strategic partners and establish new collaborations;
- successful enrollment in, and completion of, clinical trials and preclinical studies;
- our ability to demonstrate to the satisfaction of the FDA, and equivalent foreign regulatory agencies, the safety, efficacy and clinically meaningful benefit of our product candidates through completed, ongoing and any future clinical and non-clinical trials;
- our ability to obtain additional funding when needed;
- achieving and maintaining compliance with all regulatory requirements applicable to pharmaceutical products;
- the prevalence and severity of adverse side effects;
- the ability of our third-party manufacturers to manufacture clinical trial and commercial supplies and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current Good Manufacturing Practices, or cGMP;
- the availability, relative cost, safety and efficacy of alternative and competing treatments;
- acceptance of the product by patients, the medical community and third-party payors;
- launching commercial sales of the product, whether alone or in collaboration with others; and
- our ability to avoid third-party patent interference or patent infringement claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

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Any failure or delay in completing clinical trials for our product candidates, or unfavorable results from such trials, may prevent us from obtaining regulatory approval or commercializing product candidates on a timely basis, or at all, which would require us to incur additional costs and delay receipt of any product revenue.

We cannot predict whether we will encounter problems with any of our ongoing clinical trials or clinical trials we may conduct to further develop our product candidates, which could cause us or regulatory authorities to delay, suspend or terminate those clinical trials. The completion of clinical trials for product candidates may be delayed, suspended or terminated for many reasons, including:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials, or high drop-out rates of patients in our clinical trials;
- our inability to obtain additional funding when needed;
- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- delays or failure in obtaining the necessary approvals from regulators or institutional review boards in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- our inability to manufacture or obtain from third parties materials sufficient to complete our preclinical studies and clinical trials;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of our product candidates during clinical trials, including without limitation, a failure to meet study objectives or obtain the requisite level of statistical significance imposed by the FDA or other regulatory agencies;
- safety issues, including serious adverse events associated with our product candidates;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

Clinical trials often require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Our ability to enroll sufficient numbers of patients in our clinical trials depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials, the availability of approved effective drugs and the perception of the efficacy and safety of our product candidates. We may experience delays or difficulties in enrolling patients in our current and future trials. For example, in January 2014, we and Astellas decided to discontinue the BATON (Biomarker Assessment of Tivozanib in ONcology) breast cancer clinical trial, a phase 2 study in patients with locally recurrent or metastatic triple negative breast cancer, due to insufficient enrollment. If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, we may not be able to enroll a sufficient number of qualified patients in a timely or cost-effective manner.

We, the FDA, other applicable regulatory authorities or institutional review boards may suspend or terminate clinical trials of a product candidate at any time if we or they believe the patients participating in such clinical trials are being exposed to unacceptable health risks or for other reasons.

Significant clinical trial delays could allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Our product development costs also will increase if we experience delays in completing clinical trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the product candidate that is affected

or the development of any of our other product candidates.

If we are unable to successfully develop companion diagnostics for certain of our therapeutic product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of these therapeutics.

A component of our business strategy may be to develop, in collaboration with a third party, companion diagnostics for some of our therapeutic product candidates. There has been limited success to date industry-wide in developing companion diagnostics. To be successful, our collaborator will need to address a number of scientific, technical, regulatory and logistical challenges. We have limited experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any

of our therapeutic product candidates that receive marketing approval. The FDA and similar regulatory authorities outside the United States are generally expected to regulate companion diagnostics as medical devices. In each case, companion diagnostics require separate regulatory approval prior to commercialization. For example, BDX004, our companion diagnostic test for ficlatuzumab in our FOCAL study, requires separate approval by the FDA, for which we must rely on Biodesix to obtain. In addition, we require a commercializable companion diagnostic assay to identify patients with low NRP-1 in order to proceed with the development of 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. As such, we hope to identify a commercially viable assay, which will enable a prospectively defined, randomized Phase 2 study. Given our limited experience in developing diagnostics, we expect to rely in part on third parties for their design, development and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience delays in doing so, the development of our therapeutic product candidates may be adversely affected, our therapeutic product candidates may not receive marketing approval and we may not realize the full commercial potential of any therapeutics that receive marketing approval. As a result, our business would be harmed, possibly materially.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing FDA requirements and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, post-approval requirements and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our strategic partners receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing requirements and testing, including post-approval clinical trials, surveillance to monitor the safety and efficacy of the product candidate, and implementation of a risk evaluation and mitigation strategy. In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practices, or GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

and we may not achieve or sustain profitability, which would adversely affect our business.

Failure to obtain regulatory approval in jurisdictions outside the United States will prevent us from marketing our products abroad.

We intend to market our products, if approved, in international markets, which will require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product is also subject to approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the

FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We and our strategic partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Risks Related to Our Business and Industry

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of product candidates. Our objective is to design, develop and commercialize new products with superior efficacy, convenience, tolerability and safety. We expect any product candidate that we commercialize with our strategic partners will compete with existing, market-leading products.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have and several are already marketing products to treat the same indications, and having the same biological targets, as the product candidates we are developing, including with respect to cachexia. In addition, many of these competitors have significantly greater commercial infrastructures than we have. We will not be able to compete successfully unless we effectively:

- design and develop products that are superior to other products in the market in terms of, among other things, both safety and efficacy;
- obtain patent and/or other proprietary protection for our processes and product candidates;
- obtain required regulatory approvals;
- obtain favorable reimbursement, formulary and guideline status; and
- collaborate with others in the design, development and commercialization of new products.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to obtain approval, to overcome price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

We may not achieve development and commercialization goals in the time frames that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals, and make public statements regarding our expected timing for certain accomplishments, such as the initiation and completion of clinical trials, filing and approval of regulatory applications for our product candidates and other developments and milestones under our research and development programs. The actual timing of these events can vary significantly due to a number of factors, including, without limitation, delays or failures in our and our current and potential future collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us and our current and potential future collaborators and the uncertainties inherent in the regulatory approval process. As a result, there can be no assurance that our or our current and potential future collaborators' preclinical studies and clinical trials will advance or be completed in the time frames we expect or announce, that we or our current and potential future collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones described above as planned, our business could be materially adversely affected and the price of our common stock could decline.

Because we have limited experience in developing and commercializing pharmaceutical products, there is a limited amount of information about us upon which you can evaluate our business and prospects.

Although certain of our employees may have experience in developing and commercializing pharmaceutical products, as an organization we have limited experience in developing and commercializing pharmaceutical products and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan, we will need to successfully:

- execute product development activities;
- obtain required regulatory approvals for the development and commercialization of our product candidates;

- build and maintain a strong intellectual property portfolio;
- build and maintain robust sales, distribution, reimbursement and marketing capabilities;
- obtain reimbursement and gain market acceptance for our products;
- develop and maintain successful strategic relationships and partnerships; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business or continue our operations.

If we fail to attract and keep senior management, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management personnel. We are highly dependent upon our senior management, as well as others on our management team. The reduction in force related to the restructuring we completed this year could make it more difficult to retain or attract employees in the future. The loss of services of employees, and in particular, of a member of management could delay or prevent our ability to successfully maintain or enter into new licensing arrangements or collaborations, the successful development of our product candidates, the completion of our planned clinical trials or the commercialization of our product candidates. We do not carry “key person” insurance covering any members of our senior management. Our employment arrangements with all of these individuals are “at will,” meaning they or we can terminate their service at any time.

We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, many of which have substantially greater resources with which to reward qualified individuals than we do. We may face challenges in retaining our existing senior management and key employees and recruiting new employees to join our company as our business needs change. We may be unable to attract and retain suitably qualified individuals, and our failure to do so could have an adverse effect on our ability to implement our future business plans.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. Despite the adoption of an Insider Trading Policy, we may not be able to prevent a director, executive or employee

from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is

found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense could require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies in the amount of $20 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We rely significantly upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate public disclosure of confidential or proprietary information, we could incur liability and our product development and commercialization efforts could be delayed.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, including among physicians, patients, healthcare payors and, in the cancer market, acceptance by the major operators of cancer clinics.

Even if one of our product candidates obtains regulatory approval, the product may not gain market acceptance among physicians, healthcare payors, patients and the medical community. Market acceptance of any products for which we receive approval depends on a number of factors, including:

- the efficacy and safety of the product candidate, as demonstrated in clinical trials;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics, healthcare payors, physician networks and patients of the drug as a safe and effective treatment;
- the potential and perceived advantages over alternative treatments;

- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- the continued projected growth of oncology drug markets;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

If our approved drugs fail to achieve market acceptance, we would not be able to generate significant revenue.

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

Market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under Medicare. This has resulted in lower rates of reimbursement. There have been numerous other federal and state initiatives designed to reduce payment for pharmaceuticals that may set reimbursement or pricing at unsatisfactory levels.

As a result of legislative proposals and the trend towards managed healthcare in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. We expect to experience pricing pressures in connection with the sale of any products we may develop or commercialize due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, additional legislative proposals, as well as country, regional, or local healthcare budget limitations. Any products that we may develop or commercialize may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis.

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

We and our strategic partners intend to seek approval to market our future products in both the United States and in foreign jurisdictions. If approval is obtained in one or more foreign jurisdictions, we and our strategic partners will be subject to rules and regulations in those jurisdictions relating to our product.

In some foreign countries, particularly in countries in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take

considerable time after the receipt of marketing approval for a product candidate. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices which we believe are fair for any products we may develop and commercialize, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the U.S. government, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the healthcare system in ways that could affect our ability to sell any products we may develop and commercialize profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our potential products, which would adversely affect our business strategy, operations and financial results.

For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA, which may have far reaching consequences for life science companies like us. As a result of this legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals, medical devices, or our product candidates. If reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Further federal and state proposals and healthcare reforms could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the PPACA, by Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other healthcare reforms that may be enacted or adopted in the future.

We have limited sales, marketing, reimbursement and distribution experience and we will have to invest significant resources to develop those capabilities.

We have limited sales, marketing, reimbursement and distribution experience. To develop these capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any of our product candidates will be approved for commercial sale. We could face a number of

additional risks in developing our commercial infrastructure, including:

- we may not be able to attract and build an effective marketing or sales force;
- the cost of establishing a marketing or sales force may not be justifiable in light of the revenues generated by any particular product; and
- our direct sales and marketing efforts may not be successful.

Furthermore, we may elect in the future to utilize strategic partners or contract sales forces to assist in the commercialization of other products, if approved. We may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

Risks Related to Our Dependence on Third Parties

If any of our current or future strategic partners fails to perform its obligations or terminates its agreement with us, the development and commercialization of the product candidates under such agreement could be delayed or terminated and our business could be substantially harmed.

As part of our business strategy, we plan to enter into additional strategic partnerships in the future. If any current or future strategic partners do not devote sufficient time and resources to its arrangements with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. In addition, if any strategic partner were to breach or terminate its arrangements with us, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the product candidate on its own, and we may find it difficult to attract a new alliance partner for such product candidate. For example, Biodesix can opt-out of its agreement with us after the completion of the proof of concept trial prior to the first commercial sale of ficlatuzumab, at which point Biodesix would not be responsible for any future costs associated with developing and commercializing ficlatuzumab other than any ongoing clinical studies.

Much of the potential revenue from any strategic partnership we may enter into in the future will likely consist of contingent payments, such as royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon our, and our strategic partners', ability to successfully develop, introduce, market and sell new drugs. In some cases, we will not be involved in these processes, and we will depend entirely on our strategic partners. Any of our future strategic partners may fail to develop or effectively commercialize these drugs because it:

- decides not to devote the necessary resources because of internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other product candidates may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;
- does not have sufficient resources necessary to carry the product candidate through clinical development, regulatory approval and commercialization; or
- cannot obtain the necessary regulatory approvals.

If one or more of our strategic partners fails to develop or effectively commercialize product candidates for any of the foregoing reasons, we may not be able to replace the strategic partner with another partner to develop and commercialize a product candidate under the terms of the strategic partnership. We may also be unable to obtain, on terms acceptable to us, a license from such strategic partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize a product candidate. Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

We rely on third-party manufacturers to produce our preclinical and clinical product candidate supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidates. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

We do not possess all of the capabilities to fully commercialize any of our product candidates on our own. We have relied upon third-party manufacturers for the manufacture of our product candidates for preclinical and clinical testing purposes and intend to continue to do so in the future. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of such other product candidates or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the

possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications), failure of the third party to accept orders for supply of drug substance or drug product and the possibility of termination or nonrenewal of the agreement by the third-party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates previously granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that we use to manufacture our product candidates. Such suppliers may not sell this capital equipment or these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of this capital equipment or these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Because of the complex nature of many of our early stage compounds and product candidates, our manufacturers may not be able to manufacture such compounds and product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize related products. If we successfully commercialize any of our drugs, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates and we currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing in the event that one or more of our product candidates gains marketing approval, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers.

We rely on third parties, such as clinical research organizations, or CROs, to conduct clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We, in consultation with our strategic partners, where applicable, design the clinical trials for our product candidates, but we have relied, and will rely, on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out many of these trials. We compete with larger companies for the resources of these third parties.

Although we plan to continue to rely on these third parties to conduct our ongoing any future clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

The third parties on whom we rely generally may terminate their engagements with us at any time. If we are required to enter into alternative arrangements because of any such termination, the introduction of our product candidates to market could be delayed.

If these third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical trial protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of

our product candidates and our reputation could be harmed.

Risks Related to Our Intellectual Property Rights

We could be unsuccessful in obtaining adequate patent protection for one or more of our product candidates, which could result in competition and a decrease in the potential market share for our product candidates.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The scope of patent protection that the U.S. Patent and Trademark Office will grant with respect to the antibodies in our antibody product pipeline is uncertain. It is possible that

the U.S. Patent and Trademark Office will not allow broad antibody claims that cover closely related antibodies as well as the specific antibody. Upon receipt of FDA approval, competitors would be free to market antibodies almost identical to ours, including biosimilar antibodies, thereby decreasing our market share.

Issued patents covering one or more of our products could be found invalid or unenforceable if challenged in court.

If we or one of our corporate partners were to initiate legal proceedings against a third-party to enforce a patent covering one of our products, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet one or more statutory requirements for patentability, including, for example, lack of novelty, obviousness, lack of written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the United States Patent and Trademark Officer, if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. Although we have conducted due diligence on patents we have exclusively in-licensed, and we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one of our products or certain aspects of our Human Response Platform. Such a loss of patent protection could have a material adverse impact on our business.

Claims that our platform technologies, our products or the sale or use of our products infringe the patent rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that our platform technologies, our products, or the use of our products, do not infringe third-party patents. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets. Such third parties might resort to litigation against us. The basis of such litigation could be existing patents or patents that issue in the future.

It is also possible that we failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing, which is referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

With regard to tivozanib, we are aware of a third-party United States patent, and corresponding foreign counterparts, that contain broad claims related to use of an organic compound, that, among other things, inhibits the tyrosine phosphorylation of a VEGF receptor caused by VEGF binding to such VEGF receptor. We are also aware of third-party United States patents that contain broad claims related to the use of a tyrosine kinase inhibitor in combination with a DNA damaging agent such as chemotherapy or radiation and we have received written notice from the owners of such patents indicating that they believe we may need a license from them in order to avoid infringing their patents. With regard to ficlatuzumab, we are aware of two separate families of United States patents, United States patent applications and foreign counterparts, with each of the two families being owned by a different

third-party, that contain broad claims related to anti-HGF antibodies having certain binding properties and their use. With regard to AV-203, we are aware of a third-party United States patent that contains broad claims relating to anti-ErbB3 antibodies. Additionally, we are aware of a United States patent application and foreign counterparts that contains claims to the use of a companion diagnostic in conjunction with AV-203. Based on our analyses, if any of the above third-party patents were asserted against us, we do not believe our proposed products or activities would be found to infringe any valid claim of these patents. If we were to challenge the validity of any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity.

In order to avoid or settle potential claims with respect to any of the patent rights described above or any other patent rights of third parties, we may choose or be required to seek a license from a third-party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our strategic partners were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business.

Unfavorable outcomes in an intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain products.

If third parties successfully assert intellectual property rights against us, we might be barred from using aspects of our technology platform, or barred from developing and commercializing related products. Prohibitions against using specified technologies, or prohibitions against commercializing specified products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations of patent infringement or misappropriation of trade secrets, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the patent owner in order to continue our research and development programs or our existing partnerships or to market our product(s). It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This could limit our research and development activities, our ability to commercialize specified products, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or our strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all.

An intellectual property litigation could lead to unfavorable publicity that could harm our reputation and cause the market price of our common stock to decline.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. In such event, the market price of our common stock may decline.

AV-380 and tivozanib are protected by patents exclusively licensed from other companies or institutions. If the licensors terminate the licenses or fail to maintain or enforce the underlying patents, our competitive position would be harmed and our partnerships could be terminated.

Certain of our product candidates and out-licensing arrangements depend on patents and/or patent applications owned by other companies or institutions with which we have entered into intellectual property licenses. In particular, we hold exclusive licenses from St. Vincent’s for therapeutic applications that benefit from inhibition or decreased expression or activity of MIC-1, which we refer to as GDF15 and which we used in our AV-380 program, and from KHK for tivozanib. We may enter into additional license agreements as part of the development of our business in the future. Our licensors may not successfully prosecute certain patent applications under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these

patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. In addition, in spite of our best efforts, a licensor could claim that we have materially breached a license agreement and terminate the license, thereby removing our or our licensees' ability to obtain regulatory approval for and to market any product covered by such license. If these in-licenses are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, identical products. In addition, the partners to which we have sublicensed certain rights under these licenses, including Novartis and Pharmstandard, would likely have grounds for terminating our partnerships if these licenses are terminated or the underlying patents are not maintained or enforced. This could have a material adverse effect on our results of operations, our competitive business position and our business prospects.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to patents, we rely on trade secrets, technical know-how, and proprietary information concerning our business strategy in order to protect our competitive position in the field of oncology. In the course of our research, development and business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement upon joining our company. We take steps to protect our proprietary information, and we seek to carefully draft our confidentiality agreements to protect our proprietary interests. Nevertheless, there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors. Enforcing a claim that a third-party illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development strategic partners may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
    - Issued patents that we own or have exclusively licensed may not provide us with a competitive advantage; for example, our issued patents may not be broad enough to prevent the commercialization of competitive antibodies that are biosimilar to one or more of our antibody products, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.

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Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharma industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharma patents is costly, time-consuming and inherently uncertain. In addition, several recent events have increased uncertainty with regard to our ability to obtain patents in the future and the value of patents once obtained. Among these, in September 2011, patent reform legislation passed by Congress was signed into law. The new patent law introduces changes including a first-to-file system for determining which inventors may be entitled to receive patents, and a new post-grant review process that allows third parties to challenge newly issued patents. It remains to be seen how the biopharma industry will be affected by such changes in the patent system. In addition, the Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in specified circumstances or weakening the rights of patent owners in specified situations. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been, and is likely to continue to be, highly volatile, and could fall below the price you paid. A significant decline in the value of our stock price could also result in securities class-action litigation against us.

The market price of our common stock has been, and is likely to continue to be, highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- new products, product candidates or new uses for existing products introduced or announced by our strategic partners, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials;
- results of regulatory reviews relating to the approval of our product candidates;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us of material developments in our business, financial condition and/or operations;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

In the past, following periods of volatility in the market, such as the volatility in our stock price following our May 2, 2013 announcement regarding the vote of the Oncologic Drugs Advisory Committee of the FDA, or ODAC, securities

class-action litigation has often been instituted against companies. For example, we, and certain of our former officers and former directors, have been named as defendants in a consolidated purported class action lawsuit following our announcement of the ODAC vote. Moreover, a plaintiff has filed a derivative complaint allegedly on our behalf, naming us as a nominal defendant and also naming as defendants present and former members of our board of directors, alleging breach of fiduciary duty and abuse of control between January 2012 and May 2013 with respect to allegedly misleading statements and omissions regarding tivozanib. These proceedings and other similar litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

Our management has broad discretion over our use of available cash and cash equivalents and might not spend our available cash and cash equivalents in ways that increase the value of your investment.

Our management has broad discretion on where and how to use our cash and cash equivalents and you will be relying on the judgment of our management regarding the application of our available cash and cash equivalents to fund our operations. Our management might not apply our cash or cash equivalents in ways that increase the value of your investment. We expect to use a substantial portion of our cash to fund existing and future research and development of our preclinical and clinical product candidates, with the balance, if any, to be used for working capital and other general corporate purposes, which may in the future include investments in, or acquisitions of, complementary businesses, joint ventures, partnerships, services or technologies. Our management might not be able to yield a significant return, if any, on any investment of this cash. You will not have the opportunity to influence our decisions on how to use our cash reserves.

Fluctuations in our quarterly operating results could adversely affect the price of our common stock.

Our quarterly operating results may fluctuate significantly. Some of the factors that may cause our operating results to fluctuate on a period-to-period basis include:

- the status of our preclinical and clinical development programs;
- the level of expenses incurred in connection with our preclinical and clinical development programs, including development and manufacturing costs relating to our preclinical and clinical development candidates;
- any intellectual property infringement lawsuit or other litigation in which we may become involved;
- the implementation of our current restructuring and cost-savings strategies;
- the implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, and non-recurring revenue or expenses under any such agreement;
- costs associated with lawsuits against us, including the current purported class action and derivative lawsuits described in this Quarterly Report under “Part II, Item 1—Legal Proceedings;”
- changes in our loan agreement with Hercules, including the existence of any event of default that may accelerate payments due thereunder; and
- compliance with regulatory requirements.

Period-to-period comparisons of our historical and future financial results may not be meaningful, and investors should not rely on them as an indication of future performance. Our fluctuating results may fail to meet the expectations of securities analysts or investors. Our failure to meet these expectations may cause the price of our common stock to decline.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have been experiencing extreme volatility, and in some cases, disruptions, over the past several years, in many cases, over extended periods. Although certain of these trends have recently showed signs of reversing, there can be no assurance that rapid or extended periods of deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by external economic conditions and a volatile business environment or unpredictable and unstable market conditions. If the equity and credit markets are not favorable at any time we seek to raise capital, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers or other partners may not survive economically turbulent times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At September 30, 2015, we had $37.2 million of cash, cash equivalents and marketable securities consisting of cash on deposit with banks, money market funds, U.S. government agency securities, and corporate debt securities, including commercial paper. As of the date of this report, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents. However, no assurance can be given that deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Dislocations in the credit market may adversely impact the value and/or liquidity of cash equivalents owned by us.

There is a possibility that our stock price may decline because of volatility of the stock market and general economic conditions.

Future sales of shares of our common stock, including shares issued upon the exercise of currently outstanding options, could negatively affect our stock price.

A substantial portion of our outstanding common stock can be traded without restriction at any time. Some of these shares are currently restricted as a result of securities laws, but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options. The exercise of these options and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

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

- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the ability of our board of directors to make, alter or repeal our by-laws; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could be used to institute a rights plan, or a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our board of directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that a stockholder could receive a premium for shares of our common stock held by a stockholder in an acquisition.

Our business could be negatively affected as a result of the actions of activist shareholders.

Proxy contests have been waged against companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to successfully respond to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest because:

- responding to proxy contests and other actions by activist shareholders may be costly and time-consuming, and may disrupt our operations and divert the attention of management and our employees;
- perceived uncertainties as to the potential outcome of any proxy contest may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and

retain qualified personnel and business partners; and

- if individuals that have a specific agenda different from that of our management or other members of our board of directors are elected to our board as a result of any proxy contest, such an election may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls, and requires our independent registered public accounting firm to attest to the effectiveness of our internal controls. Despite our efforts, we can provide no assurance as to our, or our independent registered public accounting firm's, conclusions with respect to the

effectiveness of our internal control over financial reporting under Section 404. There is a risk that neither we nor our independent registered public accounting firm will be able to continue to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not expect to pay any cash dividends for the foreseeable future.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, our ability to pay cash dividends is currently prohibited by the terms of our debt financing arrangements and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Item 6. Exhibits.

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

SIGNATURES

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

AVEO PHARMACEUTICALS, INC.

Date: November 9, 2015 By: /s/ Keith S. Ehrlich
Keith S. Ehrlich, C.P.A.
Chief Financial Officer and Principal Financial and Accounting Officer

Exhibit Index

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
10.1	License Agreement, dated August 4, 2015, by and between the Registrant and JSC “Pharmstandard-Ufimskiy Vitamin Plant.”					X
10.2	License Agreement, dated August 13, 2015, by and between the Registrant and Novartis International Pharmaceutical Ltd.					X
10.3	Amended and Restated License Agreement, dated August 13, 2015, by and between the Registrant and St. Vincent’s Hospital Sydney Limited.					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Presentation Linkbase Document.					X

Confidential treatment has been requested as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.