AVEO PHARMACEUTICALS INC
Form 10-Q
November 07, 2013
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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 September 30, 2013

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 Incorporation or Organization)	(I.R.S. Employer 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)

75 Sidney Street, Cambridge, Massachusetts 02139

(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 November 1, 2013: 51,862,392

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AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2013

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except par value amounts)

(Unaudited)

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 50,420	$ 76,134
Marketable securities	79,942	84,468
Accounts receivable	8,893	20,649
Prepaid expenses and other current assets	7,232	9,430
Total current assets	146,487	190,681
Property and equipment, net	12,766	12,867
Other assets	303	321
Restricted cash	3,558	3,600
Total assets	$ 163,114	$ 207,469
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 6,137	$ 10,628
Accrued expenses	12,154	19,543
Loans payable, net of discount	10,043	6,809
Deferred revenue	1,294	1,294
Deferred rent	864	856
Other liabilities	1,238	
Total current liabilities	31,730	39,130
Loans payable, net of current portion and discount	11,549	19,228
Deferred revenue, net of current portion	17,421	18,391
Deferred rent, net of current portion	16,604	10,544
Other liabilities		1,238
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; 52,219 and 43,780 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	52	44
Additional paid-in capital	496,314	439,173
Accumulated other comprehensive income (loss)	8	(19)
Accumulated deficit	(410,564)	(320,260)
Total stockholders equity	85,810	118,938

Total liabilities and stockholders equity	$ 163,114	$ 207,469

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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Collaboration revenue	$ 323	$ 1,018	$ 970	$ 3,755
Operating expenses:				
Research and development	19,414	21,099	56,579	67,325
General and administrative	4,440	9,300	24,213	27,469
Restructuring	77		8,013	
	23,931	30,399	88,805	94,794
Loss from operations	(23,608)	(29,381)	(87,835)	(91,039)
Other income and expense:				
Other income (expense), net	32	46	(120)	279
Interest expense	(756)	(888)	(2,451)	(2,613)
Interest income	26	101	102	459
Other expense, net	(698)	(741)	(2,469)	(1,875)
Net loss	$ (24,306)	$ (30,122)	$ (90,304)	$ (92,914)
Net loss per share basic and diluted	$ (0.47)	$ (0.69)	$ (1.78)	$ (2.14)
Weighted average number of common shares outstanding	51,443	43,430	50,719	43,336

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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	$ (24,306)	$ (30,122)	$ (90,304)	$ (92,914)
Other comprehensive income (loss):				
Unrealized gains on available-for-sale securities	43	9	1	182
Foreign currency translation adjustment		(27)	26	(24)
Comprehensive loss	$ (24,263)	$ (30,140)	$ (90,277)	$ (92,756)

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)

	Nine Months Ended September 30,	
	2013	**2012**
Operating activities		
Net loss	$ (90,304)	$ (92,914)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,839	1,752
Net loss on disposal of fixed assets	77	40
Impairment of property and equipment	65	
Stock-based compensation	3,162	6,110
Non-cash interest expense	225	299
Amortization of premium and discount on investments	870	2,162
Changes in operating assets and liabilities:		
Accounts receivable	11,756	(2,088)
Prepaid expenses and other current assets	2,190	(1,724)
Other noncurrent assets	18	(187)
Restricted cash	42	(2,849)
Accounts payable	(4,491)	1,355
Accrued expenses	(7,294)	4,069
Deferred revenue	(970)	(970)
Other liabilities		(1,249)
Deferred rent	6,068	3,836
Net cash used in operating activities	(75,747)	(82,358)
Investing activities		
Purchases of property and equipment	(3,011)	(4,183)
Purchases of marketable securities	(154,225)	(109,996)
Proceeds from maturities and sales of marketable securities	157,881	264,361
Net cash provided by investing activities	645	150,182
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	53,638	
Proceeds from issuance of stock for stock-based compensation arrangements	384	1,297
Proceeds from refinancing of loans payable		3,672
Principal payments on loans payable	(4,660)	(2,172)
Net cash provided by financing activities	49,362	2,797
Net (decrease) increase in cash and cash equivalents	(25,740)	70,621
Effect of exchange rate changes on cash and cash equivalents	26	(24)
Cash and cash equivalents at beginning of period	76,134	43,506
Cash and cash equivalents at end of period	$ 50,420	$ 114,103
Supplemental cash flow information		
Cash paid for interest	$ 2,283	$ 2,306

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), which does business as AVEO Oncology , is a cancer therapeutics company committed to discovering and developing targeted cancer therapies to impact patients lives. The Company s product candidates are directed against important mechanisms, or targets, known or believed to be involved in cancer.

The Company and its partner Astellas Pharma, Inc. (Astellas) are evaluating tivozanib, the Company s lead product candidate, in the BATON phase 2 clinical trials of tivozanib in colorectal and breast cancer. The BATON (Biomarker Assessment of Tivozanib in Oncology) program is a series of clinical trials assessing biomarkers in solid tumors that may be predictive of clinical response to tivozanib. Patient enrollment was completed earlier this year for BATON-CRC, a phase 2 clinical trial being conducted by Astellas evaluating tivozanib in combination with modified FOLFOX6 (mFOLFOX6) compared to Avastin® (bevacizumab) in combination with mFOLFOX6 as first-line therapy in patients with advanced metastatic colorectal cancer, or CRC. Results are expected in 2014. The Company s phase 2 BATON-BC clinical trial is evaluating the efficacy and safety of tivozanib in combination with paclitaxel compared to placebo in combination with paclitaxel in patients with locally recurrent or metastatic triple negative breast cancer. Patient enrollment in this clinical trial has been slower than anticipated, and the Company expects to reassess enrollment rates and the impact on its plans in this indication in the coming months.

The Company also has a pipeline of monoclonal antibodies, including AV-203, a clinical stage monoclonal antibody that targets the ERBB3 (HER3) receptor, which the Company has partnered with Biogen Idec, Inc., and ficlatuzumab, a product candidate for which the Company has completed a phase 2 clinical study. Both AV-203 and ficlatuzumab were derived from the Company s Human Response Platform , a novel method of building preclinical models of human cancer. The Company has also initiated a program focusing on cachexia (AV-380), 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. In connection with this program, the Company recently nominated an AV-380 development candidate and initiated cell line development.

The Company has generated an accumulated deficit as of September 30, 2013 of $410.6 million and will require substantial additional capital for research and the development of its preclinical and clinical product candidates.

As used throughout these condensed consolidated financial statements, the term AVEO, refers to AVEO Pharmaceuticals, Inc. and its subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation, both of which are wholly-owned.

(2) Basis of Presentation

These condensed consolidated financial statements include the accounts of the Company and its subsidiaries. The Company has eliminated all significant intercompany accounts and transactions in consolidation.

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the condensed consolidated financial statements have been included. Interim results for the three and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2013 or any other future period.

The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2013, and for the three and nine months, respectively, ended September 30, 2013 and 2012, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2012 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, 2012, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 11, 2013.

(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

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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 consideration of the relevant facts and circumstances for each arrangement. The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units.

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

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

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

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

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

applicable collaboration.

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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 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.

Principles of Consolidation

The Company s condensed consolidated financial statements include the Company s accounts and the accounts of the Company s subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation, both of which are wholly-owned. All intercompany transactions have been eliminated.

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 in accordance with the provisions of Accounting Standards Codification (ASC) 730, *Research and Development*.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents at September 30, 2013 consisted of money market funds and corporate debt securities, including commercial paper, maintained by an investment manager. Cash equivalents at December 31, 2012 consisted of money market funds, asset-backed commercial paper, and corporate debt securities, including commercial paper, maintained by an investment manager.

Marketable Securities

Marketable securities at September 30, 2013 consisted of U.S. government agency securities, asset-backed securities, and corporate debt securities, including commercial paper, maintained by an investment manager. Marketable securities at December 31, 2012 consisted of municipal bonds, asset-backed commercial paper, 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 nine months ended September 30, 2013 and 2012.

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Available-for-sale securities at September 30, 2013 and December 31, 2012 consist of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
September 30, 2013:				
Corporate debt securities	$ 45,247	$ 15	$ (5)	$ 45,257
Government agency securities	15,787	2		15,789
Asset-backed securities	18,900		(4)	18,896
	$ 79,934	$ 17	$ (9)	$ 79,942
December 31, 2012:				
Corporate debt securities	$ 58,751	$ 16	$ (11)	$ 58,756
Municipal bonds	10,545			10,545
Asset-backed securities	6,359			6,359
Asset-backed commercial paper	8,806	2		8,808
	$ 84,461	$ 18	$ (11)	$ 84,468

The aggregate fair value of securities in an unrealized loss position for less than 12 months at September 30, 2013 was $26.0 million, representing fourteen securities. There were no securities that were in an unrealized loss position for greater than 12 months at September 30, 2013. 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 of the security. 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 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 September 30, 2013.

Marketable securities in an unrealized loss position at September 30, 2013 and December 31, 2012 consist of the following:

	Aggregate Fair Value	Unrealized Losses
	(in thousands)	
September 30, 2013:		
Corporate debt securities	$ 10,259	$ (5)
Government agency securities	1,619	
Asset-backed securities	14,078	(4)
	$ 25,956	$ (9)
December 31, 2012:		
Corporate debt securities	$ 29,806	$ (11)
Asset-backed securities	6,359	
	$ 36,165	$ (11)

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk primarily consist of cash, cash equivalents and 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.

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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. ASC 820, *Fair Value Measurements and Disclosures,* establishes a fair value hierarchy for those instruments measured at fair value 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 utilizing 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 utilizing Level 2 inputs include U.S. government agency securities, municipal bonds, asset-backed securities, asset-backed commercial paper, and corporate bonds, including commercial paper. These investments have been initially valued at the transaction price and are subsequently valued, at the end of each reporting period, utilizing third party pricing services or other observable market data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by pricing services as of September 30, 2013 or December 31, 2012.

Level 3 Unobservable inputs developed using estimates and assumptions developed by the Company, which reflect those that a market participant would use. The Company currently has no assets or liabilities recorded at fair value 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 September 30, 2013 and December 31, 2012.

	Fair Value Measurements of Cash Equivalents and Marketable Securities as of September 30, 2013			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents	$ 38,490	$ 6,076	$	$ 44,566
Marketable securities		79,942		79,942
	$ 38,490	$ 86,018	$	$ 124,508

	Fair Value Measurements of Cash Equivalents and Marketable Securities as of December 31, 2012			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents	$ 51,182	$ 18,121	$	$ 69,303
Marketable securities		84,468		84,468
	$ 51,182	$ 102,589	$	$ 153,771

The carrying amounts of the Company s financial instruments not required to be measured at fair value, which include accounts receivable and accounts payable, approximate their fair values at September 30, 2013 and December 31, 2012.

The fair value of the Company s loans payable at September 30, 2013, computed pursuant to a discounted cash flow technique using the effective interest rate under the loan, is $22.4 million and is considered a level 2 fair value measurement. The effective interest rate considers the fair value of the warrant issued in connection with the loan, loan issuance costs and a deferred financing charge, which approximates a market interest rate.

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.

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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 $0.1 million of impairment losses during the nine months ending September 30, 2013.

Basic and Diluted Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the reporting period. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding and potentially dilutive common share equivalents outstanding during the period. Potentially dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants. Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, under generally accepted accounting principles in the United States (GAAP), basic and diluted net loss per common share is presented as the same value.

The following table sets forth for the periods presented the potentially dilutive common share equivalents (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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(in thousands)			
Weighted average options outstanding	5,819	4,794	5,638	4,629
Weighted average warrants outstanding	3	10	8	10
	5,822	4,804	5,646	4,639

Stock-Based Compensation

The Company applies the provisions of ASC 718, *Compensation-Stock Compensation (ASC 718)*, to share-based awards. All awards are recognized in the Company s statements of operations on a straight-line basis over their requisite service periods. Equity-classified awards are measured based on the grant date fair values of the awards calculated using the measurement and recognition provisions of ASC 718. During the three and nine months ended September 30, 2013 and 2012, respectively, the Company recorded the following stock-based compensation expense for equity-classified awards:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(in thousands)			
Research and development	$ 530	$ 972	$ 1,677	$ 2,801
General and administrative	534	1,076	1,365	3,309
	$ 1,064	$ 2,048	$ 3,042	$ 6,110

Liability-classified awards are re-measured to the award s fair value as of each balance sheet date until settled. The Company recorded $34,000 and $0.1 million in compensation expense for liability-classified awards during the three and nine months ended September 30, 2013, respectively. No costs associated with liability-classified awards were recognized during 2012.

Allocations to research and development and general and administrative expense are based upon the department to which the associated employee to whom the award was granted reported. No related tax benefits of the stock-based compensation expense have been recognized. Share-based awards issued to nonemployees are recorded at their fair values, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.

Income Taxes

The Company provides for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined 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.

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The Company accounts for income taxes under ASC 740, *Income Taxes*, which provides a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. Unrecognized tax benefits represent tax positions for which reserves have been established.

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. The Company has $1.0 million of net assets located in the United Kingdom.

Use of Estimates

The preparation of financial statements in conformity with 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.

Recently Adopted Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. This newly issued accounting standard requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where net income (loss) is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income (loss) but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under GAAP that provide additional detail about those amounts. This ASU is effective for reporting periods beginning after December 15, 2012. The Company adopted this standard in the first quarter of 2013 and presents this information in the condensed consolidated financial statements. The adoption of this standard did not have an impact on the Company s financial position or results of operations.

For a discussion of other 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, 2012, filed with the SEC on March 11, 2013. The Company did not adopt any new accounting pronouncements during the nine months ended September 30, 2013 that had a material effect on the Company s condensed consolidated financial statements.

Subsequent Events

The Company has evaluated all events or transactions that occurred after September 30, 2013 through the date the Company issued these financial statements.

(4) Collaborations and License Agreements

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 made plans to develop and seek to commercialize tivozanib for the treatment of a broad range of cancers. The Company and Astellas are currently evaluating tivozanib in colorectal cancer and triple negative breast cancer as part of the BATON program.

Under the terms of the Astellas Agreement, the Company and Astellas share responsibility for continued development and commercialization of tivozanib in the United States, Canada and Mexico (collectively, North America) and in Europe under a joint development plan and a joint commercialization plan, respectively. Throughout the rest of the world, excluding Asia (the Royalty Territory), 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.

If tivozanib is approved for use in treating a particular indication by applicable regulatory agencies, the Company will have lead responsibility for formulating the commercialization strategy for North America under the joint commercialization plan, with each of the Company and Astellas responsible for conducting 50% of the sales efforts and medical affairs activities in North America. Astellas will have lead responsibility for commercialization activities in Europe under the joint commercialization plan, with each of the Company and Astellas responsible for conducting 50% of the medical affairs activities in the major European countries. All costs associated with each party s conduct of development and commercialization activities (including clinical manufacturing and commercial manufacturing costs, if any) in North America and Europe, and any resulting profits or losses, are shared equally between the parties.

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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 for the treatment of patients with advanced renal cell carcinoma (RCC). The milestone was considered substantive and revenue was recognized upon achievement of the milestone. The Company is also eligible to receive from Astellas an aggregate of approximately $1.2 billion in potential future milestone payments, comprised of (i) up to $65 million in substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $325 million in substantive milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $788 million in milestone payments upon the achievement of specified commercial sales events. The first anticipated clinical and development milestone will become due to the Company upon initiation of the first phase 3 clinical trial of tivozanib, if any, in breast cancer, colorectal cancer or another indication. The timing of this milestone is uncertain, as the Company has not finalized plans for its future trials, and the Company needs to complete further trials, including its phase 2 clinical trials, which do not result in any milestone payments coming due, prior to initiating any further phase 3 trials. If tivozanib is successfully developed and launched in the Royalty Territory, Astellas will be required to pay to the Company tiered, double digit royalties on net sales of tivozanib in the Royalty Territory, if any, subject to offsets under certain circumstances. The Company is required to pay KHK low to mid-teen royalties on its net sales in North America, and 30% of certain amounts the Company may receive from Astellas in connection with Astellas development and commercialization activities in Europe and the Royalty Territory, including up-front license fees, milestone payments and royalties.

Unless terminated earlier in accordance with its terms, the Astellas Agreement expires (a) with respect to the Royalty Territory, on a country-by-country basis, upon the latest to occur of: (i) the expiration of the last-to-expire valid claim of an AVEO patent or joint patent covering the composition of tivozanib, (ii) the expiration of the last-to-expire valid claim of an AVEO patent or joint patent covering the use of tivozanib, but only for so long as no generic competition exists in such country, and (iii) twelve years from first commercial sale of tivozanib in such country; and (b) with respect to North America and Europe as a whole, upon the expiration of all payment obligations between the parties related to development and commercialization of tivozanib in North America and Europe. Astellas has the right to terminate the Astellas Agreement, in its entirety or solely with respect to the Royalty Territory, at any time upon 180 days prior written notice to the Company. Either party may terminate the Astellas Agreement with respect to a specified territory or country as set forth in the Astellas Agreement, if the other party fails to cure a material breach related to such territory or country, as applicable. The Company may also terminate the Astellas Agreement in its entirety upon a patent-related challenge by Astellas, its affiliates or sublicensees if such patent-related challenge is not withdrawn within 30 days following the Company s notice to Astellas of such termination. There are no refund provisions in the Astellas Agreement.

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 joint development and commercialization 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 that have been 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 $2.3 million and $7.5 million during the three months ended September 30, 2013 and 2012, respectively, and by $14.9 million and $22.9 million during the nine months ended September 30, 2013 and 2012, respectively. The Company also reduced general and administrative expense by $0.4 million during the three months ended September 30, 2013 and 2012, and by $2.7 million and $1.9 million during the nine months ended September 30, 2013 and 2012, respectively, as a result of these provisions. The net amount due to the Company from Astellas pursuant to the cost-sharing provisions was $8.9 million at September 30, 2013.

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, *Revenue Recognition Multiple Element Arrangements* (ASC 605-25) (as amended by ASU 2009-13, *Revenue Recognition* (ASU 2009-13)) 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

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(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). The License Deliverable is not sublicensable. Astellas has the right to sublicense the exclusive royalty-bearing license to develop and commercialize tivozanib in the Royalty Territory. The Company s obligation to provide access to clinical and regulatory information as part of the Royalty Territory Deliverable includes the obligation to provide access, upon request, to all clinical data, regulatory filings, safety data and manufacturing data to Astellas for use in the development and commercialization of tivozanib in the Royalty Territory. The Clinical Material Deliverable includes the obligation to supply clinical material to Astellas in accordance with current good manufacturing practices applicable to clinical materials and other relevant regulatory authority requirements, upon request, for the 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. 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 s analysis included the following market conditions and entity-specific factors: (a) the specific rights provided under the license to develop and commercialize tivozanib in North America and Europe and the Royalty Territory, (b) the potential indications for tivozanib pursuant to the licenses, (c) the relevant territories for the respective licenses, (d) the stage of development of tivozanib by potential indication and estimated remaining development timelines and costs for each indication, (e) the development risk by indication, (f) the market size by indication, (g) the expected product life of tivozanib assuming commercialization and (h) the competitive environment. More specifically, the Company s discounted cash flow model included an assumption that the Company and Astellas would develop and commercialize tivozanib in North America and Europe as a monotherapy for RCC, and in combination with other known anti-cancer agents for RCC, breast cancer and colorectal cancer. Approximately 70% of the value of tivozanib in the discounted cash flow model was a result of the estimated market opportunity for tivozanib as a monotherapy for RCC. The market opportunity for commercialization of tivozanib in North America and Europe was generated using a patient-based forecasting approach, with key epidemiological, market penetration, dosing, compliance, length of treatment, and pricing assumptions derived from primary and secondary market research. While the RCC monotherapy opportunity represented the majority of the market opportunity, clinical trials for tivozanib in the breast cancer and colorectal cancer indications were in earlier stages of development at the time the Company completed the allocation and therefore had more development risk and were assigned a lower probability of success relative to the RCC indication, with a longer timeline to potential cash inflows. The probability of successfully developing and commercializing tivozanib in the various indications throughout the world (other than Asia) was estimated based on standard industry averages for similar product candidates being developed for oncology indications. The remaining development costs were estimated based upon budgets and estimated costs for ongoing and planned clinical trials in all contemplated indications. The time to commercialization was based on the Company s estimates, which projected the launch of tivozanib for RCC monotherapy in 2013. The market opportunity for the Royalty Territory was estimated based upon a specified percentage of total projected European sales and costs of tivozanib. The Company believes that this method for estimating market opportunity outside of North America, Europe and Asia is common in the pharmaceuticals industry. The Company utilized a discount rate of 15% in its analysis, representing the weighted average cost of capital derived from returns on equity for comparable companies.

The Company concluded that a change in the key assumptions used to determine best estimate of selling price for each license deliverable would not have a significant effect on the allocation of the consideration under the Astellas arrangement.

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 is 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. The Company estimated the period of performance considering the joint plan to develop tivozanib in several indications, including in breast cancer and colorectal cancer and potentially in other cancer indications. The clinical development of tivozanib in these indications is in earlier stages of development and, as a result, the clinical development timeline is uncertain and is expected to change as the Company obtains additional clinical data in these indications. As a result, the Company estimated the period of performance as the remaining patent life of tivozanib as it represents the longest period over which development of tivozanib could occur. The Company reassesses the period of performance at the end of each reporting period. The Company recorded approximately $0.1 million of revenue associated with the Royalty Territory Deliverable during each of the three month periods ended September 30, 2013 and 2012, and approximately $0.3 million of revenue associated with the Royalty Territory Deliverable during each of the nine month periods ended September 30, 2013 and 2012.

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The Company believes the clinical and development and regulatory milestones that may be achieved under the Astellas Agreement are consistent with the definition of a milestone included in ASU 2010-17, *Revenue Recognition Milestone Method*, and, accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when the applicable milestones are achieved. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve each milestone, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone. The Company did not recognize any milestone payments under the Astellas arrangement during the nine months ended September 30, 2013 or 2012.

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 referred to herein as Biogen Idec , regarding the development and commercialization outside of North America of the Company s discovery-stage ERBB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases.

The Company accounts for the Biogen Idec arrangement pursuant to ASC 605-25. The deliverables under the arrangement include 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 requires the Company s experience to advance the development of the products. As such, the Company determined that the agreement should be accounted for as one unit of accounting.

Under the terms of the agreement, Biogen Idec paid the Company an up-front cash payment of $5.0 million in March 2009, which is being amortized over the period of the Company s substantial involvement, defined as the patent life of the development candidate. In addition, Biogen Idec purchased 7,500,000 shares of Series E Convertible Preferred Stock at a per share price of $4.00, resulting in gross proceeds to the Company of $30.0 million. In connection with the Company s initial public offering in March 2010 and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series E Convertible Preferred Stock were converted into one share of common stock. The Company determined that the per share price of $4.00 paid by Biogen Idec included a premium of $1.09 per share over the fair value of the Series E Convertible Preferred Stock of $2.91 as calculated by the Company in its retrospective stock valuation. Accordingly, the Company is recognizing the premium of $8.2 million as revenue on a straight-line basis over the period of the Company s substantial involvement. The Company earned a $5.0 million milestone payment for achievement of the first pre-clinical discovery milestone under the agreement in June 2009, the achievement of which was not considered at risk; such milestone payment was therefore deferred and is being recognized over the period of substantial involvement. The Company earned a second $5.0 million milestone payment upon selection of a development candidate in March 2010. This milestone was considered substantive and was included in revenue for the quarter ended March 31, 2010. The Company earned a third $5.0 million milestone payment based on achieving the GLP toxicology initiation milestone in June 2011. This milestone was considered substantive and was included in revenue for the quarter ended June 30, 2011. The Company could potentially also receive an option exercise fee and regulatory milestone payments of up to $45.0 million in the aggregate if Biogen Idec exercises its option to obtain exclusive rights to commercialize ERBB3 antibody products in its territory. The first regulatory milestone that the Company could potentially receive is a $25.0 million payment due upon the receipt of the first regulatory approval of a licensed product from the EMA. The Company does not expect to achieve this milestone in the near future. The Company did not earn any milestones under the Biogen arrangement during the nine months ended September 30, 2013 or 2012.

If Biogen Idec exercises its exclusive option under the agreement, Biogen Idec will pay the Company royalties on Biogen Idec s sales of ERBB3 antibody products in its territory, and the Company will pay Biogen Idec royalties on the Company s sale of ERBB3 antibody products in North America.

Under the agreement, the Company recorded revenue of $0.2 million and $0.6 million during the three months and nine month periods ended September 30, 2013, respectively, and $0.2 million and $0.6 million during the three and nine month periods ended September 30, 2012, respectively.

OSI Pharmaceuticals Inc.

In September 2007, the Company entered into a collaboration and license agreement with OSI Pharmaceuticals, Inc. (a wholly-owned subsidiary of Astellas US Holding Inc., a holding company owned by Astellas Pharma Inc.), or OSI, which provided for the use of the Company s proprietary *in vivo* models by the Company s scientists at its facilities, use of the Company s bioinformatics tools and other target validation and biomarker research to further develop and advance OSI s small molecule drug discovery and translational research related to cancer and other diseases. In July 2009, the Company and OSI expanded the strategic partnership, and

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the Company granted OSI a non-exclusive license to use the Company s proprietary bioinformatics platform, and non-exclusive perpetual licenses to use bioinformatics data and the Company s proprietary gene index related to a specific target pathway. Further, as part of the expanded strategic partnership, the Company granted OSI an option, exercisable upon payment of an option fee, to receive non-exclusive perpetual rights to certain elements of the Company s Human Response Platform and to use the Company s bioinformatics platform, and the Company granted OSI the right to obtain certain of its tumor models and tumor archives. In November 2010, OSI exercised its option under the July 2009 expanded agreement providing the right for OSI to license certain elements of the Company s proprietary technology platform, including components of the Human Response Platform for the identification/characterization of novel epithelial-mesenchymal transition agents and proprietary patient selection biomarkers, in support of OSI s clinical development programs. The Company received $12.5 million of upfront payments from OSI and research funding payments on a quarterly basis that were recognized as revenue through July 2011. In addition, OSI purchased 1,833,334 shares of the Company s Series C Convertible Preferred Stock and 3,750,000 shares of the Company s Series E Convertible Preferred Stock that were converted into shares of common stock in connection with the Company s initial public offering. The Company determined that both equity issuances included a premium, which was recognized as additional license revenue through July 2011. The Company completed the transfer of the relevant technology to OSI in July 2011. The Company also recognized $25.0 million relating to the option exercise by OSI over the technology transfer period, which was completed in July 2011.

Under the July 2009 expanded agreement, if all applicable milestones are achieved, all remaining payments for the successful achievement of discovery, development and commercialization milestones could total, in the aggregate, over $46.0 million, comprised of approximately (i) $8.4 million in substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) $20.7 million in substantive milestone payments upon achievement of specified regulatory milestone events, and (iii) $17.5 million in milestone payments upon the achievement of specified sales amounts. In addition, the Company is eligible to receive up to $24.0 million in biomarker-related milestones.

In May 2012, the Company earned a patent-related milestone payment of $250,000 upon filing of a patent application by OSI, and the Company also earned a clinical and development milestone payment of $750,000 for commencement by OSI of GLP toxicology studies. Since these milestones were considered substantive, they were recorded as revenue during the nine month periods ended September 30, 2012.

The next milestone payment that the Company could potentially receive pursuant to this agreement is a $2.0 million clinical and development milestone for phase 1 clinical trial dosing in the United States. The Company does not expect to achieve this milestone in the near future. The next regulatory milestone payment the Company could potentially receive pursuant to this agreement is $7.0 million upon the filing of an NDA with the FDA. The Company does not expect to achieve this milestone in the near future. Upon commercialization of products under the agreement, the Company is eligible to receive tiered royalty payments on sales of products by OSI, its affiliates and sublicensees. All of the milestone payments that were earned prior to July 2011 are for selection of targets, delivery of models, delivery of tumor archives or delivery of cell lines.

Centocor Ortho Biotech

In May 2011, the Company entered into an exclusive license agreement (the Centocor License Agreement) with Centocor Ortho Biotech Inc. (Centocor), for the worldwide development and commercialization of the Company s internally-discovered antibodies targeting the RON receptor (Recepteur d Origine Nantais), including the grant to Centocor of an exclusive, worldwide license to the Company s proprietary RON-driven tumor models. The Company also granted Centocor a non-exclusive, non-sublicensable, worldwide license to the Company s proprietary list of human genes intended to predict correlation of response to RON-targeted antibodies (the RON index). On September 7, 2012, the Company received notice from Centocor of termination of the Centocor License Agreement, effective on December 6, 2012, at which point all rights to and the responsibility for future research and development, manufacturing and commercialization activities and costs of the RON antibody program granted to Centocor under the Centocor License Agreement returned to the Company.

In connection with the Centocor License Agreement, the Company received a one-time cash payment in the amount of $7.5 million and a separate equity investment in the amount of approximately $7.5 million through the purchase by Johnson & Johnson Development Corporation, an affiliate of Centocor, of 438,340 newly issued shares of the Company s common stock at a purchase price of $17.11 per share. Centocor also funded certain research which the Company conducted during the term of the Centocor License Agreement, which, as noted above, terminated on December 6, 2012.

The Company recorded revenue of $0.7 million and $1.8 million for the three and nine months ended September 30, 2012, respectively, pursuant to the license agreement.

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.

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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 for the treatment of patients with advanced RCC. 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 for the treatment of patients with advanced RCC, 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 in the United States, (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, and (iii) pay 30% of certain amounts the Company receives under the Astellas Agreement in connection with Astellas development and commercialization activities in Europe and the Royalty Territory related to tivozanib, including up-front license fees, milestone payments and royalties the Company may receive from Astellas, other than amounts the Company receives in respect of research and development funding or equity investments, subject to certain limitations.

(5) Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2013 and December 31, 2012:

	September 30, 2013	December 31, 2012
	(in thousands)	
Clinical expenses	$ 7,154	$ 6,688
Salaries and benefits	2,336	6,015
Restructuring	838	1,653
Professional fees	595	430
Accrued interest	217	275
Medical affairs	104	583
Collaboration expenses		1,807
Pre-commercialization expenses		924
Other	910	1,168
	$ 12,154	$ 19,543

(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 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.

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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 includes an additional deferred charge of $1.2 million due in June 2014 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. The Company recorded a long-term liability for the full amount of the charge since the payment of such amount is not contingent on any future event. The Company incurred approximately $193,000 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 $780,000 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%.

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. Hercules also received an option, subject to the Company s written consent, not to be unreasonably withheld, to purchase, either with cash or through conversion of outstanding principal under the loan, up to $2.0 million of equity of the Company sold in any sale by the Company to third parties of equity securities resulting in at least $10.0 million in net cash proceeds to the Company, subject to certain exceptions. The Company has evaluated the embedded conversion option, and has concluded that it does not need to be bifurcated and separately accounted for. No amount will be recognized for the conversion feature until such time as the conversion feature is exercised and it can be determined whether a beneficial conversion feature exists. As of September 30, 2013, 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 Item 1, Note 9 Legal Action, constitute 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. As of September 30, 2013, the principal balance outstanding was $21.8 million.

Future minimum payments under the loans payable outstanding as of September 30, 2013 are as follows (amounts in thousands):

Years Ending December 31:	
2013 (3 months remaining)	3,077
2014	13,546
2015	9,309
	25,932
Less amount representing interest	(2,855)
Less discount	(247)
Less deferred charges	(1,238)
Less current portion	(10,043)
Loans payable, net of current portion	$ 11,549

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(7) Stock-based Compensation

Stock Plans

The Company issued stock options and restricted stock awards during the nine months ended September 30, 2013 and 2012.

A summary of the status of the Company s stock option activity at September 30, 2013 and changes during the nine months then ended is presented in the table and narrative below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2012	4,638,388	$ 9.86		
Granted	2,709,840	$ 4.96		
Exercised	(139,903)	$ 1.37		
Forfeited	(1,983,719)	$ 10.26		
Outstanding at September 30, 2013	5,224,606	$ 7.40	6.41	$ 210,279
Vested or expected to vest at September 30, 2013	4,518,190	$ 7.80	5.95	$ 210,279
Exercisable at September 30, 2013	3,029,547	$ 8.55	4.42	$ 210,279

The aggregate intrinsic value in the table above represents the value (the difference between the Company s closing common stock price on the last trading day during the nine months ended September 30, 2013 and the exercise price of the options, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on September 30, 2013. As of September 30, 2013, there was $5.4 million of total unrecognized stock-based compensation expense related to stock options granted under the Company s 2002 Stock Incentive Plan and 2010 Stock Incentive Plan (the plans). The expense is expected to be recognized over a weighted-average period of 2.0 years.

Stock-based awards to employees are required to be measured at fair value. The Company uses the Black-Scholes pricing model in order to calculate the estimated fair value of its stock option grants. This model requires the Company to make assumptions with respect to factors such as volatility, interest rate, dividend yield and term. Because the Company only completed its initial public offering in March 2010, it has not had sufficient history as a publicly traded company to support a calculation of expected term and volatility. 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, market capitalization and similar product pipelines. The Company utilized a weighted average method of using its own historical volatility data for the quarters that it has been public, along with data it obtained with respect to its peer companies. Due to the 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. Additionally, under the provisions of ASC 718, the Company is required to include an estimate of the value of the awards that will be forfeited in calculating compensation costs, which the Company estimates based upon actual historical forfeitures. The forfeiture estimates are recognized over the requisite service period of the awards on a straight-line basis. The 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.

During the three and nine months ended September 30, 2013 and 2012, respectively, the assumptions used in the Black-Scholes pricing model for new grants were as follows:

	Three Months Ended September 30,	
	2013	2012
Volatility factor	71.13%	64.84%
Expected term (in years)	6.25	6.25
Risk-free interest rates	1.715%	0.83%
Dividend yield		

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	Nine Months Ended September 30,	
	2013	2012
Volatility factor	64.22-72.65%	64.30-64.94%
Expected term (in years)	5.50-6.25	5.50-6.25
Risk-free interest rates	1.01-1.71%	0.83-1.33%
Dividend yield		

The restricted stock activity for the nine months ended September 30, 2013 is as follows:

	Number of Shares	Weighted-Average Fair Value
Unvested at December 31, 2012	245,020	$ 13.31
Granted	689,678	5.23
Cancelled	(172,280)	9.14
Expired		
Vested/Released	(32,500)	14.16
Unvested at September 30, 2013	729,918	$ 6.62

The Company reversed $2.0 million of previously recognized stock-based compensation expense during the nine months ending September 30, 2013 associated with restricted stock awards that are no longer probable of vesting. As of September 30, 2013, there was $0.1 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 0.8 year.

(8) Strategic Restructurings

In October 2012, the Company announced a strategic restructuring designed to optimize resources and reduce expenses. The Company s restructuring and projected cost savings are being achieved through a combination of reduced spending on early stage research programs and a reduction in force of 48 positions, as well as the elimination of 30 previously open positions.

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 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 has been substantially completed. The Company expects this restructuring to be fully completed by December 31, 2013.

The following table summarizes the components of the Company s restructuring activity recorded in operating expenses and in accrued expenses in the accompanying condensed consolidated balance sheet:

	Restructuring amounts accrued at December 31, 2012	Restructuring expense incurred during the nine months ended September 30, 2013	Restructuring amounts paid during the nine months ended September 30, 2013	Restructuring amounts accrued at September 30, 2013
		(in thousands)		
Employee severance, benefits and related costs.	$ 1,653	$ 7,618	$ (8,488)	$ 783
Contract termination costs		82	(27)	55
Total	1,653	7,700	(8,515)	838

Restructuring expense for the nine months ended September 30, 2013 includes impairment charges of $0.3 million.

(9) Legal Actions

Two class action lawsuits have been filed against the Company and certain of the Company s officers in the United States District Court for the District of Massachusetts, one on May 9, 2013, captioned Paul Sanders v. Aveo Pharmaceuticals, Inc., et al., No. 1:13-cv-11157-JLT, and the other on May 31, 2013, captioned Christine Krause v. AVEO Pharmaceuticals, Inc., et al., No. 1:13-cv-11320-JLT, respectively. Each complaint purports to be brought on behalf of shareholders who purchased the Company s common

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stock between January 3, 2012 and May 1, 2013. Each complaint generally alleges that the Company and certain of the Company s officers 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 the Company s TIVO-1 study in an effort to lead investors to believe that the drug would receive approval from the FDA. Each complaint seeks unspecified damages, interest, attorneys fees, and other costs. The Company denies any allegations of wrongdoing and intends to vigorously defend against these lawsuits. However, there is no assurance that the Company will be successful in defense or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. 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.

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

Forward-Looking Information

The following discussion of our financial condition and results of operations should be read with our unaudited condensed consolidated financial statements and notes included in Part I. Item 1 of this Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2013, as well as the audited consolidated financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the Securities and Exchange Commission, or SEC, on March 11, 2013. This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management and include, without limitation, statements with respect to our expectations regarding our research, development and commercialization plans and prospects, results of operations, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as anticipate, target, project, believe, goals, estimate, potential, predict, may, expect, might, variations of these terms or the negative of those terms and similar expressions are intended to identify these forward-looking statements. Readers are cautioned that these forward-looking statements are predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading Risk Factors in Item 1A of Part II and elsewhere in this report.

Overview

We are a cancer therapeutics company, which does business as AVEO Oncology , committed to discovering and developing targeted cancer therapies to impact patients lives. Our product candidates are directed against important mechanisms, or targets, known or believed to be involved in cancer. Our proprietary Human Response Platform , a novel method of building preclinical models of human cancer, provides us with unique insights into cancer biology.

In 2006, we acquired exclusive rights to develop and commercialize tivozanib, our lead product candidate, worldwide outside of Asia pursuant to a license agreement we entered into with Kirin Brewery Co. Ltd. (now Kyowa Hakko Kirin), or KHK. Under the license agreement, we obtained an exclusive license outside of Asia to research, develop, manufacture and commercialize tivozanib, pharmaceutical compositions thereof and associated biomarkers for the diagnosis, prevention and treatment of any and all human diseases and conditions. KHK has retained all rights to tivozanib in Asia. We have obligations to make milestone and royalty payments to KHK. The royalty rates range from the low to mid-teens as a percentage of our net sales of tivozanib. We are also obligated to pay a specified percentage of certain amounts we receive from any third-party sublicensees, including Astellas Pharma, Inc., or Astellas. As discussed below under the heading Strategic Partnerships, we entered into a strategic collaboration with Astellas in which we have agreed to share responsibility, including all profits and losses, with Astellas for the continued development and commercialization of tivozanib in the United States, Mexico and Canada, which we refer to collectively as North America, and Europe. Throughout the rest of the world, outside of North America, Europe and Asia, we granted Astellas an exclusive, royalty-bearing license to develop and commercialize tivozanib. Our exclusively licensed patents covering the tivozanib molecule and its therapeutic use expire in April 2022, with the possibility of patent term extension to April 2027 in the United States and in the European countries where the tivozanib molecule and its therapeutic use are patented.

We and our partner Astellas are evaluating tivozanib in the BATON phase 2 clinical trials of tivozanib in colorectal and breast cancer. The BATON (Biomarker Assessment of Tivozanib in ONcology) program is a series of clinical trials assessing biomarkers in solid tumors that may be predictive of clinical response to tivozanib. Patient enrollment was completed earlier this year for BATON-CRC, a phase 2 clinical trial being conducted by Astellas evaluating tivozanib in combination with modified FOLFOX6 (mFOLFOX6) compared to Avastin® (bevacizumab) in combination with mFOLFOX6 as first-line therapy in patients with advanced metastatic colorectal cancer, or CRC. Results are expected in 2014. BATON-BC is a phase 2 clinical trial evaluating the efficacy and safety of tivozanib in combination with paclitaxel compared to placebo in combination with paclitaxel in patients with locally recurrent or metastatic triple negative breast cancer. Patient enrollment in this clinical trial has been slower than anticipated, and we expect to reassess enrollment rates and the impact on our plans in this indication in the coming months.

In addition to tivozanib, we have a pipeline of monoclonal antibodies derived from our proprietary Human Response Platform. The Human Response 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 our Human Response Platform provides us with unique insights into cancer biology and mechanisms of drug response and resistance, and represents a significant improvement over traditional approaches. The identification and development of potential biomarkers through our Human Response Platform is a core component of our oncology drug development efforts.

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AV-203, which is derived from our Human Response Platform, is our clinical-stage ERBB3 (HER3) inhibitory antibody candidate, which we have partnered outside of North America with Biogen Idec International GmbH, a subsidiary of Biogen Idec, Inc. (which we collectively refer to herein as Biogen Idec). ERBB3 is believed to be an important receptor regulating cancer cell growth and survival, and high ERBB3 levels have been shown to correlate with poor prognoses in several tumor types. AV-203 has demonstrated tolerability in the dose-escalation portion of a phase 1 clinical trial examining the safety, tolerability and preliminary anti-tumor activity of AV-203 in patients with metastatic or advanced solid tumors, and the recommended dose for further evaluation has been established. AV-203 is now being evaluated in an expansion cohort in a biomarker-defined patient population.

Ficlatuzumab, which was also derived from our Human Response Platform, binds to hepatocyte growth factor, or HGF, thereby blocking its function. 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 and a phase 2 clinical study evaluating ficlatuzumab. We intend, in the coming months, to explore strategic options for ficlatuzumab.

In 2012, we initiated a program focusing on cachexia (AV-380), 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. In connection with this program, we have in-licensed certain patents and patent applications from St. Vincent s Hospital in Sydney, Australia, and we recently nominated an AV-380 development candidate and initiated cell line development.

Using our Human Response Platform, we have identified a number of other promising targets that appear to be potent drivers of tumor growth. Genetic screens conducted using the Human Response Platform have demonstrated that activation of the Notch signaling pathway plays an important role in tumor formation and the maintenance of cancer stem cell populations in tumors. We have discovered antibodies that target the Notch 1 and Notch 3 receptors and are seeking to partner this program. Work in our Human Response Platform has also identified Fibroblast Growth Factor ligands and receptors, specifically FGFR2 and FGFR3, as powerful drivers of tumor growth in a variety of tumor models and implicated the activation of the pathway in tumor development. We have discovered antibodies that target these receptors and are seeking to partner this program as well.

We have devoted substantially all of our resources to our drug discovery efforts, including research and development, conducting clinical trials for our product candidates, protecting our intellectual property and supporting the general and administrative functions of these operations. We have generated no revenue from product sales through September 30, 2013, and have principally funded our operations through:

- $381.8 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;
- $26.5 million of loan proceeds in connection with our loan agreement with Hercules Technology II, L.P. and Hercules Technology III, L.P., affiliates of Hercules Technology Growth (which we refer to collectively as Hercules);
- $68.3 million of gross proceeds from unregistered private placements of our common stock; and
- $168.7 million of gross proceeds from the sale of common stock in connection with public offerings of our common stock in June 2011 and January 2013.

We do not have a history of being profitable and, as of September 30, 2013, we had an accumulated deficit of $410.6 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

Kyowa Hakko Kirin

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

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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 for the treatment of patients with advanced renal cell cancer, or RCC. We 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 by the U.S. Food and Drug Administration, or FDA, of our New Drug Application, or NDA, filing for tivozanib for the treatment of patients with advanced RCC.

Under our license agreement with KHK, we may be required to:

- make future milestone payments upon the achievement of specified regulatory milestones in the United States;
- pay tiered royalty payments on net sales we make of tivozanib in our territory ranging from the low to mid-teens as a percentage of our net sales of tivozanib. The royalty rate escalates within this range during each calendar year based on increasing tivozanib sales during such calendar year. 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, end on the later of 12 years after the date of first commercial sale of tivozanib in that country or expiration of the last-to-expire valid claim of the licensed patents covering tivozanib in that country, and are subject to offsets under certain circumstances; and
- pay 30% of certain amounts we receive under our collaboration and license agreement with Astellas, which we describe below, in connection with Astellas development and commercialization activities outside of North America and Asia related to tivozanib, other than amounts we receive in respect of research and development funding or equity investments, subject to certain limitations.

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. We and Astellas are evaluating tivozanib in colorectal cancer and triple negative breast cancer, as part of the BATON program.

Under the terms of the collaboration agreement, we and Astellas share responsibility for continued development and commercialization of tivozanib in the United States, Canada and Mexico, which we refer to collectively as North America, and Europe under the joint development plan and joint commercialization plan, respectively. Throughout the rest of the world (which excludes North America, Europe and Asia), which we refer to as the royalty territory, Astellas has an exclusive, royalty-bearing license to develop and commercialize tivozanib. Our plan to commercialize tivozanib in collaboration with Astellas, as described herein, is subject to our and Astellas receipt of necessary regulatory approvals from the FDA and foreign regulatory authorities based upon favorable results in clinical trials. There can be no assurance that such approvals will be obtained.

If tivozanib is approved by applicable regulatory agencies, we will hold all marketing authorizations in North America, including any NDA in the United States, and Astellas will hold all marketing authorizations in the rest of the world, other than Asia.

If tivozanib is approved by applicable regulatory agencies, we, as the lead commercialization party in North America, will have lead responsibility for formulating the commercialization strategy for North America under the joint commercialization plan, with each of us and Astellas responsible for conducting 50% of the sales efforts and medical affairs activities in North America. Astellas will have lead responsibility for commercialization activities in Europe under the joint commercialization plan, and we will be responsible for conducting 50% of the medical affairs activities in the major European countries. All costs associated with each party s conduct of development and commercialization activities (including clinical manufacturing and commercial manufacturing costs, if any) in North America (including any regulatory milestones and royalties associated with tivozanib in North America which may become payable by us to KHK under our license agreement with KHK), and any resulting profits or losses, are shared equally between the parties. All costs associated with each party s conduct of development and commercialization activities (including clinical manufacturing and commercial manufacturing costs, if any) in Europe, and

any resulting profits or losses, are shared equally between the parties. As between the parties, we will remain responsible for complying with our sublicense revenue sharing obligations, if any, to KHK under our license agreement with KHK in connection with the development and commercialization of tivozanib outside of North America.

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We are responsible for manufacturing, through our third-party manufacturer, all of Astellas requirements for tivozanib pursuant to a clinical supply agreement which we have entered into with Astellas, and a commercial supply agreement for supply of tivozanib in Europe and the royalty territory which the parties expect to enter into prior to any commercialization of tivozanib.

Each party is obligated to use commercially reasonable efforts to develop and commercialize tivozanib in North America, and to develop and commercialize tivozanib in each European country specified in the agreement. Astellas is also obligated to use commercially reasonable efforts to develop and commercialize tivozanib in each country in the royalty territory.

During the term of the agreement, neither party nor its controlled affiliates may commercialize anywhere in North America, Europe or the royalty territory any product that has a specified mechanism of action (as further defined in the collaboration agreement) for any oncology indication, except that Astellas may commercialize specified compounds for hematological cancer. We and Astellas may also commercialize products (other than tivozanib) in the royalty territory, on a country-by-country basis, after expiration of the applicable royalty term, and in North America and Europe after expiration of all valid claims under the licensed patents.

In connection with the agreement, we received an initial cash payment of $125 million, comprised of a $75 million license fee and $50 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 are also eligible to receive an aggregate of approximately $1.2 billion in potential future milestone payments, comprised of (i) up to $65 million in substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $325 million in substantive milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $788 million in milestone payments upon the achievement of specified commercial sales events. The first anticipated clinical and development milestone will become due to us upon initiation of a phase 3 clinical trial, if any, in breast cancer, colorectal cancer or another indication. The timing of this milestone is uncertain, as we have not finalized plans for our future trials, and we need to complete further trials, including our phase 2 trials, which do not result in any milestone payments coming due, prior to initiating any further phase 3 clinical trials. We have elected to recognize all milestone payments as revenue once the milestones have been triggered if the milestone is deemed to be substantive. If tivozanib is successfully developed and launched in the royalty territory, Astellas will be required to pay to us tiered, double digit royalties on net sales of tivozanib in the royalty territory, if any, subject to offsets under certain circumstances. We are required to pay KHK low to mid-teen royalties on our net sales in North America, and 30% of certain amounts we may receive from Astellas in connection with Astellas development and commercialization activities in Europe and the royalty territory, including up-front license fees, milestone payments and royalties.

Unless terminated earlier in accordance with its terms, the agreement expires (a) with respect to the royalty territory, on a country-by-country basis, upon the latest to occur of: (i) the expiration of the last-to-expire valid claim of an AVEO patent or joint patent covering the composition of tivozanib, (ii) the expiration of the last-to-expire valid claim of an AVEO patent or joint patent covering the use of tivozanib, but only for so long as no generic competition exists in such country, and (iii) twelve years from first commercial sale of tivozanib in such country; and (b) with respect to North America and Europe as a whole, upon the expiration of all payment obligations between the parties related to development and commercialization of tivozanib in North America and Europe. Astellas has the right to terminate the agreement, in its entirety or solely with respect to the Royalty Territory, at any time upon 180 days prior written notice to us. Either party may terminate the agreement with respect to a specified territory or country as set forth in the agreement, if the other party fails to cure a material breach related to such territory or country, as applicable. We may also terminate the agreement in its entirety upon a patent-related challenge by Astellas, its affiliates or sublicensees if such patent-related challenge is not withdrawn within 30 days following notice by us to Astellas of such termination. There are no refund provisions in the agreement.

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 research and development costs incurred by us are recorded as a reduction to expense due to the joint cost-sharing provisions of the agreement in North America and Europe. As a result of the cost-sharing provisions in our agreement with Astellas, we reduced research and development expense by $2.3 million and $7.5 million during the three months ended September 30, 2013 and 2012, respectively, and by $14.9 million and $22.9 million during the nine months ended September 30, 2013 and 2012, respectively. We also reduced general and administrative expense by $0.4 million during the three months ended September 30, 2013 and 2012, and by $2.7 million and $1.9 million during the nine months ended September 30, 2013 and 2012, respectively as a result of the cost-sharing provisions in our agreement with Astellas. The net amount due to us from Astellas pursuant to the cost-sharing provisions is $8.9 million at September 30, 2013.

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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 *Revenue Recognition Multiple Element Arrangements*, or 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. The co-exclusive license in North America and Europe is not sublicensable. Astellas has the right to sublicense the exclusive royalty-bearing license to develop and commercialize tivozanib in the royalty territory. Our obligation to provide access to clinical and regulatory information as part of the royalty territory deliverable includes the obligation to provide access, upon request, to all clinical data, regulatory filings, safety data and manufacturing data to Astellas for use in the development and commercialization of tivozanib in the royalty territory. The obligation to supply clinical material to Astellas for development in the royalty territory includes supplying such clinical material in accordance with current good manufacturing practices applicable to clinical materials and other relevant regulatory authority requirements, upon request, for the 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. ASC 605-25 establishes a selling price hierarchy for determining the selling price of a deliverable, which includes: (1) vendor-specific objective evidence if available; (2) third-party evidence if vendor-specific objective evidence is not available; and (3) estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. 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 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 are recording the $4.8 million ratably over the period of our performance through April 2022, the remaining patent life of tivozanib. We estimated the period of performance considering that we plan to develop tivozanib with Astellas in several indications, including in breast cancer and colorectal cancer and potentially in other cancer indications. The clinical development of tivozanib in these indications is in earlier stages of development and, as a result, the clinical development timeline is uncertain and is expected to change as we obtain additional clinical data in these indications. As a result, we estimated the period of performance as the remaining patent life of tivozanib as it represents the longest period over which development of tivozanib could occur. We reassess the period of performance at each reporting period. We recorded approximately $0.1 million of revenue associated with the royalty territory deliverable during each of the three months ended September 30, 2013 and 2012, and approximately $0.3 million of revenue associated with the royalty territory deliverable during the nine months ended September 30, 2013 and 2012, respectively.

Biogen Idec

In March 2009, we entered into an exclusive option and license agreement with Biogen Idec, regarding the development and commercialization outside of North America of our discovery-stage ERBB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases in humans. Under the agreement, we are responsible for developing ERBB3 antibodies through completion of the first clinical trial designed in a manner that, if successful, will generate data sufficient to support advancement to a phase 3 clinical trial. Until a specified time after we complete this clinical trial and deliver to Biogen Idec a detailed data package containing the results thereof, Biogen Idec may elect to obtain (1) a co-exclusive (with us) worldwide license, including the right to grant sublicenses, under our relevant intellectual property to develop and manufacture ERBB3 antibody products, and (2) an exclusive license, including the right to grant sublicenses, under our relevant intellectual property, to commercialize ERBB3 antibody products in all countries in the world other than North America. We retain the exclusive right to commercialize ERBB3 antibody products in North America.

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We account for the Biogen Idec arrangement pursuant to ASC 605-25. The deliverables under the arrangement include 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. As such, we determined that the agreement should be accounted for as one unit of accounting.

Under the terms of the agreement, Biogen Idec paid us an up-front cash payment of $5.0 million in March 2009, which is being amortized over the period of our substantial involvement, defined as the patent life of the development candidate. In addition, Biogen Idec purchased 7,500,000 shares of series E convertible preferred stock at a per share price of $4.00, resulting in gross proceeds to us of $30.0 million. We determined that the per share price of $4.00 paid by Biogen Idec represented a premium of $1.09 per share over the fair value of the series E convertible preferred stock of $2.91 as calculated by us in our retrospective stock valuation; accordingly, we are recognizing the premium of $8.2 million as revenue on a straight-line basis over the period of our substantial involvement. In connection with our initial public offering, consummated in March 2010, and the related 1:4 reverse stock split of our common stock, each four shares of outstanding series E convertible preferred stock were converted into one share of common stock.

In June 2009, we earned a $5.0 million milestone payment for achievement of the first pre-clinical discovery milestone under the agreement. Since the $5.0 million milestone payment earned in June 2009 was related to a near-term milestone and not considered to be substantive, the revenue is being amortized as additional license revenue over the period of our substantial involvement. We also earned a second $5.0 million milestone payment upon selection of a development candidate in March 2010 and a third $5.0 million milestone payment based on achieving the GLP toxicology initiation milestone in June 2011. These milestones were considered substantive and were included in revenue for the quarters ended March 31, 2010 and June 30, 2011, respectively. We could also receive an option exercise fee of $5.0 million and regulatory milestone payments of up to $45.0 million in the aggregate if Biogen Idec exercises its option to obtain exclusive rights to commercialize ERBB3 antibody products in its territory. The first regulatory milestone payment we may receive pursuant to this agreement of $25.0 million is due upon the receipt of the first regulatory approval of a licensed product from the EMA. We do not expect to achieve this milestone in the near future.

If Biogen Idec exercises its exclusive option under the agreement, Biogen Idec will pay us royalties on its sales of ERBB3 antibody products in its territory, and we will pay Biogen Idec royalties on our sale of ERBB3 antibody products in North America.

OSI Pharmaceuticals

In September 2007, we entered into a collaboration and license agreement with OSI Pharmaceuticals, Inc. (a wholly-owned subsidiary of Astellas US Holding Inc., a holding company owned by Astellas Pharma Inc.), or OSI. This strategic partnership is primarily focused on the identification and validation of genes and targets involved in the processes of epithelial-mesenchymal transition or mesenchymal-epithelial transition, in cancer. In July 2009, we expanded our strategic partnership with OSI and we granted OSI a non-exclusive license to use our proprietary bioinformatics platform, and non-exclusive, perpetual licenses to use bioinformatics data and to use a proprietary gene index related to a specific target pathway. As part of our expanded strategic partnership, in November 2010, OSI exercised an option to license certain elements of our proprietary technology platform, including components of the Human Response Platform for the identification/characterization of novel epithelial-mesenchymal transition agents and proprietary patient selection biomarkers, in support of OSI s clinical development programs. We received $12.5 million of upfront payments from OSI and research funding payments on a quarterly basis that were recognized as revenue through July 2011. In addition, OSI purchased 1,833,334 shares of our Series C Convertible Preferred Stock and 3,750,000 shares of our Series E Convertible Preferred Stock that were converted into shares of common stock in connection with our initial public offering. We determined that both equity issuances included a premium, which was recognized as additional license revenue through July 2011.

Under the July 2009 expanded agreement, if all applicable milestones are achieved, all remaining payments for the successful achievement of discovery, development and commercialization milestones under the agreement could total, in the aggregate, over $46.0 million, comprised of approximately (i) $8.4 million in substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) $20.7 million in substantive milestone payments upon achievement of specified regulatory milestone events, and (iii) $17.5 million in milestone payments upon the achievement of specified sales amounts. In addition, we are eligible to receive up to $24.0 million in biomarker-related milestones.

In May 2012, we earned a patent-related milestone payment of $250,000 upon filing of a patent application by OSI, and we also earned a clinical and development milestone payment of $750,000 for commencement by OSI of GLP toxicology studies.

The next milestone payment that we may receive pursuant to this agreement is a $2.0 million clinical and development milestone for phase 1 clinical trial dosing. The next regulatory milestone payment we may receive pursuant to this agreement is $7.0 million to be achieved for the filing of an NDA with the FDA. We do not expect to achieve either of these milestones in the near future. Upon commercialization of products under the agreement, we are eligible to receive tiered royalty payments on sales of products by OSI, its affiliates and sublicensees.

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Centocor Ortho Biotech

In May 2011, we entered into an exclusive license agreement with Centocor Ortho Biotech Inc., or Centocor, for the worldwide development and commercialization of antibodies, including our internally-discovered antibodies targeting the Recepteur d Origine Nantais, or RON receptor, including the grant to Centocor of an exclusive, worldwide license to our proprietary RON-driven tumor models. In September 2012, we received notice from Centocor of termination of the Centocor License Agreement, effective on December 6, 2012, at which point all rights and the responsibility for future research and development, manufacturing and commercialization activities and costs of the RON antibody program granted to Centocor under the Centocor License Agreement returned to us.

In connection with the Centocor license agreement, we received a one-time cash payment in the amount of $7.5 million and a separate equity investment in the amount of approximately $7.5 million through the purchase by Johnson & Johnson Development Corporation, an affiliate of Centocor, of 438,340 newly issued shares of our common stock at a purchase price of $17.11 per share. Centocor also funded certain research which we conducted during the term of the Centocor License Agreement, which, as noted above, terminated on December 6, 2012.

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. 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 and benefits;
- 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 materials produced in support of regulatory filings for tivozanib;
- 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;

stock-based compensation expense; 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 agreement with Astellas for Astellas share of development costs incurred by us under our joint development plan with Astellas.

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 advance our pipeline programs.

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We track external development expenses and personnel expenses 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. Below is a summary of our research and development expenses for the three and nine months ended September 30, 2013 and 2012:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(in thousands)		(in thousands)	
Tivozanib	$ 4,092	$ 7,580	$ 21,204	$ 26,759
AV-203	927	1,753	4,905	7,008
Ficlatuzumab	8,179	3,163	11,326	11,387
Cachexia program (AV-380)	1,297	1,086	2,974	2,061
Platform collaborations		425		1,239
Other research and development	177	1,497	1,601	4,681
Overhead	4,742	5,595	14,569	14,190
Total research and development expenses	$ 19,414	$ 21,099	$ 56,579	$ 67,325

Tivozanib

We and our partner Astellas are evaluating tivozanib in the BATON phase 2 clinical trials of tivozanib in colorectal and breast cancer. The BATON program is a series of clinical trials assessing biomarkers in solid tumors that may be predictive of clinical response to tivozanib. Patient enrollment was completed earlier this year for BATON-CRC, a phase 2 clinical trial being conducted by Astellas evaluating tivozanib in combination with mFOLFOX6 compared to Avastin in combination with mFOLFOX6 as first-line therapy in patients with advanced CRC. Results are expected in 2014. BATON-BC is a phase 2 clinical trial evaluating the efficacy and safety of tivozanib in combination with paclitaxel compared to placebo in combination with paclitaxel in patients with locally recurrent or metastatic triple negative breast cancer. Patient enrollment in this clinical trial has been slower than anticipated, and we expect to reassess enrollment rates and the impact on our plans in this indication in the coming months. Future research and development costs for the tivozanib program are uncertain because such costs are dependent on a number of variables, including the cost and design of any additional clinical trials including additional trials in combination with other drugs and the timing of the regulatory process.

We entered into a collaboration and license agreement with Astellas in February 2011, pursuant to which we and Astellas share responsibility for tivozanib, including expenses for continued development and any future commercialization of tivozanib, in North America and Europe. Astellas is responsible for continued development and any future commercialization of tivozanib outside of North America, Europe and Asia. All costs associated with each party s conduct of development and commercialization activities in North America and Europe, and any resulting profits or losses, are shared equally between the parties pursuant to a joint development plan. We have included $2.3 million and $7.5 million in research and development cost reimbursements as a reduction in tivozanib-related expenses for the three months ended September 30, 2013 and 2012, respectively, and $14.9 million and $22.9 million in research and development cost reimbursements as a reduction in tivozanib-related expenses for the nine months ended September 30, 2013 and 2012, respectively. Upon entering into our license agreement with KHK, we made a cash payment in the amount of $5.0 million to KHK. In the first quarter of 2010, we paid KHK a $10.0 million milestone payment in connection with the initiation of our phase 3 clinical trial of tivozanib for the treatment of patients with advanced RCC. In the first quarter of 2011, we paid KHK $22.5 million related to the up-front license payment received under the collaboration and license agreement with Astellas. In December 2012, we made a $12.0 million milestone payment to KHK in connection with the acceptance of our NDA filing for tivozanib for the treatment of patients with advanced RCC.

In June 2013, we received a Complete Response letter from the FDA informing us that the FDA would not approve the NDA for tivozanib for the treatment of patients with advanced RCC. In view of the FDA s decision, and our subsequent decision not to pursue tivozanib development in RCC, we announced a strategic restructuring to refocus our efforts on the on-going clinical development of tivozanib in colorectal and breast cancer and on the advancement of key pipeline and preclinical assets.

AV-203

AV-203, which was derived from our Human Response Platform, is our clinical-stage ERBB3 (HER3) inhibitory antibody candidate. ERBB3 is believed to be an important receptor regulating cancer cell growth and survival, and high ERBB3 levels have been shown to correlate with poor prognoses in several tumor types. We have 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.

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AV-203 has demonstrated tolerability in the dose-escalation portion of a phase 1 clinical trial examining the safety, tolerability and preliminary anti-tumor activity of AV-203 in patients with metastatic or advanced solid tumors, and the recommended dose for further evaluation has been established. AV-203 is now being evaluated in an expansion cohort in a biomarker-defined patient population. 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.

Ficlatuzumab

Ficlatuzumab, which was also derived from our Human Response Platform, binds to hepatocyte growth factor, or HGF, thereby blocking its function. 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. In March 2007, we entered into a license agreement related to ficlatuzumab with Merck (formerly Schering-Plough) pursuant to which Merck was responsible for all expenses relating to development of ficlatuzumab in accordance with an agreed-upon budget. The agreement terminated on December 27, 2010. As of the December 27, 2010 termination date, we became responsible for the performance and funding of all future research, development, manufacturing and commercialization activities for ficlatuzumab.

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. We have retained all rights to the development and commercialization of ficlatuzumab. 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.

We have completed two phase 1 clinical studies and a phase 2 clinical study evaluating ficlatuzumab. In September 2012, we announced detailed data from our phase 2 clinical trial comparing the combination of ficlatuzumab and Iressa® (gefitinib) to Iressa monotherapy in previously untreated Asian subjects with non-small cell lung cancer. In the intent-to-treat population, the addition of ficlatuzumab to Iressa did not result in a statistically significant improved overall response rate. We intend, in the coming months, to explore strategic options for ficlatuzumab.

Cachexia Program (AV-380)

In 2012, we initiated a program (AV-380) focusing on cachexia, a serious and common complication of advanced cancer and a number of chronic diseases which is characterized by symptoms of unintentional weight loss, progressive muscle wasting, and a loss of appetite. In connection with this program, we have in-licensed certain patents and patent applications from St. Vincent s Hospital in Sydney, Australia, and we recently nominated an AV-380 development candidate and initiated cell line development. Due to the early stage of this program and the unpredictable nature of preclinical and clinical development, we are unable to estimate with any certainty the future research and development costs for our cachexia program.

Platform Collaborations

In September 2012, we received notice from Centocor of the termination, effective December 6, 2012, of its license agreement with us, at which point all rights to and the responsibility for future research and development of the RON antibody program returned to us. Centocor funded certain translational research studies using our proprietary Human Response Platform related to the RON program. The related expenses were captured as a cost of the agreement with Centocor.

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.

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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 progress and results of our clinical trials;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for any product candidate;
- 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.

We anticipate that our general and administrative expenses will decrease due to the elimination of activities supporting the planned commercialization of tivozanib for RCC and the continued reduction of infrastructure that supported those efforts. This decrease may be partially offset by an increase in legal costs associated with the ongoing shareholder litigation and SEC investigation described 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 primarily of interest, amortization of debt discount, and amortization of deferred financing costs associated with our loans payable.

Income Taxes

We calculate our provision for income taxes on ordinary income based on our projected annual tax rate for the year. As of September 30, 2013, we are projecting an ordinary loss for the year ended December 31, 2013, 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.

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Our significant accounting policies are described in the notes to our condensed consolidated financial statements appearing elsewhere in this report. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2013. 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, 2012 for a further discussion of our critical accounting policies and significant judgments and estimates.

Results of Operations

Comparison of Three Months Ended September 30, 2013 and 2012

The following table summarizes the results of our operations for each of the three months ended September 30, 2013 and 2012, together with the changes in those items in dollars and as a percentage:

	Three Months Ended September 30,		Increase/ (decrease)	%
	2013	2012		
	(in thousands)			
Revenue	$ 323	$ 1,018	$ (695)	(68)%
Operating expenses:				
Research and development	19,414	21,099	(1,685)	(8)%
General and administrative	4,440	9,300	(4,860)	(52)%
Restructuring and impairment	77		77	100%
Total operating expenses	23,931	30,399	(6,468)	(21)%
Loss from operations	(23,608)	(29,381)	5,773	(20)%
Other income, net	32	46	(14)	(30)%
Interest expense	(756)	(888)	132	(15)%
Interest income	26	101	(75)	(74)%
Net loss	$ (24,306)	$ (30,122)	$ 5,816	19%

The following table sets forth revenue for the three months ended September 30, 2013 and 2012:

Revenue	Three Months Ended September 30,		Increase/ (decrease)	%
	2013	2012		
	(in thousands)			
Strategic Partner:				
Biogen Idec	$ 216	$ 216		
Astellas	107	107		
Centocor		695	$ (695)	(100)%
	$ 323	$ 1,018	$ (695)	(68)%

Revenue. Revenue for the three months ended September 30, 2013 was $0.3 million compared to $1.0 million for the three months ended September 30, 2012, a decrease of $0.7 million or 68%. The decrease is due to revenue recognized during the third quarter of 2012 related to research funding under our collaboration agreement with Centocor that did not recur during the third quarter of 2013 due to the termination of the collaboration agreement in December 2012. Revenue for the three months ended September 30, 2013 consisted of the amortization of previously deferred revenue associated with our collaboration agreements with Biogen Idec and Astellas.

Research and development. Research and development, or R&D, expenses for the three months ended September 30, 2013 were $19.4 million compared to $21.1 million for the three months ended September 30, 2012, a decrease of approximately $1.7 million or 8%. The decrease is

primarily attributable to a decrease of $6.8 million in salaries, benefits, contract labor and employee travel following the reduction in personnel as part of our strategic restructurings announced in October 2012 and June 2013; a decrease of $1.2 million in external research and licensing fees; a decrease in clinical trial costs of $1.8 million due to a decrease in the number of active patients enrolled in ficlatuzumab and tivozanib studies; and a decrease of $3.2 million of regulatory and consulting fees supporting the development of tivozanib. These decreases are partially offset by a $5.2 million decrease in reimbursements to us from Astellas for shared tivozanib development costs, which we record as a reduction in R&D expense; and an increase in development costs of $6.5 million relating to the manufacture of ficlatuzumab that began in 2012 and was completed in the third quarter of 2013.

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General and administrative. General and administrative, or G&A, expenses for the three months ended September 30, 2013 were $4.4 million compared to $9.3 million for the three months ended September 30, 2012, a decrease of $4.9 million or 52%. The decrease is primarily the result of a $2.1 million decrease in pre-commercialization costs associated with tivozanib and a $2.8 million decrease in salaries, benefits and other employee costs due to an overall decrease in personnel related to our strategic restructuring announced in June 2013.

Restructuring. Restructuring expense for the three months ended September 30, 2013 was $77,000, with no corresponding expense for the three months ending September 30, 2012. The restructuring charges related to our strategic restructuring announced in June 2013, which has been substantially completed.

Other income, net. Other income, net for the three months ended September 30, 2013 was $32,000 compared to $46,000 for the three months ended September 30, 2012, a decrease of $14,000 or 30%. Other income for the three months ended September 30, 2013 and September 30, 2012 was due to gains on foreign currency transactions.

Interest expense. Interest expense for the three months ended September 30, 2013 was $0.8 million compared to $0.9 million for the three months ended September 30, 2012, a decrease of $0.1 million or 15%. Interest expense is related to our loan with Hercules.

Interest income. Interest income for the three months ended September 30, 2013 was $26,000 compared to $101,000 for the three months ended September 30, 2012, a decrease of $75,000 or 74%. The decrease in interest income is primarily due to a lower average cash and investments balance during the three months ended September 30, 2013 compared to the three months ended September 30, 2012.

Comparison of Nine Months Ended September 30, 2013 and 2012

The following table summarizes the results of our operations for each of the nine months ended September 30, 2013 and 2012, together with the changes in those items in dollars and as a percentage:

	Nine Months Ended September 30,		Increase/ (decrease)	%
	2013	2012		
	(in thousands)			
Revenue	$ 970	$ 3,755	$ (2,785)	(74)%
Operating expenses:				
Research and development	56,579	67,325	(10,746)	(16)%
General and administrative	24,213	27,469	(3,256)	(12)%
Restructuring and impairment	8,013		8,013	100%
Total operating expenses	88,805	94,794	(5,989)	(6)%
Loss from operations	(87,835)	(91,039)	3,204	(4)%
Other (expense) income, net	(120)	279	(399)	(143)%
Interest expense	(2,451)	(2,613)	162	(6)%
Interest income	102	459	(357)	(78)%
Net loss	$ (90,304)	$ (92,914)	$ 2,610	(3)%

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The following table sets forth revenue for the nine months ended September 30, 2013 and 2012:

Revenue	Nine Months Ended September 30, 2013	2012	Increase/ (decrease)	%
		(in thousands)		
Strategic Partner:				
Biogen Idec	$ 648	$ 648		
Astellas	322	322		
Centocor		1,765	$ (1,765)	(100)%
OSI		1,000	(1,000)	(100)%
Other		20	(20)	(100)%
	$ 970	$ 3,755	$ (2,785)	(74)%

Revenue. Revenue for the nine months ended September 30, 2013 was $1.0 million compared to $3.8 million for the nine months ended September 30, 2012, a decrease of $2.8 million or 74%. The decrease was primarily due to revenue recognized during the first nine months of 2012 that did not recur during the comparable period of 2013, including revenue related to milestones achieved under our collaboration agreement with OSI, as well as research funding under our collaboration agreement with Centocor. Revenue for the nine months ended September 30, 2013 consisted of the amortization of previously deferred revenue associated with our collaboration agreements with Biogen Idec and Astellas.

Research and development. R&D expenses for the nine months ended September 30, 2013 were $56.6 million compared to $67.3 million for the nine months ended September 30, 2012, a decrease of approximately $10.7 million or 16%. The decrease is primarily attributable to a decrease of $10.9 million in salaries, benefits and contract labor following the reduction in personnel as part of our strategic restructurings announced in October 2012 and June 2013; a decrease in clinical trial costs of $2.1 million associated with ficlatuzumab as a result of a decrease in the number of active patients; a decrease in external research and laboratory supply expenses of $1.8 million associated with ficlatuzumab and our pipeline programs primarily due to an overall decrease in R&D activity following our strategic restructuring announced in October 2012; a decrease in manufacturing costs of $0.6 million primarily related to AV-203; a decrease of $0.6 million in tivozanib development costs; and a decrease in licensing costs of $0.8 million primarily related to AV-203 and other pipeline programs. These decreases are partially offset by a $1.7 million increase in facility costs that were allocated to R&D expenses, primarily due to rent expense associated with our headquarters at 650 East Kendall Street in Cambridge, Massachusetts; and an increase in development costs of $4.2 million relating to the manufacture of ficlatuzumab that began in 2012 and was completed in the third quarter of 2013.

General and administrative. G&A expenses for the nine months ended September 30, 2013 were $24.2 million compared to $27.5 million for the nine months ended September 30, 2012, a decrease of $3.3 million or 12%. The decrease is primarily the result of a decrease of $2.3 million in employee compensation and benefits following our strategic restructuring announced in June 2013; a decrease in stock-based compensation of $1.4 million due to the reversal of stock-based compensation expense for certain awards that are no longer probable of vesting; and a decrease of $0.5 million in expenses for tivozanib pre-commercialization activities. These amounts were partially offset by an increase of $1.0 million in facilities costs associated with our headquarters at 650 East Kendall Street.

Restructuring. Restructuring expense for the nine months ended September 30, 2013 was $8.0 million, with no corresponding expense for the nine months ending September 30, 2012. The restructuring charges related to our strategic restructuring announced in June 2013, which has been substantially completed.

Other (expense) income, net. Other (expense) income, net for the nine months ended September 30, 2013 was $(120,000) compared to $279,000 for the nine months ended September 30, 2012, a decrease of $399,000 or 143%. Other expense for the nine months ended September 30, 2013 is primarily due to losses on foreign exchange rates and fixed asset disposals, while the income for the nine months ended September 30, 2012 is primarily due to proceeds from the sale of excess drug supplies.

Interest expense. Interest expense for the nine months ended September 30, 2013 was $2.5 million compared to $2.6 million for the nine months ended September 30, 2012, a decrease of $0.1 million or 6%. Interest expense is related to our loan with Hercules.

Interest income. Interest income for the nine months ended September 30, 2013 was $102,000 compared to $459,000 for the nine months ended September 30, 2012, a decrease of $357,000 or 78%. The decrease in interest income is primarily due to a lower average cash and investments balance during the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012.

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Liquidity and Capital Resources

We have funded our operations principally through the sale of equity securities in public offerings and private placements, revenue and expense reimbursements from strategic partnerships, debt financings and interest income. As of September 30, 2013, 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 our subsequent public offerings 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 September 30, 2013, we had received an aggregate of $382.5 million in cash from our agreements with OSI, Biogen Idec, Astellas, Centocor and Eli Lilly and our three agreements with Merck, and $26.5 million in funding from our debt financing with Hercules. As of September 30, 2013, we had cash, cash equivalents and marketable securities of approximately $130.4 million. Currently, our funds are invested in money market funds, U.S. government agency securities, asset-backed securities, and corporate debt, including commercial paper. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Nine Months Ended September 30,	
	2013	2012
	(in thousands)	
Net cash used in operating activities	$ (75,747)	$ (82,358)
Net cash provided by investing activities	645	150,182
Net cash provided by financing activities	49,362	2,797
Net (decrease) increase in cash and cash equivalents	$ (25,740)	$ 70,621

For the nine months ended September 30, 2013 and 2012, our operating activities used cash of $75.7 million and $82.4 million, respectively. The cash used in operations for the nine months ended September 30, 2013 was primarily due to our net loss adjusted for non-cash items, partially offset by a decrease in the accounts receivable balance of $11.8 million due to the receipt of payments from Astellas during the nine months ended September 30, 2013. The cash used by operations for the nine months ended September 30, 2012 was due primarily to our net loss adjusted for non-cash items.

For the nine months ended September 30, 2013 and 2012, our investing activities provided cash of $0.6 million and $150.2 million, respectively. The cash provided by investing activities for the nine months ended September 30, 2013 and 2012 was primarily the net result of purchases, maturities and sales of marketable securities, in addition to purchases of property and equipment of $3.0 million and $4.2 million, respectively.

For the nine months ended September 30, 2013 and 2012, our financing activities provided $49.4 million and $2.8 million, respectively. The cash provided by financing activities for the nine months ended September 30, 2013 was due to the sale and issuance of 7,667,050 shares of common stock at a price of $7.50 per share in our public offering in January 2013 with net proceeds of $53.6 million, as well as proceeds from stock option exercises of $0.4 million, partially offset by principal payments on our loans payable of $4.7 million. The cash provided by financing activities for the nine months ended September 30, 2012 was due to net proceeds of $3.7 million due to an increase in the principal amount of our loan with Hercules, as well as proceeds from stock option exercises of $1.3 million, offset partially by principal payments on loans payable in the amount of $2.2 million.

Credit Facilities. On May 28, 2010, we entered into a loan and security agreement, which we refer to as the loan agreement, with Hercules 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 beginning on April 1, 2013. We began repaying principal related to the loan agreement on April 1, 2013. The loan agreement includes an obligation to pay a deferred charge of $1.2 million due on June 1, 2014. We recorded a long-term liability for the full amount of the charge since the payment of such amount is not contingent upon any future event. 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%. 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 September 30, 2013, the principal balance outstanding was $21.8 million. While we do 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 recent adverse developments relating to the development and commercialization of tivozanib for RCC, including the FDA informing us that it would not approve the NDA for tivozanib for the treatment of patients with advanced RCC and the related shareholder litigation described below under Part II, Item 1 Legal Proceedings, constitute 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.

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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 through at least the second 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;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- 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;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- 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 purported class action lawsuits described below under Part II, Item 1 Legal Proceedings;
- our ability to maintain our collaboration with Astellas;

our ability to secure alternative leasing or subleasing arrangements for our underutilized office and laboratory space at 650 East Kendall Street in Cambridge, Massachusetts, and to achieve related cost savings with respect to our current lease obligation; and

the timing, receipt and amount of sales of, or royalties on, our future products, if any.

In connection with the June 2013 restructuring, 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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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, 2012 filed with the SEC on March 11, 2013.

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 SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We invest in short-term marketable securities for investment purposes. We are exposed to market risk related to changes in interest rates. As of September 30, 2013, we had cash and cash equivalents and marketable securities of $130.4 million, consisting of cash on deposit with banks, money market funds, U.S. government agency securities, asset-backed securities, and corporate debt, including commercial paper. As of December 31, 2012, we had cash and cash equivalents and marketable securities of $160.6 million, consisting of cash on deposit with banks, money market funds, municipal bonds, 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 will 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 invest in any auction rate securities.

We contract with contract research organizations and investigational sites globally. We may be subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk.

Our long-term debt bears interest at variable rates. At September 30, 2013, the aggregate principal amount of our outstanding loan with Hercules was $21.8 million. Per annum interest is payable on the principal balance of the loan 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 loan agreement, we have limited exposure to changes in interest rates on borrowings under this loan. For every 1% increase in prime over 4.75% on the outstanding debt amount as of September 30, 2013, we would have a decrease in future cash flows of approximately $173,000 over the next twelve-month period.

Item 4. Controls and Procedures.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of September 30, 2013, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes 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 applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2013 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 officers 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. Each complaint purports to be brought on behalf of shareholders who purchased our common stock between January 3, 2012 and May 1, 2013. Each complaint generally alleges that we and certain of our officers 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. Each complaint seeks unspecified damages, interest, attorneys fees, and other costs. We deny any allegations of wrongdoing and intend to vigorously defend against these lawsuits. 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 these actions. 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 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. These risk factors restate and supersede the risk factors set forth under the heading Risk Factors in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013.

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. Clinical trials of tivozanib and our other product candidates may not be successful, or may not result in approval by the U.S. Food and Drug Administration. 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.

We have invested a significant portion of our efforts and financial resources in the development of tivozanib and our other clinical and pipeline candidates for the treatment of various types of cancer. All of our therapeutic product candidates are still in preclinical and clinical development. Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of tivozanib and our other 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.

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. For example, although our pivotal phase 3 trial of tivozanib for the treatment of patients with advanced RCC met its primary endpoint of progression-free survival, the U.S. Food and Drug Administration, or FDA, made an adverse determination with respect to our New Drug Application, or NDA.

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

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- 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;
- 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 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, such as Astellas with respect to tivozanib;
- our ability to maintain collaborations with our strategic partners; 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.

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

We cannot predict whether we will encounter problems with any of our ongoing or 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;
- 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 of tivozanib in the coming months due to various factors, including the FDA s Complete Response Letter, pursuant to which the FDA informed us that it would not approve our New Drug Application for tivozanib for the treatment of patients with advanced RCC. For example, patient enrollment in our BATON-BC trial has been slower than anticipated, and we expect to reassess enrollment rates and the impact on our plans in the triple negative breast cancer indication in the coming months. In addition, patients may withdraw from a clinical trial for a variety of reasons. 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.

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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.

Although a substantial amount of our efforts will focus on the continued development of our preclinical and clinical product candidates, 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;
- 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.

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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 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 will need to address a number of scientific, technical, regulatory and logistical challenges. We have limited experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our therapeutic product candidates that receive marketing approval. The FDA and similar regulatory authorities outside the United States are generally expected to regulate companion diagnostics as medical devices. In each case, companion diagnostics require separate regulatory approval prior to commercialization. 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 Financial Position and Capital Requirements

We and certain of our executive officers have been named as defendants in two lawsuits that could result in substantial costs and divert management s attention.

We, and certain of our executive officers, have been named as defendants in two purported class action lawsuits initiated earlier this year that generally allege that we and certain of our officers 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.

We intend to engage in a vigorous defense of the 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. In addition, any of these matters could require payments that are not covered by, or exceed the limits of, our available directors and officers liability insurance, which could have a material adverse effect on our operating results or financial condition.

Additional similar lawsuits might be filed.

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 product development or commercialization efforts.

Since our inception, most of our resources have been dedicated to the discovery, preclinical and clinical development of our product candidates. In particular, we are currently conducting multiple clinical trials of our product candidates, each of which will require substantial funds to complete. 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

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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. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts of capital necessary to successfully complete the development and commercialization of our product candidates.

We believe that our existing cash, cash equivalents, and marketable securities will allow us to fund our operating plan through at least the second 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;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- 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;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- 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 purported class action lawsuits described above under Part II, Item 1 Legal Proceedings;
- our ability to maintain our collaboration with Astellas;

our ability to secure alternative leasing or subleasing arrangements for our underutilized office and laboratory space at 650 East Kendall Street in Cambridge, Massachusetts, and to achieve related cost savings with respect to our current lease obligation; 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 FDA s decision not to approve our NDA for tivozanib for the treatment of advanced RCC constitutes a material adverse change under our loan and security agreement with Hercules, under which we had $21.8 million in loans outstanding as of September 30, 2013, which could trigger a repayment of all principal and interest due under the loan, unless such event of default is waived by Hercules.

Furthermore, in June 2013, due to the adverse FDA determination relating to our NDA for tivozanib for the treatment of patients with advanced RCC, we implemented a restructuring plan that included a reduction in our workforce. We may not be able to successfully implement the restructuring and we may not realize the planned cost savings benefits of any such restructuring, which could adversely affect our estimate of the period in which we have capital to fund our operating plan.

In connection with the June 2013 restructuring, 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:

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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.

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 $90.3 million during the nine months ended September 30, 2013. As of September 30, 2013, we had an accumulated deficit of $410.6 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 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. If any of our strategic partners, including Astellas which has significant development and commercialization responsibilities with respect to tivozanib, 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 the 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 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 a discussion of additional risks that we face with respect to our strategic partnership agreements, see Risks Related to Our Dependence on Third Parties If any of our current 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 below.

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:

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- 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 tivozanib, AV-203, and ficlatuzumab;
- 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, including our agreement with Astellas, and non-recurring revenue or expenses under any such agreement;
- costs associated with lawsuits against us, including the current purported class action lawsuits described above under Part II, Item 1 Legal Proceedings;
- changes in our loan agreement with Hercules, including the existence of any event of default that may accelerate payments due thereunder; and
- compliance with regulatory requirements.

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

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

As widely reported, global credit and financial markets have been experiencing extreme volatility, and in some cases, disruptions, over the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. 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 deteriorate further, or do not 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 difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At September 30, 2013, we had $130.4 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, 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 further 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. Further 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, due in part to the volatility of the stock market and general economic conditions.

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 tivozanib. 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:

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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.

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.

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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. In addition, as a result of our October 2012 and June 2013 corporate restructurings and workforce reductions, we may face additional 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.

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;

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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.

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 have granted Astellas the rights to commercialize tivozanib in Europe and other areas of the world outside of Asia and, where appropriate, 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;

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the availability of adequate reimbursement and pricing by third parties and government authorities;

the continued projected growth of oncology drug markets;

relative convenience and ease of administration;

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

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

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

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

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

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

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

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.

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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.

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

If any of our current 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.

We currently have strategic partnerships in place relating to certain of our product candidates and technologies as follows:

- We have entered into a strategic partnership with Astellas in connection with which we and Astellas have agreed to develop and commercialize tivozanib in North America and Europe and we have exclusively licensed to Astellas rights to develop and commercialize tivozanib in the rest of the world other than Asia.

- We have entered into an exclusive option and license agreement with Biogen Idec regarding the development and commercialization of our ERBB3-targeted antibodies, including AV-203, for the potential treatment and diagnosis of cancer and other diseases outside of the United States, Canada and Mexico.

We have entered into a strategic partnership with OSI, under which we licensed rights to OSI to research, develop, manufacture and commercialize products related to targets involved in the processes of epithelial-mesenchymal transition or mesenchymal-epithelial transition in cancer.

These strategic partnerships may not be scientifically or commercially successful due to a number of important factors, including the following:

Each of our strategic partners has significant discretion in determining the efforts and resources that it will apply to its strategic partnership with us. The timing and amount of any cash payments, related royalties and milestones that we may receive under such strategic partnerships will depend on, among other things, the efforts, allocation of resources and successful development and commercialization of our product candidates by our strategic partners under their respective agreements. If we cannot agree with any of our strategic partners with respect to specific development or commercialization initiatives, development of our product candidates may be delayed or unsuccessful. For instance, under our collaboration with Astellas, we and Astellas must agree on all development and commercialization plans and strategies for North America and Europe before initiating such activities.

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Our strategic partners may change the focus of their development and commercialization efforts or pursue higher-priority programs. For example, in light of the FDA s decision not to approve our NDA for tivozanib for the treatment of patients with advanced RCC, Astellas informed us that it does not intend to fund any future trial(s) in RCC under its strategic collaboration with us and we face the further risk that Astellas may invoke its right under the agreement to terminate its collaboration with us in favor of other programs that it perceives to be more promising.

Our strategic partners may, under specified circumstances, terminate their strategic partnership with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new strategic partners or adversely affect how we are perceived in the scientific and financial communities. For example, Astellas can terminate its agreement with us with six months notice and can terminate the entire agreement with us in connection with a material breach of the agreement by us that remains uncured for a specified cure period. OSI can terminate its agreement with us, with respect to any or all collaboration targets and all associated products, upon written notice to us and can terminate the entire agreement with us in connection with a material breach of the agreement by us that remains uncured for a specified cure period. Biogen Idec may not elect to exercise its option to develop and commercialize products relating to our ERBB3 program and, after exercise of its option, may terminate its agreement with us for convenience with respect to any product(s) by providing us with three months prior written notice, or due to a material breach of the agreement by us that is not cured within a short time period or if all of our assets are acquired by, or we merge with, another entity, and the other entity is independently developing or commercializing a product containing an ERBB3 antibody and fails to divest the ERBB3 product within a specified time period.

Our strategic partnership agreements with OSI and Biogen Idec permit our strategic partners wide discretion in deciding which product candidates to advance through the clinical trial process. For example, under our strategic partnership with OSI, it is possible for OSI to reject product candidates at any point in the research, development and clinical trial process, without triggering a termination of the strategic partnership agreement. In the event of any such decision, our business and prospects may be adversely affected due to our inability to progress such candidates ourselves.

OSI or Biogen Idec may develop and commercialize, either alone or with others, products that are similar to or competitive with the product candidates that are the subject of their strategic partnerships with us.

Our strategic partners may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of a substantial amount of its assets, sale of a substantial amount of its stock or change in control, which could divert the attention of a strategic partner s management and adversely affect a strategic partner s ability to retain and motivate key personnel who are important to the continued development of the programs under the applicable strategic partnership with us. In addition, the third party in such a transaction with our strategic partner could determine to reprioritize the strategic partner s development programs such that the strategic partner ceases to diligently pursue the development of our programs and/or cause the respective strategic partnership with us to terminate.

Certain of our strategic partners may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our strategic partners do not, our ability to do so may be compromised by our strategic partners acts or omissions.

Our strategic partners may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.

Our strategic partners may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.

If Astellas or OSI breaches or terminates its arrangement with us, or if Biogen Idec does not elect to exercise its option to participate in development of an ERBB3 antibody candidate, 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 our own.

Our strategic partners may not have sufficient resources necessary to carry the product candidate through clinical development or may not obtain the necessary regulatory approvals.

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

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

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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, including ficlatuzumab and AV-380, 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.

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. For instance, we rely on third parties to produce materials required for the clinical and commercial production of our product candidates, including tivozanib, AV-203 and ficlatuzumab. 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.

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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, 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, 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.

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.

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

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

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

With regard to tivozanib, we are aware of a third-party United States patent, and corresponding foreign counterparts, that contain broad claims related to use of an organic compound, that, among other things, inhibits the tyrosine phosphorylation of a VEGF receptor caused by VEGF binding to such VEGF receptor. Additionally, tivozanib falls within the scope of certain pending patent applications that have broad generic disclosure and disclosure of certain compounds possessing structural similarities to tivozanib. Although we believe it is unlikely that such applications will lead to issued claims that would cover tivozanib and still be valid in view of the prior art, patent prosecution is inherently unpredictable. 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. We are also aware of a United States patent that contains claims related to a method of treating a tumor by administering an agent that blocks the ability of HGF to promote angiogenesis in the tumor. With regard to AV-203, we are aware of a third-party United States patent that contains broad claims relating to anti-ERBB3 antibodies. 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

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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.

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.

Tivozanib and certain of our other assets 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 Kyowa Hakko Kirin 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 and directed complementation technology. However, patent protection on other aspects of our technology platform, such as our reconstituted human breast tumor model, is still pending. There is no guarantee that any of such 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.

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

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

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

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

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with 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.

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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, such as the substantial decline in our stock price that occurred when we announced that the FDA s Oncologic Drugs Advisory Committee, or ODAC, voted 13 to 1 that our NDA for tivozanib for the treatment of patients with advanced RCC did not demonstrate a favorable benefit/risk evaluation in an adequate and well-controlled trial;
- 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 two purported class action lawsuits following our announcement of the ODAC vote. See Part II, Item 1 Legal Proceedings and We and certain of our executive officers have been named as defendants in two 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 executive officers, directors, entities affiliated with such executive officers and directors, and certain other significant stockholders own a significant percentage of our stock and may be able to exercise significant influence over matters subject to stockholder approval.

To our knowledge, as of September 30, 2013, our executive officers, directors, entities affiliated with such executive officers and directors, and certain other significant stockholders, owned approximately 18% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after September 30, 2013. These stockholders, acting together or individually, may be able to exert influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in control of our company or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the market price of our common stock.

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

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Our management has broad discretion on where and how to use our cash and you will be relying on the judgment of our management regarding the application of our available cash to fund our operations. Our management might not apply our cash 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.

Future sales of shares of our common stock, including shares issued upon the exercise of currently outstanding options and warrants, 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 and warrants. The exercise of these options and warrants and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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

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

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

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

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

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

Proxy contests have been waged against 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.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls, and requires our independent registered public accounting firm to attest to the effectiveness of our internal controls. Despite our efforts, we can provide no assurance as to our, or our independent registered public accounting firm s conclusions with respect to the effectiveness of our internal control over financial reporting under Section 404. There is a risk that neither we nor our independent registered public accounting firm will be able to continue to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

Item 6. Exhibits.

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

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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: November 7, 2013

By: /s/ DAVID B. JOHNSTON
David B. Johnston
Chief Financial Officer and principal financial and 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	
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

* Submitted electronically herewith