AVEO PHARMACEUTICALS INC
Form 10-Q
August 11, 2014
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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 June 30, 2014

OR

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

For the transition period from _____ to _____.

Commission file number 001-34655

AVEO PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

650 East Kendall Street, Cambridge, Massachusetts 02142

(Address of Principal Executive Offices) (Zip Code)

(617) 299-5000

(Registrant s Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 August 1, 2014: 52,297,026

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AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2014

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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)

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 43,362	$ 50,826
Marketable securities	21,575	67,680
Accounts receivable	1,235	984
Tenant improvement allowance receivable	14,900	5,833
Restricted cash	687	598
Prepaid expenses and other current assets	3,665	2,998
Total current assets	85,424	128,919
Property and equipment, net	15,863	14,140
Other assets	97	290
Restricted cash	2,863	2,997
Total assets	$ 104,247	$ 146,346
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 3,500	$ 4,238
Accrued expenses	16,193	13,263
Loans payable, net of discount	11,096	10,383
Deferred revenue	1,128	1,294
Other liabilities		1,238
Deferred rent	1,080	992
Total current liabilities	32,997	31,408
Loans payable, net of current portion and discount	3,088	8,822
Deferred revenue, net of current portion	128	17,098
Deferred rent, net of current portion	13,430	19,080
Lease exit obligation, net of current portion	7,646	
Stockholders equity:		

Preferred stock, $.001 par value: 5,000 shares authorized; no shares issued and outstanding		
Common stock, $.001 par value: 100,000 shares authorized; 52,303 and 51,809 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	52	52
Additional paid-in capital	498,602	497,177
Accumulated other comprehensive income (loss)	2	(2)
Accumulated deficit	(451,698)	(427,289)
Total stockholders equity	46,958	69,938
Total liabilities and stockholders equity	$ 104,247	$ 146,346

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

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Collaboration revenue	$ 1,846	$ 324	$ 17,135	$ 647
Operating expenses:				
Research and development	9,300	16,203	21,067	37,165
General and administrative	4,846	7,324	10,400	19,773
Restructuring and lease exit	5,165	7,869	9,025	7,936
	19,311	31,396	40,492	64,874
Loss from operations	(17,465)	(31,072)	(23,357)	(64,227)
Other income and expense:				
Other (expense) income, net	(2)	(51)	5	(152)
Interest expense	(502)	(825)	(1,083)	(1,695)
Interest income	10	35	26	76
Other expense, net	(494)	(841)	(1,052)	(1,771)
Net loss	$ (17,959)	$ (31,913)	$ (24,409)	$ (65,998)
Net loss per share basic and diluted	$ (0.35)	$ (0.62)	$ (0.47)	$ (1.31)
Weighted average number of common shares outstanding	51,663	51,312	51,649	50,351

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

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Net loss	$ (17,959)	$ (31,913)	$ (24,409)	$ (65,998)
Other comprehensive (loss) income:				
Unrealized (loss) gain on available-for-sale securities	(4)	(49)	4	(42)
Foreign currency translation adjustment				26
Comprehensive loss	$ (17,963)	$ (31,962)	$ (24,405)	$ (66,014)

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

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2014	**2013**
Operating activities		
Net loss	$ (24,409)	$ (65,998)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of property and equipment	7,600	65
Depreciation and amortization	1,690	1,871
Net loss on disposal of fixed assets	18	77
Stock-based compensation	1,366	1,978
Non-cash interest expense	100	156
Amortization of premium and discount on investments	197	674
Changes in operating assets and liabilities:		
Accounts receivable	(251)	12,752
Tenant improvement allowance receivable	(9,069)	(541)
Prepaid expenses and other current assets	(672)	748
Other noncurrent assets	192	(9)
Restricted cash	46	42
Accounts payable	(738)	(3,398)
Accrued expenses	3,763	(5,637)
Deferred revenue	(17,136)	(647)
Other liabilities	7,646	
Deferred rent	(5,563)	4,391
Net cash used in operating activities	(35,220)	(53,476)
Investing activities		
Purchases of property and equipment	(11,833)	(1,975)
Purchases of marketable securities	(38,056)	(146,062)
Proceeds from maturities and sales of marketable securities	83,967	107,466
Net cash provided by (used in) investing activities	34,078	(40,571)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs		53,638
Proceeds from exercise of stock options	30	365
Principal payments on loans payable	(6,352)	(2,294)
Net cash (used in) provided by financing activities	(6,322)	51,709

Net decrease in cash and cash equivalents	(7,464)	(42,338)
Effect of exchange rate changes on cash and cash equivalents		26
Cash and cash equivalents at beginning of period	50,826	76,134
Cash and cash equivalents at end of period	$ 43,362	$ 33,822
Supplemental cash flow information		
Cash paid for interest	$ 1,040	$ 1,570

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

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) Organization

AVEO Pharmaceuticals, Inc. (the Company) is a biopharmaceutical company committed to discovering and developing targeted therapies designed to provide substantial impact in the lives of people with cancer by addressing unmet medical needs. The Company s proprietary Human Response Platform provides the Company with unique insights into cancer biology and is leveraged in the discovery and clinical development of therapeutics.

The Company has a pipeline of monoclonal antibodies, including

(i) AV-380, 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. In 2012, the Company initiated a program focusing on 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. Cachexia is characterized by symptoms of unintentional weight loss, progressive muscle wasting, and a loss of appetite. The program s primary research focus is in the area of cancer cachexia, where there is a major unmet need,

(ii) ficlatuzumab, a potent anti-HFG antibody that inhibits the activity of the HGF/c-Met pathway for which the Company has completed a phase 2 clinical study, and has entered into a partnership with Biodesix, Inc. (Biodesix) to advance clinical development, and

(iii) AV-203, a potent, high affinity inhibitor of ErbB3 function that has demonstrated anti-tumor activity in multiple preclinical models for which the Company has completed a phase 1 dose escalation study.

The Company and Astellas Pharma, Inc. (Astellas) were developing tivozanib for the treatment of various types of cancers such as renal cell carcinoma, colorectal cancer and breast cancer pursuant to a worldwide collaboration and license agreement. Astellas notified the Company in February 2014 that it had elected to terminate the license agreement. This termination will become effective on August 11, 2014, at which time the tivozanib rights will be returned to the Company.

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 an accumulated deficit as of June 30, 2014 of approximately $451.7 million, and will require substantial additional capital for research and product development.

(2) Basis of Presentation

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

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the condensed consolidated financial statements have been included. Interim results for the three and six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2014 or any other future period.

The information presented in the condensed consolidated financial statements and related footnotes at June 30, 2014, and for the three and six months ended June 30, 2014 and 2013, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2013 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, 2013, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 13, 2014.

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(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

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

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

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including personnel-related costs such as salaries and stock-based compensation, facilities, research-related overhead, clinical trial costs, manufacturing costs and costs of other contracted services, license fees, and other external costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents at June 30, 2014 consisted of money market funds and corporate debt securities, including commercial paper, maintained by an investment manager totaling $19.0 million and $11.8 million, respectively. Cash equivalents at December 31, 2013 consisted of money market funds and corporate debt securities, including commercial paper, maintained by an investment manager totaling $29.9 million and $15.9 million, respectively. The carrying values of our cash equivalent securities approximate fair value due to their short term maturities.

Marketable Securities

Marketable securities at June 30, 2014 consisted of asset-backed securities and corporate debt securities, including commercial paper, maintained by an investment manager. Marketable securities at December 31, 2013 consisted of municipal bonds, asset-backed securities, and corporate debt securities, including commercial paper, maintained by an investment manager. Credit risk is reduced as a result of the Company s policy to limit the amount invested in any one issue. 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 (loss) income 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 securities during the three and six months ended June 30, 2014 and 2013.

Available-for-sale securities at June 30, 2014 and December 31, 2013 consist of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
June 30, 2014:				
Corporate debt securities (Due within 1 year)	$ 17,073	$ 3	$ (1)	$ 17,075
Asset-backed securities (Due within 1 year)	4,500			4,500
	$ 21,573	$ 3	$ (1)	$ 21,575
December 31, 2013:				
Corporate debt securities (Due within 1 year)	$ 52,156	$ 4	$ (4)	$ 52,156
Municipal bonds (Due within 1 year)	7,519			7,519
Asset-backed securities (Due within 1 year)	8,007		(2)	8,005
	$ 67,682	$ 4	$ (6)	$ 67,680

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The aggregate fair value of securities in an unrealized loss position for less than 12 months at June 30, 2014 was $8.9 million, representing five securities. There were no securities that were in an unrealized loss position for greater than 12 months at June 30, 2014. The unrealized loss was caused by a temporary change in the market for those securities primarily caused by changes in market interest rates. There was no change in the credit risk of the securities. To determine whether an other-than-temporary impairment exists, the Company performs an analysis to assess whether it intends to sell, or whether it would more likely than not be required to sell, the security before the expected recovery of the amortized cost basis. Where the Company intends to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded in the statement of operations as an other-than-temporary impairment charge. When this is not the case, the Company performs additional analyses on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where the Company does not expect to receive cash flows, based on using a single best estimate, sufficient to recover the amortized cost basis of a security and these are recognized in other income (expense), net. The Company does not believe an other-than-temporary impairment exists with respect to those securities in an unrealized loss position at June 30, 2014.

Marketable securities in an unrealized loss position at June 30, 2014 and December 31, 2013 consist of the following:

	Aggregate Fair Value (in thousands)
June 30, 2014:	
Corporate debt securities	$ 4,436
Asset-backed securities	4,500
	$ 8,936
December 31, 2013:	
Corporate debt securities	$ 30,106
Government agency securities	7,519
Asset-backed securities	8,005
	$ 45,630

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk primarily consist of cash, cash equivalents and available-for-sale marketable securities. 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 issue.

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, asset-backed 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

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industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by pricing services as of June 30, 2014 or December 31, 2013.

Level 3 Unobservable inputs developed using estimates and assumptions developed by the Company, which reflect those that a market participant would use. The Company made one nonrecurring fair value measurement associated with a lease exit liability. 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 consolidated balance sheets as of June 30, 2014 and December 31, 2013.

	Fair Value Measurements of Cash Equivalents and Marketable Securities as of June 30, 2014			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents	$ 19,012	$ 11,755	$	$ 30,767
Marketable securities		21,575		21,575
	$ 19,012	$ 33,330	$	$ 52,342

	Fair Value Measurements of Cash Equivalents and Marketable Securities as of December 31, 2013			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents	$ 29,865	$ 15,958	$	$ 45,823
Marketable securities		67,680		67,680
	$ 29,865	$ 83,638	$	$ 113,503

In 2014, the Company has recorded liabilities totaling $15.2 million associated with the exit of portions of its leased facilities (refer to footnote 9). The Company measured the fair values of the liabilities based on the present value of the remaining lease payments less the amount of sublease income the Company estimates it could reasonably obtain. The Company estimated its future rental and operating expense payment obligations using the terms of its lease agreement and its historical share of the building s expenses, adjusting for the effects of inflation. The estimated sublease income to be received is based upon market rates for comparable spaces in the Cambridge area. The net cash outflows over the remaining life of the lease were discounted using a credit-risk adjusted risk-free rate. The Company has classified these lease liabilities as Level 3 fair value measurements.

The fair value of the Company s loans payable at June 30, 2014, computed pursuant to a discounted cash flow technique using the effective interest rate under the loan, is $14.1 million and is considered a Level 2 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 charge.

Tenant Improvement Allowance Receivable

The Company is entitled to be reimbursed by the Company s landlord for certain expenditures associated with improvements made to its leased facility at 650 E. Kendall Street in Cambridge, Massachusetts. These receivables are recorded in the period that the improvements are made and the reimbursement is earned.

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.

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. The Company recognized $5.1 million and $7.6 million of impairment losses for three and six months ended June 30, 2014, respectively, related to leasehold improvements (refer to Footnote 9). During the year ended December 31, 2013, the Company recognized $0.1 million of impairment losses.

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Basic and Diluted Loss per Common Share

Basic (loss) earnings per share is computed by dividing net (loss) income available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted (loss) earnings per share is computed by dividing net (loss) income available to common stockholders by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common share equivalents consist of restricted stock awards and the incremental common shares issuable upon the exercise of stock options and warrants. Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per common share is the same. Under the treasury stock method, unexercised in-the-money stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period. Stock-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting are considered participating securities and are included in the calculation of basic and diluted earnings per share. Common share equivalents have not been included in the net loss per share computation for the three and six months ended June 30, 2014 and June 30, 2013 because their effect is anti-dilutive.

The following table sets forth for the periods presented the potential common shares (prior to consideration of the treasury stock method) excluded from the calculation of net loss per common share because their inclusion would have been anti-dilutive:

	Three Months Ended June 30,	
	2014	2013
Options outstanding	6,243	5,696
Warrants outstanding		10
	6,243	5,706

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 fair value of equity-classified awards to employees and directors are measured at fair value on the date the awards are granted. Awards to nonemployee consultants are recorded at their fair values and are re-measured as of each balance sheet date until the recipient s services are complete. During the three and six months ended June 30, 2014 and June 30, 2013, the Company recorded the following stock-based compensation expense:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands)			
Research and development	$ 197	$ 33	$ 515	$ 1,147
General and administrative	459	(643)	851	831
	$ 656	$ (610)	$ 1,366	$ 1,978

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. No related tax benefits of the stock-based compensation expense have been recognized.

Income Taxes

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

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Segment and Geographic Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment principally in the United States. As of June 30, 2014, the Company has $1.1 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, 2013, filed with the SEC on March 13, 2014. The Company did not adopt any new accounting pronouncements during the three months ended June 30, 2014 that had a material effect on the Company s condensed consolidated financial statements.

In May 2014, the FASB and the International Accounting Standards Board (IASB) (collectively, the Boards) jointly issued a comprehensive new revenue recognition standard that will supersede nearly all existing revenue recognition guidance under US GAAP and IFRS. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016. Early adoption is not permitted under US GAAP. 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.

Reclassifications

The Company has reclassified the tenant improvement allowance receivable from prepaid expenses and other current assets on the consolidated balance sheets at December 31, 2013 to a separate financial statement line to conform to the current period presentation.

Subsequent Events

The Company has evaluated all events or transactions that occurred after June 30, 2014 through the date the Company issued these financial statements.

(4) Collaborations and License Agreements

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 Biodesix s proprietary companion diagnostic test, 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 VeriStrat. Biodesix granted the Company perpetual, non-exclusive rights to certain intellectual property, including diagnostic data related to VeriStrat, 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 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 VeriStrat development costs, as well as VeriStrat sales and marketing costs. Subject to and following the approval of the VeriStrat test as a companion diagnostic for ficlatuzumab, Biodesix has agreed to make the VeriStrat 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 VeriStrat tests performed.

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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 VeriStrat. If AVEO elects to Opt-Out, it will continue to make the existing supply of ficlatuzumab available to Biodesix for the purposes of enabling Biodesix to complete the development of ficlatuzumab, and Biodesix will have the right to commercialize ficlatuzumab.

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

Activities under the agreement with Biodesix were evaluated under ASC 605-25 *Revenue Recognition Multiple Element Arrangements*, or ASC 605-25, to determine whether such activities represented a multiple element revenue arrangement. The agreement with Biodesix includes the following non-contingent deliverables: perpetual, non-exclusive rights to certain intellectual property including clinical and biomarker data related to ficlatuzumab for use in developing and commercializing VeriStrat; the Company s obligation to deliver technology improvements and data developed during the NSCLC POC Trial to Biodesix; the Company s obligation to participate in the joint steering committee during the NSCLC POC Trial; the Company s obligation to perform certain development activities associated with the NSCLC POC Trial; and the Company s obligation to supply clinical material for use in conducting the NSCLC POC Trial; and the Company s obligation to deliver clinical specimens and data during the NSCLC POC Trial. The Company concluded that any deliverables that would be delivered after the NSCLC POC Trial is complete are contingent deliverables because these services are contingent upon the results of the NSCLC POC Trial. As these deliverables are contingent, and are not at an incremental discount, they are not evaluated as deliverables at the inception of the arrangement. These contingent deliverables will be evaluated and accounted for separately as each related contingency is resolved. As of June 30, 2014, 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 VeriStrat did not have standalone value from the remaining deliverables since the customer 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 of 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 $0.2 million during the three and six months ended June 30, 2014. The amount due to the Company from Biodesix pursuant to the cost-sharing provision was $0.2 million at June 30, 2014.

Astellas Pharma

In February 2011, the Company, together with its wholly-owned subsidiary AVEO Pharma Limited, entered into a Collaboration and License Agreement with Astellas (the Astellas Agreement), pursuant to which the Company and Astellas intended to develop and commercialize tivozanib for the treatment of a broad range of cancers. Under the terms of the Astellas Agreement, the Company and Astellas shared responsibility for continued development and commercialization of tivozanib in North America and in Europe under a joint development plan and a joint commercialization plan, respectively. Throughout the rest of the world (the Royalty Territory), excluding Asia, where Kyowa Hakko Kirin (KHK) has retained all development and commercialization rights, Astellas has an exclusive, royalty-bearing license to develop and commercialize tivozanib. The terms of the Astellas Agreement are subject to the Company s obligations to KHK under a license agreement entered into with KHK in 2006 pursuant to which the Company acquired exclusive rights to develop and commercialize tivozanib worldwide outside of Asia.

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In June 2013, the Company received a complete response letter from the FDA informing the Company that the FDA will not approve in its present form the Company s NDA for tivozanib for the treatment of patients with advanced renal cell carcinoma, or RCC. In January 2014, AVEO and Astellas jointly decided to discontinue a Phase 2 breast cancer clinical trial due to insufficient enrollment. Further, Astellas elected in February 2014 to terminate the Astellas Agreement as a result of the limited scope of development for tivozanib moving forward. This termination will be effective on August 11, 2014, at which time the tivozanib rights will be returned to the Company. In accordance with the Astellas Agreement, committed development costs, including the costs of winding down discontinued tivozanib clinical development programs, will be shared equally. There are no refund provisions in the Astellas Agreement.

Under the Astellas Agreement, the Company received an initial cash payment of $125.0 million, comprised of a $75.0 million license fee and $50.0 million in research and development funding. The Company retained net proceeds of approximately $97.6 million of the initial cash payment from Astellas, after payments to KHK and strategic, legal and financial advisors. In December 2012, the Company received a $15.0 million milestone payment from Astellas in connection with the acceptance by the FDA of the NDA filing for tivozanib. The milestone was considered substantive and revenue was recognized upon achievement of the milestone.

The Company is accounting 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 consolidated financial statements due to the joint risk-sharing nature of the activities in North America and Europe. As a result of the cost-sharing provisions in the Astellas Agreement, the Company reduced research and development expense by $1.1 million and $6.4 million during the three months ended June 30, 2014 and 2013, respectively, and by $2.3 million and $12.7 million during the six months ended June 30, 2014 and 2013, respectively. The Company also reduced general and administrative expense by $8,000 and $1.0 million during the three months ended June 30, 2014 and 2013, respectively, and by $0.1 million and $2.3 million during the six months ended June 30, 2014 and 2013, respectively, as a result of the cost-sharing provisions in the Astellas Agreement. The net amount due to the Company from Astellas pursuant to the cost-sharing provisions was $1.0 million at June 30, 2014.

Activities under the Astellas Agreement outside of the joint development and commercialization activities in North America and Europe, including the co-exclusive license to develop and commercialize tivozanib in North America and Europe that was delivered prior to the initiation of the collaborative activities in North America and Europe, were evaluated under ASC 605-25 to determine if they represented a multiple element revenue arrangement. The Astellas Agreement includes the following deliverables: (1) a co-exclusive license to develop and commercialize tivozanib in North America and Europe (the License Deliverable); (2) a combined deliverable comprised of an exclusive royalty-bearing license to develop and commercialize tivozanib in the Royalty Territory and the Company s obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its development and commercialization of tivozanib in the Royalty Territory (the Royalty Territory Deliverable); and (3) the Company s obligation to supply clinical material to Astellas for development of tivozanib in the Royalty Territory (the Clinical Material Deliverable). All of these deliverables were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting under ASC 605-25. Factors considered in this determination included, among other things, the subject of the licenses and the research and development and commercial capabilities of Astellas.

The Company allocated the up-front consideration of $125.0 million to the deliverables based on management s best estimate of selling price of each deliverable using the relative selling price method as the Company did not have VSOE or TPE of selling price for such deliverables. The Company s best estimate of selling price considered discounted cash flow models, the key assumptions of which included the market opportunity for commercialization of tivozanib in North America and Europe and the Royalty Territory, the probability of successfully developing and commercializing tivozanib, the remaining development costs for tivozanib, and the estimated time to commercialization of tivozanib. The Company allocated up-front consideration of $120.2 million to the License Deliverable and up-front consideration of $4.8 million to the Royalty Territory Deliverable. The relative selling price of the Company s obligation under the Clinical Material Deliverable had *de minimis* value.

The Company recorded the $120.2 million relative selling price of the License Deliverable as collaboration revenue during the three months ended March 31, 2011 upon delivery of the license, and deferred approximately $4.8 million of revenue representing the relative selling price of the Royalty Territory Deliverable. The Company was recording the $4.8 million of revenue attributed to the Royalty Territory Deliverable ratably over the Company s period of performance through April 2022, the remaining patent life of tivozanib. Upon being notified that the collaboration would be terminated effective August 2014, the Company reassessed the period of performance associated with the Royalty Territory Deliverable and accelerated the recognition of the remaining deferred revenue such that the balance would be recognized through August 2014. This change in estimate resulted in the recognition of an additional $1.7 million during the three months ended June 30, 2014, and an additional $2.6 million during the six months ended June 30, 2014. The Company recorded approximately $1.8 million and $0.1 million of revenue associated with the Royalty Territory Deliverable

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during the three month periods ended June 30, 2014 and 2013, respectively, and approximately $2.8 million and $0.2 million of revenue associated with the Royalty Territory Deliverable during each of the six month periods ended June 30, 2014 and 2013, respectively.

Under the agreement, the Company received cash payments related to up-front license fees, reimbursable payments and milestone payments of $1.2 million and $7.8 million during the three months ended June 30, 2014 and 2013, respectively, and received payments of $2.2 million and $26.5 million during the six months ended June 30, 2014 and 2013, respectively.

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.

The deliverables under the original arrangement included an option for a co-exclusive, worldwide license to develop and manufacture ErbB3 antibody products and an option for an exclusive license to commercialize ErbB3 antibody products in all countries in the world other than North America. The Company determined that these deliverables did not have standalone value due to the fact that the program was still in preclinical development and required the Company s experience to advance development of the product candidates. As such, the Company determined that the original agreement should be accounted for as one unit of accounting.

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 for the quarters ended March 31, 2010 and June 30, 2011, respectively. The remaining $10.0 million was amortized as additional license revenue over our 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 standalone 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 $14.3 million as collaboration revenue in the six months ended June 30, 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.

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Under the agreement, the Company recorded revenue of $0.1 million and $14.4 million during the three and six month periods ended June 30, 2014, respectively, and $0.2 million and $0.4 million during the three and six month periods ended June 30, 2013, respectively.

Kirin Brewery

In December 2006, the Company entered into an exclusive license agreement, with the right to grant sublicenses, subject to certain restrictions, with Kirin Brewery Co. Ltd. (now Kyowa Hakko Kirin) (KHK) to research, develop, manufacture and commercialize tivozanib, pharmaceutical compositions thereof and associated biomarkers in all territories in the world except for Asia (the KHK Agreement). Upon entering into the KHK Agreement, the Company made a cash payment in the amount of $5.0 million.

In March 2010, the Company made a $10.0 million milestone payment to KHK in connection with the dosing of the first patient in the Company s phase 3 clinical trial of tivozanib. The Company recorded $22.5 million of research and development expense during the year ended December 31, 2011 associated with a payment made to KHK related to the up-front license payment received under the Astellas Agreement. In December 2012, the Company made a $12.0 million milestone payment to KHK in connection with the acceptance by the FDA of the Company s NDA filing for tivozanib, all of which was expensed as research and development expense during the year ended December 31, 2012. In connection with this payment, $6.0 million was reimbursed from Astellas and recorded as a reduction of research and development expense.

Under the KHK Agreement, the Company may be required to (i) make future milestone payments upon the achievement of specified regulatory milestones and (ii) pay tiered royalty payments on net sales it makes of tivozanib in its territory ranging from the low to mid-teens as a percentage of the Company s net sales of tivozanib. In the event the Company sublicenses the rights licensed to the Company under the KHK Agreement (after the termination of the agreement with Astellas in August 2014), the Company is required to pay KHK a specified percentage of any amounts the Company receives from any third party sublicensees, other than amounts the Company receives in respect of research and development funding or equity investments, subject to certain limitations.

St. Vincent s Hospital

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. The Company believes GDF15 is a novel target for cachexia and the Company is exploiting this license in its AV-380 program for cachexia. Under the agreement, the Company has the right to grant sublicenses subject to certain restrictions. The Company has 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 the Company non-exclusive rights for certain related diagnostic products and research tools.

Under the license agreement, the Company is obligated to use diligent efforts to conduct research and clinical development and commercially launch at least one licensed therapeutic product, and to maximize profits from licensed therapeutic products for the benefit of the Company and St. Vincent s. Subject to certain conditions, the Company has also agreed to achieve specified research, development and regulatory milestones by specified dates. If the Company does not achieve a given milestone by the agreed date, the Company has the option of paying the amount the Company would have been obligated to pay had the Company timely achieved the milestone, and, if the Company does so, St. Vincent s will not have the right to terminate the license agreement based on its failure to timely

achieve such milestone.

The Company has also agreed that, for as long as there is a valid claim in the licensed patents, the Company will not, and the Company will ensure that its affiliates and its sublicensees do not, develop or commercialize any product, other than a licensed therapeutic product, for the treatment, prevention or prophylaxis of cachexia, decreased appetite or body weight, that binds to GDF15 or the GDF15 receptor and that is a GDF15 antagonist, and will not license or induce any other person to do the same.

In connection with entering into the license agreement with St. Vincent s, the Company paid St. Vincent s an upfront license fee of $0.7 million and a low five-figure amount to reimburse St. Vincent s for patent-related expenses it incurred with respect to a specified licensed patent.

Under the Company s license agreement with St. Vincent s, the Company may be required to:

make milestone payments, up to an aggregate total of $9.2 million, upon achievement of specified research, development and regulatory milestones for the first three indications for licensed therapeutic products, some of which payments may be increased by a mid to high double-digit percentage rate for milestones payments made after the Company grants any sublicense under the license agreement, depending on the sublicensed territory or territories;

pay tiered royalty payments equal to a low-single-digit percentage of any net sales the Company or its sublicensees make of licensed therapeutic products. The royalty rate escalates within the low-single-digit range during each calendar year

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based on increasing licensed therapeutic product sales during such calendar year. The Company s royalty payment obligations for a licensed therapeutic product in a particular country end on the later of 10 years after the date of first commercial sale of such licensed therapeutic product in such country or expiration of the last-to-expire valid claim of the licensed patents covering such licensed therapeutic product in such country, and are subject to offsets under certain circumstances;

pay St. Vincent s sublicensing fees of up to an aggregate amount in the low-to-mid six-digits, depending on the sublicensed territory or territories, at the time the Company grants any sublicense; and

reimburse St. Vincent s for some or all of the reasonable costs and expenses it incurs in patent management, filing, prosecuting and maintaining the licensed patents.

The license agreement will remain in effect until the later of 10 years after the date of first commercial sale of licensed therapeutic products in the last country in which a commercial sale is made, or expiration of the last-to-expire valid claim of the licensed patents, unless the Company elects, or St. Vincent s elects, to terminate the license agreement earlier.

Either party has the right to terminate the agreement in connection with a material breach of the agreement by the other party that remains uncured for a specified cure period, or in connection with events relating to the other party s insolvency or bankruptcy, or if a force majeure event continues for more than four months.

St. Vincent s has the right to terminate the agreement due to any patent-related challenge by the Company, its affiliates or any sublicensee, or if the Company or its affiliates or any sublicensee cause or induce any other person to make a patent-related challenge, and such challenge continues after a specified cure period.

The Company has the right to terminate the agreement on six months notice if the Company terminates its GDF15 research and development programs as a result of the failure of a licensed therapeutic product in pre-clinical or clinical development, or if the Company forms the reasonable view that further GDF15 research and development is not commercially viable, and the Company is not then in breach of any of its obligations under the agreement. If the Company forms the reasonable view that further GDF15 research and development is not commercially viable and terminate the agreement before the Company starts a phase 1 clinical trial on a licensed therapeutic product, the Company will be required to pay St. Vincent s a low-to-mid six-figure termination payment.

Any termination of the agreement, in whole or in part, will result in a loss of the Company s rights to the relevant licensed patents and know-how. If St. Vincent s terminates the agreement in its entirety due to the Company s breach, insolvency or a patent-related challenge, or the Company terminates the agreement due to a development failure or lack of commercial viability, as described above, St. Vincent s will have a non-exclusive license from the Company to certain intellectual property rights and know-how relating to the licensed therapeutic products, and the Company must transfer to St. Vincent s certain then-existing regulatory approvals and related documents for the licensed therapeutic products.

(5) Accrued Expenses

Accrued expenses consisted of the following as of June 30, 2014 and December 31, 2013:

	June 30, 2014	December 31, 2013
	(in thousands)	
Clinical expenses	$ 3,310	$ 5,319
Facility lease exit costs	6,986	
Salaries and benefits	2,347	2,027
Property and equipment	1,110	1,905
Professional fees	485	811
Manufacturing and distribution	633	1,362
Restructuring	34	587
Other	1,288	1,252
	$ 16,193	$ 13,263

(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 initially required to repay the aggregate principal balance under the Loan Agreement in 30 equal monthly installments of principal starting on April 1, 2011. However, the Loan Agreement provided that such date would be extended under certain circumstances. During 2011, the Company

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triggered two possible extensions to the date from which principal payments were to be made and, as a result, the initial date for principal repayment was extended to 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. The Company accounted for this amendment as a loan modification in accordance with ASC 470-50, *Debt Modifications and Extinguishments.*

Per annum interest is payable on the principal balance of the loan at the greater of 11.9% and an amount equal to 11.9% plus the prime rate of interest minus 4.75%, provided however, that the per annum interest shall not exceed 15.0%. The Company must make interest payments on the loan each month following the date of borrowing under the Loan Agreement. The unpaid principal balance and all accrued but unpaid interest will be due and payable on September 1, 2015. The loan is secured by a lien on all of the Company s personal property as of, or acquired after, the date of the Loan Agreement, except for intellectual property.

The Loan Agreement required a deferred 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 charge of $1.2 million which was paid in June 2014, and is recorded as a loan discount and is being amortized to interest expense over the term of 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 the lenders 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, the Company issued warrants to the lenders on June 2, 2010 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. The relative fair value of the warrants was calculated using the Black-Scholes option-pricing model with the following assumptions: volatility of 64.12%, an expected term equal to the contractual life of the warrant (seven years), a risk-free interest rate of 2.81% and no dividend yield. The resulting effective interest rate for the loans outstanding under the Loan Agreement is approximately 13.1%.

Hercules also received an option, subject to the Company s written consent, not to be unreasonably withheld, to purchase, either with cash or through conversion of outstanding principal under the loan, up to $2.0 million of equity of the Company sold in any sale by the Company to third parties of equity securities resulting in at least $10.0 million in net cash proceeds to the Company, subject to certain exceptions. The Company has evaluated the embedded conversion option, and has concluded that it does not need to be bifurcated and separately accounted for. No amount will be recognized for the conversion feature until such time as the conversion feature is exercised and it can be determined whether a beneficial conversion feature exists. As of June 30, 2014, the principal balance outstanding was $14.3 million.

The 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 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. As of June 30, 2014, the lenders have not asserted any events of default under the loan. While the Company does not believe that there has been a material adverse change, as defined in the Loan Agreement, it is possible that Hercules could take the position that the adverse outcome relating to the development and commercialization of tivozanib for RCC, including the FDA informing the Company that it

would not approve the NDA for tivozanib for the treatment of patients with advanced RCC and the related shareholder litigation described below in footnote 10 Legal Proceedings, and Astellas decision to terminate its collaboration with the Company, collectively constitutes a material adverse change, and, accordingly, an event of default, which could trigger a repayment of all principal and interest due under the loan unless such event of default is waived by Hercules. The Company has classified the principal amount of the loan as current and non-current on its consolidated balance sheet based upon the expected timing of the remaining payments.

Future minimum payments under the loans payable outstanding as of June 30, 2014 are as follows (amounts in thousands):

Years Ending December 31:	
2014 (6 months remaining)	$ 6,155
2015	9,309
	15,464
Less amount representing interest	(1,182)
Less discount	(98)
Less current portion	(11,096)
Loans payable, net of current portion and discount	$ 3,088

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(7) Stock-based Compensation

Stock Plans

The Company issued stock options and restricted stock awards during the three months ended June 30, 2014. In June 2014, the Company issued stock options to purchase 2,250,000 shares of common stock which contained market performance conditions which were not deemed probable of vesting at June 30, 2014.

A summary of the status of the Company s stock option activity at June 30, 2014 and changes during the six 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, 2013	4,296,694	$ 7.36		
Granted	2,962,100	$ 1.60		
Exercised				
Forfeited	(1,015,604)	$ 7.16		
Outstanding at June 30, 2014	6,243,190	$ 4.66	7.67	$ 801,501
Vested or expected to vest at June 30, 2014	3,416,319	$ 6.89	5.91	$ 204,403
Exercisable at June 30, 2014	2,401,542	$ 8.04	4.62	$ 155,461

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

	Three Months Ended June 30,	
	2014	2013
Volatility factor	72.06-73.98%	71.35-72.65%
Expected term (in years)	5.50-6.25	5.50-6.25
Risk-free interest rates	1.88%	1.69%
Dividend yield		

	Six Months Ended June 30,	
	2014	2013

Volatility factor	72.06%-73.98%	64.22-72.65%
Expected term (in years)	5.50-6.25	5.50-6.25
Risk-free interest rates	1.88-2.02%	1.01-1.69%
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.

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Per ASC 718 *Share-Based Payments,* market conditions must be considered in determining the estimated grant-date fair value of share-based payments and the market conditions must be considered in determining the requisite service period over which compensation cost is recognized. The Company estimates the fair value of the awards with market conditions using a Monte Carlo simulation, which utilizes several assumptions including the risk-free interest rate, the volatility of the Company s stock and the exercise behavior of award recipients. The grant-date fair value of the awards is then recognized over the requisite service period, which represents the derived service period for the awards as determined by the Monte Carlo simulation.

The 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. Based upon these assumptions, the weighted-average grant date fair value of stock options granted to employees during the three months ended June 30, 2014 and 2013 was $0.77 and $1.76 per share, respectively. The weighted-average grant date fair value of stock options granted to employees during the six months ended June 30, 2014 and 2013 was $0.83 and $3.06 per share, respectively.

As of June 30, 2014, there was $3.7 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 2.2 years. No options were exercised during the three and six months ended June 30, 2014. The intrinsic value of options exercised was $0.2 million for the three months ended June 30, 2013.

The restricted stock activity for the six months ended June 30, 2014 is as follows:

	Number of Shares	Weighted-Average Fair-Value
Unvested at December 31, 2013	241,500	$ 2.50
Granted	501,000	1.62
Cancelled	(133,420)	2.02
Expired		
Vested/Released	(73,280)	2.50
Unvested at June 30, 2014	535,800	$ 1.80

As of June 30, 2014, there was $0.2 million 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 1.4 years.

(8) Strategic Restructuring

In connection with the receipt of a Complete Response Letter from the FDA informing the Company that the FDA would not approve the Company s NDA for tivozanib for the treatment of patients with advanced RCC, the Company announced a strategic restructuring in June 2013 to refocus the Company s efforts on the then on-going clinical development of tivozanib in colorectal and breast cancer and on the advancement of key pipeline and preclinical assets. As part of this restructuring, the Company decided not to pursue the development of tivozanib in RCC. This

restructuring was completed as of December 31, 2013 and resulted in costs totaling $8.0 million, which includes impairment charges of $0.3 million.

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, 2013	Restructuring expense incurred during the six months ended June 30, 2014	Restructuring amounts paid during the six months ended June 30, 2014	Restructuring amounts accrued at June 30, 2014
			(in thousands)	
Employee severance, benefits and related costs	$ 587		$ (553)	$ 34

All remaining accrued amounts are current and are reflected within accrued expenses on the consolidated balance sheet.

(9) Facility Lease Exit

During the six months ending June 30, 2014, the Company completed the planned build-out of portions of the office space it currently leases at its 650 E. Kendall Street facility. Upon completion of these build-outs, the Company ceased use of these spaces and

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recorded liabilities totaling $15.2 million. The fair value of these liabilities was determined using the credit-adjusted risk-free rate to discount the estimated future net cash outflows associated with the space that met the cease use criteria. The estimate of future net cash outflows included the Company s expected minimum rental payments and incremental operating, utility and tax payments to the landlord less the amount of sublease income that the Company estimates it could reasonably expect to obtain during the remainder of the lease period.

The following table summarizes the components of the Company s lease exit activity recorded in current and long-term liabilities:

	Lease Exit Expense incurred during the six months ended June 30, 2014	Accretion Expense incurred during the six months ended June 30, 2014	Amounts paid during the six months ended June 30, 2014	Amounts accrued at June 30, 2014
			(in thousands)	
Lease exit costs	$ 15,154	$ 275	$ (797)	$ 14,632

The total expense associated with recording the fair value of lease exit liabilities of $9.2 million and $15.2 million for the three and six months ending June 30, 2014, respectively, has been recorded within Restructuring and Lease Exit expense on the Condensed Consolidated Statements of Operations. The Company wrote-off $9.3 million and $14.0 million of deferred rent associated with the portions of the facility that met the cease use criteria under ASC 420-10 during the three and six months ending June 30, 2014, respectively. Further, the Company wrote-off leasehold improvements totaling $5.1 million and $7.6 million during the three and six months ending June 30, 2014, respectively. These transactions resulted in net charges of $5.0 million and $8.8 million being recorded during the three and six months ended June 30, 2014, respectively. The Company also recorded $0.3 million of accretion expense during the three and six months ended June 30, 2014. Approximately $7.0 million of the amounts are reflected within accrued expenses on the consolidated balance sheet and the remaining $7.6 million has been recorded within other noncurrent liabilities on the consolidated balance sheet.

(10) Legal Proceedings

Two class action lawsuits have been filed against the Company and certain present and former officers and members of the Company s board of directors, (Tuan Ha-Ngoc, David N. Johnston, William Slichenmyer and Ronald DePinho), in the United States District Court for the District of Massachusetts, one captioned Paul Sanders v. Aveo Pharmaceuticals, Inc., et al., No. 1:13-cv-11157-JLT, filed on May 9, 2013, and the other captioned Christine Krause v. AVEO Pharmaceuticals, Inc., et al., No. 1:13-cv-11320-JLT, filed on May 31, 2013. On December 4, 2013, the District Court consolidated the complaints as In re AVEO Pharmaceuticals, Inc. Securities Litigation et al., No. 1:13-cv-11157-DJC, and an amended complaint was filed on February 3, 2014. The amended complaint purports to be brought on behalf of shareholders who purchased the Company s common stock between January 3, 2012 and May 1, 2013. The amended complaint generally alleges that the Company and certain of its present and former officers and directors violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the phase 3 trial design and results for our TIVO-1 study in an effort to lead investors to believe that the drug would receive approval from the FDA. The amended complaint seeks unspecified damages, interest, attorneys fees, and other costs. On April 4, 2014, the Company filed a motion to dismiss the consolidated class action complaint with prejudice. Lead plaintiffs filed an

opposition to the motion to dismiss on June 10, 2014, and the Company filed a reply to the opposition on July 10, 2014. The Court heard oral argument on the Company s motion to dismiss on July 22, 2014. The Company denies any allegations of wrongdoing and intends to vigorously defend against this lawsuit. However, there is no assurance that the Company will be successful in our defense or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of the action. Moreover, the Company is unable to predict the outcome or reasonably estimate a range of possible loss at this time.

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

On April 4, 2014, Karen J. van Ingen, a 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, Civil Action No. 1:14-cv-11672-DJC, naming AVEO, as a nominal defendant and also naming as defendants present and former members of the Company s 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 breach of fiduciary duty and abuse of control between January 2012 and May 2013 with respect to allegedly misleading statements and omissions regarding tivozanib. The complaint seeks, among other relief, unspecified damages,

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costs and expenses, including attorneys fees, an order requiring the Company to implement certain corporate governance reforms, restitution from the defendants and such other relief as the court might find just and proper. On July 25, 2014, defendants filed a motion to dismiss the derivative complaint with prejudice. The Company denies any allegations of wrongdoing and intends to vigorously defend 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.

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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 of similar meaning. You also can identify them by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery, preclinical trials and clinical development activities, our ability to obtain any necessary financing to conduct our planned activities, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our drug candidates, our ability to obtain, maintain and enforce intellectual property rights for our drug candidates, our dependence on our existing and future strategic partners, and other risk factors. Please refer to the section entitled Risk Factors in Item 1A of Part II and elsewhere in this report for a description of these risks and uncertainties. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.

Company Overview

We are a biopharmaceutical company committed to discovering and developing targeted therapies designed to provide substantial impact in the lives of people with cancer by addressing unmet medical needs. Our proprietary Human Response Platform , or HRP, provides us with unique insights into cancer and related disease biology and is being leveraged in the discovery and clinical development of its therapeutic candidates. This platform was designed to overcome many of the limitations of traditional approaches to modeling human cancer, as we use patented genetic engineering techniques to grow populations of spontaneous tumors in animals containing human-relevant, cancer-causing mutations and tumor variations akin to what is seen in populations of human tumors. Because we believe that these populations of tumors better replicate what is seen in human cancer, we believe that HRP represents a significant improvement over traditional approaches.

Our strategy for building value is to leverage partner resources to advance the development of our clinical pipeline while primarily focusing our internal resources on our innovative GDF15 (AV-380) program in cachexia.

Our lead programs are as follows:

AV-380 Program: 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. In 2012, we initiated a program focusing on cachexia, a serious and common complication of advanced cancer and a number of chronic diseases. 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. The pathophysiology is characterized by a negative protein and energy balance driven by a variable combination of reduced food intake and abnormal metabolism. Other symptoms or conditions associated with cachexia include anemia, breathing difficulties, edema, insulin resistance, muscle weakness/asthenia, and fatigue. In preclinical animal models, AV-380 has been shown to increase

food intake, reverse body weight loss and restore normal body composition. We believe that AV-380 represents a unique approach to treating cachexia because it addresses key underlying mechanisms of the syndrome. Appropriate IND-enabling efforts, including cell line development, are underway to prepare AV-380 for potential future clinical development, and we expect that we will begin a phase 1 clinical study of AV-380 in cachexia in the second half of 2015.

We believe cancer cachexia represents a significant area of patient need. Weight loss during cancer treatment is associated with more chemotherapy-related side effects, fewer completed cycles of chemotherapy, a reduction in response to therapy and decreased survival rates (*J Gastroenterol* 2013; *Eur J Cancer* 1998; *Br J Cancer* 2004). In a cohort of over 3,000 patients in the U.S. studied by the Eastern Cooperative Oncology Group, or ECOG, the prevalence of weight loss even before starting chemotherapy was observed to be substantial across several cancers: over 80% in pancreatic and gastric cancers and over 50% in prostate, colorectal and lung cancers (*Am Med Journal* 1980). It is estimated that more than 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, the estimated prevalence of cancer cachexia is over 400,000 patients (*Am J Clin Nutr* 2006). In addition, cachexia is also associated with diseases outside of cancer including chronic kidney disease, or CKD, congestive heart failure or CHF, and chronic obstructive pulmonary disease, or COPD. There are currently few effective treatment options for cachexia. Cancer cachexia is diagnosed and treated according to four categories: anorexia and food intake, catabolic drive (the breakdown of molecules into smaller units to release energy), muscle mass and strength, and the resulting function and psychosocial effect. Only megesterol acetate and medroxyprogesterone are approved to treat cachexia, each exclusively in Europe, despite only about 30% of treated

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patients showing improvements in appetite and weight gain, which are short term and not accompanied by improvement in quality of life or survival (*Curr Opin Oncol.* 2006). Treatments currently in clinical development attempt to address or reverse only one or two contributory factors of the cachexia syndrome. As such, we believe that an effective treatment that potentially targets the underlying cause of the complex cachexia syndrome may addresses a broad spectrum of the resulting cachexia symptoms to potentially improve patient outcomes and address a major medical need in patients with cancer as well as other chronic diseases, such as obstructive lung disease, heart failure and kidney disease that where, in the aggregate, millions of patients suffer from cachexia associated with these conditions. (*Am J Clin Nutr* 2006).

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 plan to evaluate opportunities for partnerships to expand the development of AV-380, including in cachexia associated with non-cancer indications, including chronic heart failure, chronic kidney disease and chronic obstructive pulmonary disease to leverage the full potential of this asset.

Ficlatuzumab: Ficlatuzumab is a potent hepatocyte growth factor, or 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 tyrosine-kinase inhibitor, or TKI, of the epidermal growth factor receptor, or EGFR, and a phase 2 clinical study evaluating ficlatuzumab in combination with gefitinib, an EGFRTKI, 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 in the phase 2 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. In April 2014, we entered into a worldwide agreement with Biodesix, Inc. to develop and commercialize ficlatuzumab with VeriStrat®, which is commercially available to help physicians guide treatment decisions for patients with 2nd line advanced NSCLC. Under the terms of the agreement, we plan to conduct an additional phase 2 study of ficlatuzumab in combination with erlotinib. In 1st line advanced NSCLC patients who have an EGFR mutation selected using the VeriStrat test to identify the patient subset which is most likely to benefit from the addition of ficlatuzumab to the EGFR TKI.

AV-203: AV-203 is a potent anti-ErbB3 monoclonal antibody with broad therapeutic potential. AV-203 has high ErbB3 affinity and potent anti-tumor activity in mouse models. AV-203 inhibits the activity of the ErbB3 receptor and our preclinical studies suggest that neuregulin-1, or NRG1 (also known as heuregulin), 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 resume clinical development with a third party collaborator.

Tivozanib: In 2006, we acquired exclusive rights to develop and commercialize tivozanib, worldwide outside of Asia pursuant to a license agreement we entered into with Kirin Brewery Co. Ltd. (now Kyowa

Hakko Kirin), or KHK. Tivozanib is an investigational TKI of all three VEGF receptors. As discussed below under the heading Strategic Partnerships, we entered into a strategic collaboration with Astellas in which we agreed to share responsibility with Astellas for the continued development and commercialization of tivozanib. In February 2014, Astellas informed us of its intent to end our collaboration for tivozanib. Currently, our primary focus with tivozanib is to wind down our activities related to our partnership with Astellas, including on-going support for patients who continue to receive treatment with tivozanib related to our clinical trials in RCC, breast cancer and colorectal cancer. On August 11, 2014, pursuant to the terms of the license agreement, in connection with the termination, all Astellas rights for the development and commercialization of tivozanib will revert to AVEO. After August 11, 2014, we intend to pursue partnering options to fund further tivozanib development in appropriate clinical settings.

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 of these operations. We have generated no revenue from product sales through June 30, 2014, and through such date have principally funded our operations through:

$393.0 million of non-dilutive capital in the form of license fees, milestone payments and research and development funding received from our strategic partners;

$169.6 million of funding from the sale of convertible preferred stock to investors prior to our initial public offering, including $77.5 million of equity sales to our strategic partners;

$89.7 million of gross proceeds from the sale of common stock in connection with the completion of our initial public offering;

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$26.5 million of loan proceeds in connection with our loan agreement with Hercules Technology II, L.P. and Hercules Technology III, L.P.;

$68.3 million of gross proceeds from private placements of our common stock; and

$168.7 million of gross proceeds from the sale of common stock in connection with follow-on public offerings of our common stock in June 2011 and January 2013.

We do not have a history of being profitable and, as of June 30, 2014, we had an accumulated deficit of $451.7 million. We anticipate that we will continue to incur significant operating costs over the next several years as we continue our planned development activities for our preclinical and clinical products. We will need additional financing to support our operating activities.

Strategic Partnerships

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.

Under the license agreement, we are obligated to use diligent efforts to conduct research and clinical development and commercially launch at least one licensed therapeutic product, and to maximize profits from licensed therapeutic products for the benefit of us and St. Vincent s. Subject to certain conditions, we have also agreed to achieve specified research, development and regulatory milestones by specified dates. If we do not achieve a given milestone by the agreed date, we have the option of paying the amount we would have been obligated to pay had we timely achieved the milestone, and, if we do so, St. Vincent s will not have the right to terminate the license agreement based on our failure to timely achieve such milestone.

We have also agreed that, for as long as there is a valid claim in the licensed patents, we will not, and we will ensure that our affiliates and our sublicensees do not, develop or commercialize any product, other than a licensed therapeutic product, for the treatment, prevention or prophylaxis of cachexia, decreased appetite or body weight, that binds to GDF15 or the GDF15 receptor and that is a GDF15 antagonist, and will not license or induce any other person to do the same.

In connection with entering into the license agreement with St. Vincent s, we paid St. Vincent s an upfront license fee of $0.7 million and a low five-figure amount to reimburse St. Vincent s for patent-related expenses it incurred with respect to a specified licensed patent.

Under our license agreement with St. Vincent s, we may be required to:

make milestone payments, up to an aggregate total of $9.2 million, upon achievement of specified research, development and regulatory milestones for the first three indications for licensed therapeutic products, some of which payments may be increased by a mid to high double-digit percentage rate for milestones payments made after we grant any sublicense under the license agreement, depending on the sublicensed territory or territories;

pay tiered royalty payments equal to a low-single-digit percentage of any net sales we or our sublicensees make of licensed therapeutic products. The royalty rate escalates within the low-single-digit range during each calendar year based on increasing licensed therapeutic product sales during such calendar year. Our royalty payment obligations for a licensed therapeutic product in a particular country end on the later of 10 years after the date of first commercial sale of such licensed therapeutic product in such country or expiration of the last-to-expire valid claim of the licensed patents covering such licensed therapeutic product in such country, and are subject to offsets under certain circumstances;

pay St. Vincent s sublicensing fees of up to an aggregate amount in the low-to-mid six-digits, depending on the sublicensed territory or territories, at the time we grant any sublicense; and

reimburse St. Vincent s for some or all of the reasonable costs and expenses it incurs in patent management, filing, prosecuting and maintaining the licensed patents.

The license agreement will remain in effect until the later of 10 years after the date of first commercial sale of licensed therapeutic products in the last country in which a commercial sale is made, or expiration of the last-to-expire valid claim of the licensed patents, unless we elect, or St. Vincent s elects, to terminate the license agreement earlier.

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St. Vincent s has the right to terminate the agreement due to any patent-related challenge by us, our affiliates or any sublicensee, or if we or our affiliates or any sublicensee cause or induce any other person to make a patent-related challenge, and such challenge continues after a specified cure period.

We have the right to terminate the agreement on six months notice if we terminate our GDF15 research and development programs as a result of the failure of a licensed therapeutic product in pre-clinical or clinical development, or if we form the reasonable view that further GDF15 research and development is not commercially viable, and we are not then in breach of any of our obligations under the agreement. If we form the reasonable view that further GDF15 research and development is not commercially viable and terminate the agreement before we start a phase 1 clinical trial on a licensed therapeutic product, we will be required to pay St. Vincent s a low-to-mid six-figure termination payment.

Any termination of the agreement, in whole or in part, will result in a loss of our rights to the relevant licensed patents and know-how. If St. Vincent s terminates the agreement in its entirety due to our breach, insolvency or a patent-related challenge, or we terminate the agreement due to a development failure or lack of commercial viability, as described above, St. Vincent s will have a non-exclusive license from us to certain intellectual property rights and know-how relating to the licensed therapeutic products, and we must transfer to St. Vincent s certain then-existing regulatory approvals and related documents for the licensed therapeutic products.

Biodesix

In April 2014, we entered into a worldwide agreement with Biodesix to develop and commercialize our HGF inhibitory antibody ficlatuzumab, with Biodesix s proprietary companion diagnostic test, 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 VeriStrat. Biodesix granted us perpetual, non-exclusive rights to certain intellectual property, including diagnostic data related to VeriStrat, 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, we retain primary responsibility for clinical development of ficlatuzumab in a phase 2 proof of concept, or POC, clinical study of ficlatuzumab for NSCLC, in which VeriStrat will be used to select clinical trial subjects, referred to as NSCLC POC Trial. The NSCLC POC Trial will be fully funded by Biodesix up to a maximum of $15 million, referred to as the Cap. After the Cap is reached, we and Biodesix will share equally in the costs of the NSCLC POC trial, and we and Biodesix will each be responsible for 50% of development and regulatory costs associated with all future clinical trials agreed-upon by Biodesix and us, 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 our right to be the lead commercialization party.

Biodesix is solely responsible for the VeriStrat development costs, as well as VeriStrat sales and marketing costs. Subject to and following the approval of the VeriStrat test as a companion diagnostic for ficlatuzumab, Biodesix has agreed to make the VeriStrat test available and use commercially reasonable efforts to seek reimbursement in all geographies where ficlatuzumab is approved. We have agreed to reimburse Biodesix a pre-specified amount, under certain circumstances for VeriStrat 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 we 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 in 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 VeriStrat. If we elect to Opt-Out, we 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.

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Activities under the agreement with Biodesix were evaluated under ASC 605-25 *Revenue Recognition Multiple Element Arrangements*, or ASC 605-25, to determine such activities represented a multiple element revenue arrangement. The agreement with Biodesix includes the following non-contingent deliverables: perpetual, non-exclusive rights to certain intellectual property including clinical and biomarker data related to ficlatuzumab for use in developing and commercializing VeriStrat; our obligation to deliver technology improvements and data developed during the NSCLC POC Trial to Biodesix; our obligation to participate in the joint steering committee during the NSCLC POC Trial; our obligation to perform certain development activities in associated with the NSCLC POC Trial; and our obligation to supply clinical material for use in conducting the NSCLC POC Trial; and our obligation to deliver clinical specimens and data during the NSCLC POC Trial. We concluded that any deliverables that would be delivered after the NSCLC POC Trial is complete are contingent deliverables because these services are contingent upon the results of the NSCLC POC Trial. As these deliverables are contingent, and are not at an incremental discount, they are not evaluated as deliverables at the inception of the arrangement. These contingent deliverables will be evaluated and accounted for separately as each related contingency is resolved. As of June 30, 2014, no contingent deliverables had been provided by us.

We have determined that the delivered item, or the perpetual, non-exclusive rights to certain intellectual property for use in developing and commercializing VeriStrat did not have standalone value from the remaining deliverables since the customer 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 of unit or multiple units of accounting, and therefore, we are accounting for the deliverables as one unit of accounting.

We record the consideration earned while conducting the NSCLC POC Trial, which consists of reimbursement by 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, we reduced research and development expenses by approximately $0.2 million during the three and six months ended June 30, 2014. The amount due to us from Biodesix pursuant to the cost-sharing provision was $0.2 million at June 30, 2014.

Kyowa Hakko Kirin

In December 2006, we entered into a license agreement with Kirin Brewery Co. Ltd. (now Kyowa Hakko Kirin), which we sometimes refer to as 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, including meeting certain specified diligence goals. 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 maximum payments for clinical and regulatory milestones under our license agreement with KHK are $60.0 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 (upon termination in August 2014 of our agreement with Astellas), 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, subject to certain limitations.

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Astellas Pharma

In February 2011, we entered into a collaboration and license agreement with Astellas and certain of its indirect wholly-owned subsidiaries in connection with 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, as a result of the limited scope of development for tivozanib moving forward. The termination of the agreement will be effective August 11, 2014, at which time tivozanib rights will be returned to us. In accordance with the agreement, committed development costs, including the costs of winding own discontinued tivozanib clinical development programs, will be shared equally. There are no refund provisions in the agreement.

In connection with the agreement, we received an initial cash payment of $125.0 million, comprised of a $75.0 million license fee and $50.0 million in research and development funding, both of which are non-creditable and non-refundable against any amounts due under the collaboration agreement. We retained net proceeds of approximately $97.6 million of the initial cash payment from Astellas, after payments to KHK and strategic, legal and financial advisors. In December 2012, we received a $15.0 million milestone payment from Astellas in connection with the acceptance by the FDA of our NDA filing for tivozanib for the treatment of patients with advanced RCC. We have elected to recognize all milestone payments as revenue once the milestones have been triggered if the milestone is deemed to be substantive.

We are accounting for the joint development and commercialization activities in North America and Europe as a joint risk-sharing collaboration in accordance with Accounting Standards Codification, or ASC, 808 *Collaborative Arrangements*. In addition, these joint development and commercialization activities were not deemed to be separate deliverables under the agreement with Astellas.

Payments from Astellas with respect to Astellas share of tivozanib development and commercialization costs incurred by us pursuant to the joint development plan are recorded as a reduction to research and development expense and general and administrative expense in the accompanying consolidated financial statements due to the joint risk-sharing nature of the activities in North America and Europe. As a result of the cost-sharing provisions in the Astellas Agreement, we reduced research and development expense by $1.1 million and $6.4 million during the three months ended June 30, 2014 and 2013, respectively, and by $2.3 million and $12.7 million during the six months ended June 30, 2014 and 2013, respectively. We also reduced general and administrative expense by $8,000 and $1.0 million during the three months ended June 30, 2014 and 2013, respectively, and by $0.1 million and $2.3 million during the six months ended June 30, 2014 and 2013, respectively, as a result of the cost-sharing provisions in the Astellas Agreement. The net amount due to us from Astellas pursuant to the cost-sharing provisions was $1.0 million at June 30, 2014.

Activities under the agreement with Astellas outside of the joint development and commercialization activities in North America and Europe were evaluated under ASC 605-25 to determine if they represented a multiple element revenue arrangement. The agreement with Astellas includes the following deliverables outside of the joint development and commercialization activities in North America and Europe: a co-exclusive license to develop and commercialize tivozanib in North America and Europe; a royalty-bearing license to develop and commercialize tivozanib in the royalty territory, which includes our obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its development and commercialization of tivozanib in the royalty territory; and our obligation to supply clinical material to Astellas for development of tivozanib in the royalty territory. All of these deliverables were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting under ASC 605-25.

We allocated the up-front consideration of $125 million to the deliverables based on our best estimate of selling price of each deliverable using the relative selling price method as we did not have vendor specific objective evidence or third-party evidence for such deliverables. Our best estimate of selling price considered discounted cash flow models, the key assumptions of which included the market opportunity for commercialization of tivozanib in North America and Europe and in the royalty territory, the development costs and market opportunity for the expansion of tivozanib into other solid tumor types, and the time to commercialization of tivozanib for all potential oncology indications. We allocated $120.2 million of the up-front consideration from Astellas to the co-exclusive license in North America and Europe and $4.8 million of the up-front consideration from Astellas to the combined deliverable representing a royalty-bearing license to develop and commercialize tivozanib in the royalty territory along with our obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its use in the royalty territory. The relative selling price for our obligation to supply clinical material to Astellas for development in the royalty territory had *de minimis* value.

We recorded the $120.2 million relative selling price of the co-exclusive license granted in North America and Europe as collaboration revenue during the three months ended March 31, 2011 upon delivery of the license, and deferred approximately $4.8

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million of revenue representing the relative selling price of the royalty-bearing license to develop and commercialize tivozanib in the royalty territory along with our obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its use in the royalty territory. We were recording the $4.8 million ratably over the period of our performance through April 2022, the remaining patent life of tivozanib. Upon being notified that the collaboration would be terminated effective August 2014, we reassessed the period of performance associated with the royalty territory deliverable and accelerated the recognition of the remaining deferred revenue such that the balance would be recognized through August 2014. This change in estimate resulted in the recognition of an additional $1.7 million during the three months ended June 30, 2014, and an additional $2.6 million during the six months ended June 30, 2014. We recorded approximately $1.8 million and $0.1 million of revenue associated with the Royalty Territory Deliverable during the three month periods ended June 30, 2014 and 2013, respectively, and approximately $2.8 million and $0.2 million of revenue associated with the Royalty Territory Deliverable during each of the six month periods ended June 30, 2014 and 2013, respectively.

Biogen Idec

In March 2009, we entered into an exclusive option and license agreement with Biogen Idec International GmbH, or Biogen Idec, regarding the development and commercialization of our discovery-stage ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases in humans outside of North America. Under the agreement, we were responsible for developing ErbB3 antibodies through completion of the first phase 2 clinical trial designed in a manner that, if successful, will generate data sufficient to support advancement to a phase 3 clinical trial. In March 2014, we amended our agreement with Biogen Idec, whereby Biogen Idec agreed to the termination of its rights and obligations under the agreement, including Biogen Idec s option to (i) obtain a co-exclusive (with us) license to develop and manufacture ErbB3 targeted antibodies and (ii) obtain exclusive commercialization rights to ErbB3 products in countries in the world other than North America. As a result, we retain worldwide rights to AV-203, a clinical stage ErbB3-targeted antibody. Pursuant to the amendment, we are obligated to in good faith use reasonable efforts to seek a collaboration partner for the purpose of funding further development and commercialization of ErbB3 targeted antibodies. Pursuant to the amendment, we are obligated to pay Biogen Idec a percentage of milestone payments received by us from future partnerships after March 28, 2016 and single digit royalty payments on net sales related to the sale of ErbB3 products, up to cumulative maximum amount of $50 million.

The deliverables under the original arrangement included an option for a co-exclusive, worldwide license to develop and manufacture ErbB3 antibody products and an option for an exclusive license to commercialize ErbB3 antibody products in all countries in the world other than North America. We determined that these deliverables did not have standalone value due to the fact that the program was still in preclinical development and required our experience to advance development of the product candidates. As such, we determined that the agreement should be accounted for as one unit of accounting.

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 for the quarters ended March 31, 2010 and June 30, 2011, respectively. The remaining $10.0 million was amortized as additional license revenue over our period of substantial involvement.

We concluded that the amendment materially modified the terms of the agreement and, as a result, required application of the guidance included ASC 605-25. Based upon the terms of the amended arrangement, the remaining deliverables included our obligation to seek a collaboration partner to fund further development of the program and our obligation to continue development and commercialization of the licensed products if a collaboration partner is secured. We concluded that our obligation to use best efforts to seek a collaboration partner does not have standalone

value from our efforts to continue development and commercialization of the licensed products and thus the deliverables should be treated as a single unit of accounting.

Upon modifying the arrangement, we had $14.7 million of deferred revenue remaining to be amortized. We are not entitled to receive any further consideration from Biogen Idec under the amended arrangement. We allocated a portion of the remaining deferred revenue to the undelivered unit of accounting based upon our best estimate of the selling price. We determined the best estimate of the selling price to be approximately $0.6 million and recognized the remaining $14.1 million as collaboration revenue in the three months ended March 31, 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 our historical experience with marketing our product candidates to potential partners.

The best estimate of the selling price was based upon a cost approach pursuant to which we estimated the costs expected to be incurred in executing a partnership agreement and then applied a reasonable markup. We 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. We estimated our 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. Our analysis also considered the legal charges we anticipate we will incur. Changes to the assumptions within the reasonable range of possible values would not have a material impact on the amounts recorded in current or future periods.

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Under the agreement, we recorded revenue of $0.1 million and $14.4 million during the three months and six month periods ended June 30, 2014, respectively, and $0.2 million and $0.4 million during the three and six month periods ended June 30, 2013, respectively.

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 winding down discontinued tivozanib clinical development programs;
- 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.

Conducting a significant amount of research and development is central to our business model. 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 plan to continue to expend considerable resources on our research and development expenses as we seek to complete development of product candidates. In the near-term, we expect our total research and development expenses to decrease year over year as we continue to wind-down our tivozanib development program and focus our efforts on potential first-in-class opportunities that are currently in earlier stages of development, such as our AV-380 program.

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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 decrease in future periods as we plan to consolidate our leased facilities in 2014. Below is a summary of our research and development expenses for the three and six months ended June 30, 2014 and 2013:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands)		(in thousands)	
Tivozanib	$ 3,551	$ 6,367	$ 6,418	$ 17,112
AV-380 Program in Cachexia	1,898	891	4,162	1,677
Ficlatuzumab	852	1,474	1,532	3,147
AV-203	726	2,671	1,199	3,978
Other pipeline programs	25	360	25	1,140
Other research and development	26	104	42	284
Overhead	2,222	4,336	7,689	9,827
Total research and development expenses	$ 9,300	$ 16,203	$ 21,067	$ 37,165

Tivozanib

On November 27, 2012, the FDA, accepted for filing our NDA for tivozanib, our lead product candidate, with the proposed indication for the treatment of patients with advanced renal cell carcinoma, or RCC. On May 2, 2013, we were informed by the FDA that its Oncologic Drugs Advisory Committee, or ODAC, voted 13 to 1 that our NDA for investigational agent tivozanib did not demonstrate a favorable benefit-to-risk evaluation for the treatment of advanced RCC in an adequate and well-controlled trial. We subsequently announced on June 10, 2013 that we had received a complete response letter from the FDA informing us that the FDA will not approve in its present form our NDA for our investigational agent tivozanib for the treatment of patients with advanced RCC.

In addition to our program to develop tivozanib for RCC, we also evaluated tivozanib in two clinical trials: BATON-CRC, a phase 2 clinical trial conducted by our partner, Astellas, to evaluate tivozanib in combination with mFOLFOX6 compared to Avastin in combination with mFOLFOX6 as first-line therapy in patients with advanced metastatic colorectal cancer, or CRC; and BATON-BC, a phase 2 clinical trial to evaluate the efficacy of tivozanib in combination with paclitaxel compared to placebo in combination with paclitaxel in patients with locally recurrent or metastatic triple negative breast cancer who have received no prior systemic therapy, for which we initiated enrollment in the fourth quarter of 2012. On January 30, 2014, we announced that we and Astellas jointly decided to discontinue the BATON-BC clinical trial, due to insufficient enrollment. On December 13, 2013, we announced that the BATON-CRC study was unlikely to meet the primary endpoint in the intent-to-treat population and on February 14, 2014, we announced that we and Astellas agreed to discontinue this study.

We entered into a collaboration and license agreement with Astellas in February 2011, pursuant to which we and Astellas shared responsibility for tivozanib, including expenses for continued development and commercialization of tivozanib, in North America and Europe. We have included $1.1 million and $6.4 million in research and development

cost reimbursements as a reduction in tivozanib-related expenses for the three months ended June 30, 2014 and 2013, respectively, and $2.3 million and $12.7 million in research and development cost reimbursements as a reduction in tivozanib-related expenses for the six months ended June 30, 2014 and 2013, respectively. 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. In December 2012, we made a $12.0 million milestone payment to KHK in connection with the acceptance of our NDA filing for tivozanib. On February 12, 2014, as a result of the limited scope of development for tivozanib moving forward, Astellas elected to terminate our collaboration and license agreement pursuant to its terms. Pursuant to the terms of the agreement, the termination will be on August 11, 2014, at which time tivozanib rights will be returned to us. Committed development costs, including the costs of winding down discontinued tivozanib clinical development programs, will be shared equally.

With the termination of our partnership with Astellas, at this time we do not plan to commit further financial resources for new clinical development activities for tivozanib. We and Astellas will share the costs of winding down the discontinued tivozanib clinical development programs. We expect our share of tivozanib wind down costs to be approximately $12.0 million during 2014. The actual amount that we will incur may differ from this estimate depending upon our ability to expedite the termination of our existing obligations while continuing to satisfy our patient and regulatory requirements. As a result of the wind down activities, we

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expect research and development expenses related to tivozanib to decrease in the near-term as compared to prior periods. In connection with regaining the rights for the development and commercialization of tivozanib, we have begun actively pursuing partnering options to fund further tivozanib development in appropriate clinical settings

AV-380 Program in Cachexia

In 2012, we initiated a program focusing on cachexia, which we now refer to as our AV-380 program. Cachexia is a serious and common complication of advanced cancer and a number of chronic diseases that is characterized by symptoms of unintentional weight loss, progressive muscle wasting, and a loss of appetite. Cancer 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. The pathophysiology is characterized by a negative protein and energy balance driven by a variable combination of reduced food intake and abnormal metabolism. Other symptoms of cachexia include anemia, breathing difficulties, edema, insulin resistance, muscle weakness/asthenia, and fatigue. Our primary research focus is in the area of cancer cachexia which we believe represents a significant are of patient need. In addition, cachexia is also associated with diseases outside of cancer including CKD, CHF, and COPD.

In connection with our cachexia program, we have in-licensed certain patents and patent applications from St. Vincent s. In December 2013, we presented preclinical data at the th Annual Cachexia Conference in Kobe, Japan, demonstrating that growth differentiating factor-15, or GDF15, induces anorexia and cachexia in mice, suggesting GDF15 to be a novel target for cachexia. In 2013, we initiated cell line development of AV-380, an antibody discovered using our Human Response Platform, and nominated AV-380 as the development candidate for the program. Appropriate IND-enabling efforts, including cell line development, and animal toxicology studies have been initiated to prepare AV-380 for future clinical development. We expect to initiate clinical development of AV-380 in the second half of 2015.

As we focus our efforts on our cachexia program, we expect our costs associated with this program to increase.

Ficlatuzumab

In April 2014, we entered into a worldwide agreement with Biodesix to develop and commercialize AVEO s potent HGF inhibitory antibody ficlatuzumab, with Biodesix s proprietary companion diagnostic test, VeriStrat®, a serum protein test that is commercially available to help physicians guide treatment decisions for patients with advanced NSCLC. In September 2012, we announced detailed data from our phase 2 clinical trial comparing the combination of ficlatuzumab and gefitinib to gefitinib monotherapy in previously untreated Asian subjects with 1st 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 1st line advanced NSCLC patients selected using the VeriStrat test and fund the further development and registration of Veristrat as a companion diagnostic. After the completion of the Phase 2 trial, any additional development, regulatory or commerical expenses for ficlatuzumab will be equally shared, as well as profits, if any.

In November 2011, we entered into an agreement with Boehringer Ingelheim for large-scale process development and clinical manufacturing of ficlatuzumab. Boehringer Ingelheim will produce ficlatuzumab at its biopharmaceutical site in Fremont, CA. 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

Through the use of our Human Response Platform, we have identified antibodies that have been shown to be potent and selective inhibitors of ErbB3 in preclinical studies. In preclinical testing, these antibodies have significantly inhibited the growth of a number of different tumors, including in breast, prostate and pancreatic cancers. We granted Biogen Idec an exclusive option to co-develop (with us) and commercialize our ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases outside of North America. Upon the selection of AV-203 as a development candidate in the first quarter of 2010, we earned a $5.0 million milestone payment from Biogen Idec, and we earned an additional $5.0 million milestone payment in June 2011 based on initiation of a GLP toxicology study. In May 2012, we announced the initiation of a phase 1 clinical trial examining the safety, tolerability and preliminary efficacy of AV-203 along with exploratory biomarkers in patients with metastatic or advanced solid tumors. In May 2014, we presented the results of our first-in-human study of AV-203 at the 2014 American Society of Clinical Oncology Annual Meeting. Among the results, the study established a recommended phase 2 dose of AV-203, demonstrated good tolerability and promising early signs of activity, and reached the maximum planned dose of AV-203 monotherapy. 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.

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Due to the unpredictable nature of preclinical and clinical development and given the early stage of this program, we are unable to estimate with any certainty the costs we will incur in the future development of AV-203.

Other Pipeline Programs

The expenses related to our other pipeline programs are expected to decrease as a result of our strategic decision to prioritize certain product candidates currently in clinical or preclinical development. Future research and development costs for our pipeline programs are not reasonably certain because such costs are dependent on a number of variables, including the success of preclinical studies and the identification of other potential candidates.

Other Research and Development

Other research and development includes expenses related to our Human Response Platform, which are not specifically related to a particular product candidate or a specific strategic partnership.

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:

- 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 related to the winding down of the discontinued tivozanib clinical development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- 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 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, marketing, 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.

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We anticipate that our general and administrative expenses will decrease due to the elimination of activities and infrastructure supporting tivozanib. This decrease may be partially offset by an increase in legal costs associated with the ongoing shareholder litigation and 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 June 30, 2014, we are projecting an ordinary loss for the year ended December 31, 2014, 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 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 three and six month periods ended June 30, 2014. 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, 2013 for further discussion of our critical accounting policies and significant judgments and estimates.

Results of Operations

Comparison of Three Months Ended June 30, 2014 and 2013

The following table summarizes the results of our operations for each of the three months ended June 30, 2014 and 2013, together with the changes in those items in dollars and as a percentage:

	Three Months Ended June 30,		Increase/ (decrease)	%
	2014	2013		
	(in thousands)			
Revenue	$ 1,846	$ 324	$ 1,522	470%
Operating expenses:				
Research and development	9,300	16,203	(6,903)	(43)%
General and administrative	4,846	7,324	(2,478)	(34)%
Restructuring and lease exit	5,165	7,869	(2,704)	(34)%
Total operating expenses	19,311	31,396	(12,085)	(38)%
Loss from operations	(17,465)	(31,072)	13,607	(44)%
Other income (expense), net	(2)	(51)	49	(96)%
Interest expense	(502)	(825)	323	(39)%
Interest income	10	35	(25)	(71)%
Net loss	$ (17,959)	$ (31,913)	$ 13,954	(44)%

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The following table sets forth revenue for the three months ended June 30, 2014 and 2013:

Revenue	Three Months Ended June 30, 2014	2013	Increase/ (decrease)	%
		(in thousands)		
Strategic Partner:				
Biogen Idec	$ 77	$ 216	(139)	(64)%
Astellas	1,769	108	1,661	1,538%
	$ 1,846	$ 324	$ 1,522	470%

Revenue. Revenue for the three months ended June 30, 2014 was $1.8 million compared to $0.3 million for the three months ended June 30, 2013, an increase of approximately $1.5 million. The increase was primarily due to an additional $1.7 million in revenue recognized in connection with the change in the estimated period of performance associated with our collaboration with Astellas as a result of the expected termination of the agreement in August 2014.

Research and development. Research and development, or R&D, expenses for the three months ended June 30, 2014 were $9.3 million compared to $16.2 million for the three months ended June 30, 2013, a decrease of $6.9 million or 43%. The decrease is primarily attributable to a $3.5 million decrease in employee compensation and travel costs as well as a decrease of $1.4 million in facilities and IT costs following our June 2013 restructuring, and a $7.1 million decrease in external clinical trial, consulting and manufacturing costs associated with the winding down of the discontinued tivozanib clinical development programs. These decreases are partially offset by a $5.1 million decrease in reimbursements to us from Astellas for shared tivozanib development costs, which we record as a reduction in R&D expense in the prior year period.

General and administrative. General and administrative, or G&A, expenses for the three months ended June 30, 2014 were $4.8 million compared to $7.3 million for the three months ended June 30, 2013, a decrease of $2.5 million of 34%. The decrease is primarily the result of a $1.0 million decrease in employee costs following our June 2013 restructuring and a $2.4 million decrease in marketing and consulting costs due to termination of work related to tivozanib pre-commercialization activities. These amounts were partially offset by a $0.5 million increase in external legal costs associated with various ongoing legal matters and a $0.4 million increase in annual retention bonus to employees.

Restructuring and lease exit. Restructuring and lease exit expenses for the three months ended June 30, 2014 were $5.2 million compared to $7.9 million for the three months ended June 30, 2013. The expense incurred during the three months ended June 30, 2014 relates to space that we ceased using at 650 E Kendall St, Cambridge, and was triggered upon the completion of the build-out for that space. The expenses incurred during the three months ended June 30, 2013 relate to severance and employee benefits incurred as part of the June 2013 strategic restructuring.

Other (expense) income, net. Other income, net for the three months ended June 30, 2014 was $(2,000) compared to $(51,000) for the three months ended June 30, 2013, an increase of $49,000 or 96%. The increase in other (expense) income is due to decreased losses attributable to foreign exchange rates.

Interest expense. Interest expense for the three months ended June 30, 2014 was $0.5 million compared to $0.8 million for the three months ended June 30, 2013, a decrease of 39%. The decrease is primarily attributable to the declining outstanding balance on our loan with Hercules Technology Growth.

Interest income. Interest income for the three months ended June 30, 2014 was $10,000 compared to $35,000 for the three months ended June 30, 2013, a decrease of $25,000 or 71%. The decrease in interest income is primarily due to a lower average cash balance and lower average interest rates during the three months ended June 30, 2014 compared to the three months ended June 30, 2013.

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Comparison of Six Months Ended June 30, 2014 and 2013

The following table summarizes the results of our operations for each of the six months ended June 30, 2014 and 2013, together with the changes in those items in dollars and as a percentage:

	Six Months Ended June 30,		Increase/	
	2014	2013	(decrease)	%
	(in thousands)			
Revenue	$ 17,135	$ 647	$ 16,488	2,548%
Operating expenses:				
Research and development	21,067	37,165	(16,098)	(43)%
General and administrative	10,400	19,773	(9,373)	(47)%
Restructuring and lease exit	9,025	7,936	1,089	14%
Total operating expenses	40,492	64,874	(24,382)	(38)%
Loss from operations	(23,357)	(64,227)	40,870	(64)%
Other income (expense), net	5	(152)	157	(103)%
Interest expense	(1,083)	(1,695)	612	(36)%
Interest income	26	76	(50)	(66)%
Net loss	$ (24,409)	$ (65,998)	$ 41,589	(63)%

The following table sets forth revenue for the six months ended June 30, 2014 and 2013:

	Six Months Ended June 30,		Increase/	
Revenue	2014	2013	(decrease)	%
	(in thousands)			
Strategic Partner:				
Biogen Idec	$ 14,367	$ 432	$ 13,935	3,226%
Astellas	2,768	215	2,553	1,187%
	$ 17,135	$ 647	$ 16,488	2,548%

Revenue. Revenue for the six months ended June 30, 2014 was $17.1 million compared to $0.6 million for the six months ended June 30, 2013, an increase of $16.5 million or 2,548%. The increase was primarily due to the recognition of an additional $14.1 million of previously deferred revenue as a result of the amendment to our arrangement with Biogen. Pursuant to the amendment, Biogen agreed to the termination of its rights and obligations under the previous arrangement. As a result, we recognized as revenue all previously deferred amounts in excess of the estimated selling price of the remaining deliverables under the modified arrangement. In addition, we recognized an additional $2.6 million in revenue for the six months ending June 30, 2014 from our arrangement with Astellas upon a change in estimate to the period of performance associated with the remaining deliverables following Astellas

decision to terminate the arrangement.

Research and development. R&D expenses for the six months ended June 30, 2014 were $21.1 million compared to $37.2 million for the six months ended June 30, 2013, a decrease of approximately $16.1 million or 43%. The decrease is primarily attributable to a $9.3 million decrease in employee compensation and travel costs as well as a decrease of $1.2 million in facilities and IT costs following our June 2013 restructuring, and a $15.8 million decrease in external clinical trial, consulting and manufacturing costs associated with the winding down of the discontinued tivozanib clinical development programs. These decreases are partially offset by a $10.3 million decrease in reimbursements to us from Astellas for shared tivozanib development costs, which we record as a reduction in R&D expense in the prior year period. We expect our costs related to the winding down of the discontinued tivozanib clinical development programs to decrease in future quarters.

General and administrative. G&A expenses for the six months ended June 30, 2014 were $10.4 million compared to $19.8 million for the six months ended June 30, 2013, a decrease of $9.4 million or 47%. The decrease is primarily the result of a $6.3 million decrease in employee and facilities costs following our June 2013 restructuring and a $6.6 million decrease in marketing and consulting costs due to termination of work related to tivozanib pre-commercialization activities. These amounts were partially offset by a $1.5 million increase in external legal costs associated with various ongoing legal matters, and by a $2.2 million decrease in reimbursements to us from Astellas for shared tivozanib G&A costs, which we recorded as a reduction in G&A expense in the prior year period.

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Restructuring and lease exit. Restructuring and lease exit expenses for the six months ended June 30, 2014 were $9.0 million compared to $7.9 million for the three months ended June 30, 2013. Most of the expenses incurred during the six months ended June 30, 2014 relate to space that we ceased using during at 650 E Kendall St, Cambridge and was triggered upon the completion of the build-outs for that space. The expenses incurred during the six months ended June 30, 2013 relate to severance and employee benefits incurred as part of the June 2013 strategic restructuring.

Other (expense) income, net. Other (expense) income, net for the six months ended June 30, 2014 was $5,000 compared to $(152,000) for the six months ended June 30, 2013, an increase of $157,000 or 103%. Other expense for the six months ended June 30, 2013 is primarily due to losses on foreign exchange rates and fixed asset disposals, while the income for the six months ended June 30, 2014 is primarily due to proceeds from the sale of excess supplies.

Interest expense. Interest expense for the six months ended June 30, 2014 was $1.1 million compared to $1.7 million for the six months ended June 30, 2014, a decrease of 36%. The decrease is primarily attributable to the declining outstanding balance on our loan with Hercules Technology Growth.

Interest income. Interest income for the six months ended June 30, 2014 was $26,000 compared to $76,000 for the six months ended June 30, 2013, a decrease of $50,000 or 66%. The decrease in interest income is primarily due to a lower average cash balance during the six months ended June 30, 2014 compared to the six months ended June 30, 2013.

Liquidity and Capital Resources

We have funded our operations principally through the sale of equity securities sold in private placements and underwritten public offerings, revenue and expense reimbursements from strategic partnerships, debt financing and interest income. As of June 30, 2014, we have received gross proceeds of $89.7 million from the sale of common stock in our initial public offering, $68.3 million from private placements of shares of our common stock to institutional and accredited investors, $168.7 million from a follow-on public offering of shares of our common stock, and $169.6 million from the sale of convertible preferred stock prior to becoming a public company. As of June 30, 2014, we had received an aggregate of $393.0 million in cash from our agreements with strategic partners, and $26.5 million in funding from our debt financing with Hercules Technology Growth and certain of its affiliates. As of June 30, 2014, we had cash, cash equivalents and marketable securities of approximately $64.9 million. Currently, our funds are invested in money market funds, asset-backed securities, asset-backed commercial paper and corporate debt securities, including commercial paper. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Six Months Ended June 30,	
	2014	2013
	(in thousands)	
Net cash used in operating activities	$ (35,220)	$ (53,476)
Net cash provided by (used in) investing activities	34,078	(40,571)
Net cash (used in) provided by financing activities	(6,322)	51,709
Net decrease in cash and cash equivalents	$ (7,464)	$ (42,338)

For the six months ended June 30, 2014 and 2013, our operating activities used cash of $35.2 million and $53.5 million, respectively. The cash used by operations for the six months ended June 30, 2014 was due primarily to our net loss adjusted for non-cash items such as a $7.6 million impairment of property due to the write-off of leased space during the six months ended June 2014, a $9.1 million tenant improvement receivable related to the build-out of our headquarters at 650 E Kendall Street, and working capital adjustments. The cash used by operations for the six months ended June 30, 2013 was due primarily to our net loss adjusted for non-cash items, as well as a decrease in the accounts receivable balance of $12.8 million primarily related to payments received from Astellas during the six months ended June 30, 2013.

For the six months ended June 30, 2014 and 2013, our investing activities provided (used) cash of $34.1 million and $(40.6) million, respectively. The cash provided by (used in) investing activities for the six months ended June 30, 2014 and 2013 was primarily the net result of maturities and sales of marketable securities partially offset by purchases of marketable securities, in addition to purchases of property and equipment of $11.8 million and $2.0 million, respectively, which were primarily associated with the build-out of our leased facilities.

For the six months ended June 30, 2014 and 2013, our financing activities (used) provided $(6.3) million and $51.7 million, respectively. The decrease in cash (used) provided by financing activities is primarily the result of the receipt of proceeds from the issuance on common stock during the three months ended March 31, 2013 that did not recur during the six months ended June 30, 2014.

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Credit Facilities. On May 28, 2010, we entered into a loan and security agreement, which we refer to as the loan agreement, with Hercules Technology II, L.P. and Hercules Technology III, L.P., affiliates of Hercules Technology Growth, which we amended on December 21, 2011 and March 31, 2012, and under which we received a loan in an aggregate principal amount of $26.5 million. We are required to repay the aggregate principal balance of the loan that is outstanding under the loan agreement in 30 equal monthly installments of principal, which started on April 1, 2013. The loan agreement also includes an obligation to pay an additional deferred 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 loan agreement using the effective interest rate method. We recorded a liability for the full amount of the charge since the payment of such amount was not contingent on any future event. Per annum interest is payable at the greater of 11.9% and an amount equal to 11.9% plus the prime rate of interest minus 4.75%, provided however, that the per annum interest shall not exceed 15.0%. We must make interest payments on the loan each month the loan remains outstanding. The unpaid principal balance and all accrued but unpaid interest will be due and payable on September 1, 2015.

The loan is secured by a lien on all of our personal property (other than intellectual property), whether owned as of, or acquired after, the date of the amended loan agreement. As of June 30, 2014, the principal balance outstanding was $14.3 million.

Operating Capital Requirements. We anticipate that we will continue to incur significant operating costs for the next several years as we incur expenses to continue to advance our preclinical and clinical programs.

We believe that our existing cash, cash equivalents and marketable securities will allow us to fund our operating plan into at least the fourth quarter of 2015.

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:

- 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;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to secure alternative leasing or subleasing arrangements for our underutilized office space at 650 East Kendall Street in Cambridge, Massachusetts, and to achieve related cost savings with respect to our current lease obligation;
- 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;

whether we realize the full amount of any projected cost savings associated with our strategic restructurings;

the absence of any breach or event of default under our loan agreement with Hercules or under any other agreements with third parties;

the outcome of lawsuits against us, including the current lawsuits described below under Part II, Item 1A 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.

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In connection with the June 2013 restructuring, we are reevaluating our facilities requirements for our headquarters, office and laboratory space at 650 East Kendall Street in Cambridge, Massachusetts. Failure to secure alternative arrangements with respect to our lease commitments could have an adverse effect on our operating results or financial condition.

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 preclinical studies, clinical trials or other research and 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, 2013 filed with the SEC on March 13, 2014.

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 June 30, 2014, we had cash and cash equivalents and marketable securities of $64.9 million, consisting of cash on deposit with banks, money market funds, U.S. government agency securities, asset-backed securities, asset-backed commercial paper, 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, particularly because our investments are in short-term marketable securities. Our marketable securities are subject to interest rate risk and could fall in value if market interest rates increase. 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 marketable securities 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, pursuant to which we increased the principal amount to $26.5 million. As of June 30, 2014, the principal balance outstanding was $14.3 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 June 30, 2014, and expected loan payments during 2014, 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, Chief Executive Officer and Acting Chief Financial Officer (our principal executive and financial officer), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2014. 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

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relationship of possible controls and procedures. Based on this evaluation, our President, Chief Executive Officer and Acting Chief Financial Officer (our principal executive and financial officer) concluded that as of June 30, 2014, 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 June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Two class action lawsuits have been filed against us and certain of our present and former officers and members of our board of directors, (Tuan Ha-Ngoc, David N. Johnston, William Slichenmyer and Ronald DePinho), in the United States District Court for the District of Massachusetts, one captioned Paul Sanders v. Aveo Pharmaceuticals, Inc., et al., No. 1:13-cv-11157-JLT, filed on May 9, 2013, and the other captioned Christine Krause v. AVEO Pharmaceuticals, Inc., et al., No. 1:13-cv-11320-JLT, filed on May 31, 2013. On December 4, 2013, the District Court consolidated the complaints as In re AVEO Pharmaceuticals, Inc. Securities Litigation et al., No. 1:13-cv-11157-DJC, and an amended complaint was filed on February 3, 2014. The amended complaint purports to be brought on behalf of shareholders who purchased our common stock between January 3, 2012 and May 1, 2013. The amended complaint generally alleges that we and certain of our present and former officers and directors violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the phase 3 trial design and results for our TIVO-1 study in an effort to lead investors to believe that the drug would receive approval from the FDA. The amended complaint seeks unspecified damages, interest, attorneys fees, and other costs. On April 4, 2014, we filed a motion to dismiss the consolidated class action complaint with prejudice. . Lead plaintiffs filed an opposition to the motion to dismiss on June 10, 2014, and we filed a reply to the opposition on July 10, 2014. The Court heard oral argument on our motion to dismiss on July 22, 2014. We deny any allegations of wrongdoing and intend 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, Karen J. van Ingen, a 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, Civil Action No. 1:14-cv-11672-DJC, naming AVEO, as a nominal defendant and also naming 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 breach of fiduciary duty and abuse of control between January 2012 and May 2013 with respect to allegedly misleading statements and omissions regarding tivozanib. 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. On July 25, 2014, defendants filed a motion to dismiss the derivative complaint with prejudice. We deny any allegations of wrongdoing and intend to vigorously defend 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, we received a subpoena from the SEC, requesting documents and information concerning tivozanib, including related communications with the FDA, investors and others. We are fully cooperating with the SEC regarding this fact-finding inquiry. The SEC has informed us that this inquiry should not be construed as an indication that any violations of law have occurred or that the SEC has any negative opinion of any person, entity or security.

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

Since our inception, most of our resources have been dedicated to the discovery and preclinical and clinical development of our product candidates. We believe that we will continue to expend substantial resources for the foreseeable future developing our preclinical and clinical product candidates. These expenditures will include costs associated with research and development, conducting preclinical and clinical trials, obtaining regulatory approvals and products from third-party manufacturers, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise.

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Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

We believe that our existing cash, cash equivalents and marketable securities will allow us to fund our operating plan into at least the fourth quarter of 2015.

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 capital requirements depend on many factors, including:

- 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;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to secure alternative leasing or subleasing arrangements for our underutilized office at 650 East Kendall Street in Cambridge, Massachusetts, and to achieve related cost savings with respect to our current lease obligation;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the costs related to the winding down of the discontinued tivozanib clinical development programs;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- whether we realize the full amount of any projected cost savings associated with our strategic restructurings;
- the absence of any breach or event of default under our loan agreement with Hercules or under any other agreements with third parties;

the outcome of lawsuits against us, including the current lawsuits 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.

In addition, it is possible that Hercules Technology II, L.P. and Hercules Technology III, L.P., affiliates of Hercules Technology Growth, which we refer to collectively as Hercules, could take the position that the adverse outcome relating to the development and commercialization of tivozanib for RCC, including the FDA informing us that it would not approve our NDA for tivozanib for the treatment of patients with advanced RCC, the related shareholder litigation described under Part II, Item 1 Legal Proceedings and Astellas decision to terminate its collaboration with us, collectively, constitute a material adverse change under our loan and security agreement with Hercules, under which we had $14.3 million in loans outstanding as of June 30, 2014, which could trigger a repayment of all principal and interest due under the loan, unless such event of default is waived by Hercules.

In connection with our June 2013 restructuring and related reduction in workforce, we are reevaluating our facilities requirements for our headquarters and laboratory space at 650 East Kendall Street in Cambridge, Massachusetts. Failure to secure alternative arrangements with respect to our lease commitments could have an adverse effect on our operating results or financial condition.

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 preclinical studies, clinical trials or other research and 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.

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

We have incurred net losses in all prior reporting periods, other than for the year ended December 31, 2011, including a net loss of $107.0 million during the twelve months ended December 31, 2013 and a net loss of $24.4 million for the six months ended June 30, 2014. As of June 30, 2014, we had an accumulated deficit of $451.7 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 in the future. 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 preclinical and clinical product candidates.

If we do not successfully develop and obtain regulatory approval for our existing and future pipeline product candidates and effectively manufacture, market and sell any product candidates that are approved, we may never generate product sales, and 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.

Raising additional capital may cause dilution to our existing stockholders, and the terms of additional capital may impose restrictions on our operations or require us to relinquish rights to our technologies or product candidates.

We are likely to seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. Even if we reach a point where we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect stockholders rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

A substantial portion of our future revenues may be dependent upon our existing and future strategic partnerships.

Our success will depend in significant part on our ability to attract and maintain strategic partners and strategic relationships to support the development and commercialization of our product candidates. As part of our business strategy, we have historically entered, and expect to enter in the future, into strategic partnerships relating to the development and commercialization of product candidates. In these partnerships, we would expect our strategic partner to provide substantial funding, as well as significant capabilities in development, marketing and sales. We may not be successful in entering into any such partnerships on favorable terms, if at all. Even if we do succeed in securing such partnerships, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved drug are disappointing.

If any of our strategic partners were to terminate their agreements with us, fail to meet their obligations or otherwise decrease their level of efforts, allocation of resources or other commitments under these agreements with us, our future revenues could be negatively impacted and the development and commercialization of product candidates could be interrupted.

In addition, if some or any of the development, regulatory and commercial milestones are not achieved or if certain net sales thresholds are not achieved, as set forth in the respective agreements, we will not fully realize the expected economic benefits of these partnership agreements. Further, the achievement of certain of the milestones under our partnership agreements will depend on factors that are outside of our control and most milestones are not expected to be achieved for several years, if at all. Any failure to successfully maintain our strategic partnership agreements could materially and adversely affect our ability to generate revenues. For example, in February 2014, Astellas gave us notice of its exercise of its right to terminate our collaboration agreement, for strategic reasons, based on the clinical status of tivozanib. As a result, we will not realize any future revenues from our partnership with Astellas.

Furthermore, any delay in entering into strategic partnerships could delay the development and commercialization of our product candidates and reduce their competitiveness, even if they reach the market. Any such delay related to our strategic partnerships could adversely affect our business.

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We and certain of our present and former officers and 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 present and former officers and directors, were named as defendants in a consolidated class action lawsuit initiated in 2013 that generally alleges that we and certain of our present and former officers and directors violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the phase 3 trial design and results for our TIVO-1 study in an effort to lead investors to believe that the drug would receive approval from the FDA. The complaints seek unspecified damages, interest, attorneys fees, and other costs. Additionally, we received a subpoena from the SEC requesting documents and information concerning tivozanib, including related communications with the FDA, investors and others. 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 the 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. 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.

We intend to engage in a vigorous defense of these lawsuits and are fully cooperating with the SEC regarding its fact-finding inquiry. 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 would have a material adverse effect on our financial condition and business. For example, we could incur substantial costs not covered by our directors and officers 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. Additional similar lawsuits might be filed.

Our business is in the preclinical and early clinical testing stage, 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 preclinical development and clinical testing. 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 ten to 15 years to develop one new medicine from the time it is discovered to when it is available for treating patients. 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 preclinical and early clinical testing 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 focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Our failure to successfully discover, acquire, develop and market additional product candidates or approved products could impair our ability to grow.

As part of our strategic plan, we intend to explore further development opportunities, and to develop and market additional products and product candidates. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional products or product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

exposure to unknown liabilities;

disruption of our business and diversion of our management s time and attention to develop acquired products, product candidates or technologies;

incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

higher than expected acquisition and integration costs;

difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;

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- increased amortization expenses;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we acquire will most likely require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

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:

- 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;

our ability to maintain collaborations with our strategic partners;

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 planned clinical trials that will 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 planned trials. 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 not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to discover, develop and commercialize novel antibody-based products. We are seeking to do so through our internal research programs and intend to explore strategic partnerships for such development. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet may fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;

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a product candidate may upon further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

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.

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, either alone or 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, we or 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

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case, companion diagnostics require separate regulatory approval prior to commercialization. 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.

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 or on our own 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;
- attract qualified scientific, medical, sales and marketing and commercial personnel;
- 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 research, 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 commencement and completion of preclinical studies, 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.

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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 individual employees may have extensive 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 and key scientific personnel, 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, clinical and scientific personnel. We are highly dependent upon our senior management, as well as others on our management team. The loss of services of any of these individuals or one or more of our other members of management could delay or prevent the successful development of our product pipeline, 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.

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We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we may need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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 may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We use hazardous chemicals and radioactive and biological materials in certain aspects of our business and are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, distribution, storage, handling, treatment and disposal of these materials. Although we believe our safety procedures for handling and disposing of these materials and waste products comply with these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials. In the event of contamination or injury, or failure to comply with environmental, occupational health and safety and export control laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. We do not maintain insurance for any environmental liability or toxic tort claims that may be asserted against us.

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Risks Related to Commercialization of Our Product Candidates

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.

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.

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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.

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 that we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

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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.

Risks Related to Our Dependence on Third Parties

We may not be successful in establishing and maintaining additional strategic partnerships, which could adversely affect our ability to develop and commercialize products.

In addition to our current strategic partnerships, a part of our strategy is to enter into additional strategic partnerships in the future, including alliances with major biotechnology or pharmaceutical companies. 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 research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/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:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development of any such product candidates.

In addition, if we fail to establish and maintain additional strategic partnerships involving our Human Response Platform, we would not realize its potential as a means of identifying and validating targets for new cancer therapies in collaboration with strategic partners or of identifying biomarkers to aid in the development of our strategic partners drug candidates.

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 shall not be responsible for any future costs associated in 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.

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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 drug 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 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 drugs. 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 to conduct preclinical and 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 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 rely on these third parties to conduct many of our 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.

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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.

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, 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 any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. 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.

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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. With regard to GDF15, we are aware of a United States patent that contains claims related to antibodies binding to GDF15 protein, which is set to expire in 2014. 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 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 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.

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Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes 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. Accordingly, 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 and our market share in the markets for any of our approved products will be harmed.

We are a party to several license agreements under which certain aspects of our business depend on patents and/or patent applications owned by other companies or institutions. 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 are using in our AV-380 program and from KHK for tivozanib. We are likely to 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, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to obtain regulatory approval and to market products covered by these license agreements. 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, products identical to ours. This could have a material adverse effect on our competitive business position and our business prospects.

We could be unsuccessful in obtaining patent protection on one or more components of our technology platform.

We believe that an important factor in our competitive position relative to other companies in the field of targeted oncology therapeutics is our proprietary Human Response Platform. This platform is useful for identifying new targets for drug discovery, confirming that newly-identified drug targets actually play a role in cancer, testing new compounds for effectiveness as drugs, and identifying traits useful for predicting which patients will respond to which drugs. We own issued U.S. patents covering our chimeric model technology, directed complementation technology, and our reconstituted human breast tumor model. There is no guarantee that any of our pending patent applications, in the United States or elsewhere, will result in issued patents, and, even if patents eventually issue, there is no certainty that the claims in the eventual patents will have adequate scope to preserve our competitive position. Third parties might invent alternative technologies that would substitute for our technology platform while being outside the scope of the patents covering our platform technology. By successfully designing around our patented technology, third parties could substantially weaken our competitive position in oncology research and development.

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.

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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 any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- 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;

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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 ODAC vote, securities class-action litigation has often been instituted against companies. For example, we, and certain of our executive officers, 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 the 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. See Part II, Item 1 Legal Proceedings and We and certain of our executive officers have been named as defendants in multiple lawsuits that could result in substantial costs and divert management s attention. 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 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 elsewhere 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.

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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, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability, in many cases, over extended periods. Though certain of these trends have recently showed signs of reversing, there can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by the current adverse economic conditions and volatile business environment and continued unpredictable and unstable market conditions. If the equity and credit markets do not continue to improve, 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 these economically turbulent times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At June 30, 2014, we had $64.9 million of cash, cash equivalents and marketable securities consisting of cash on deposit with banks, money market funds, U.S. government agency securities, asset-backed securities, asset-backed commercial paper 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 or marketable securities. 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 marketable securities or our ability to meet our financing objectives. Dislocations in the credit market may adversely impact the value and/or liquidity of cash equivalents or marketable securities 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.

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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 many 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.

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Item 6. Exhibits.

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

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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: August 11, 2014

By: /s/ Matt Dallas
Matthew Dallas
Principal Accounting Officer

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Exhibit Index

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
		8-K	001-34655	6-23-2014	99.1	
10.1	Amended and Restated 2010 Stock Incentive Plan, as amended by Amendment No. 1					
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