AVEO PHARMACEUTICALS INC
Form 10-Q
May 13, 2010
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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 March 31, 2010

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.)**

75 Sidney Street, Cambridge, Massachusetts 02139

(Address of principal executive offices) (zip code)

(617) 299-5000

(Registrant s telephone number, including area code)

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

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x	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 March 31, 2010: 29,904,236

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AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2010

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements.

AVEO Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except per share amounts)

(unaudited)

	March 31, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$ 71,647	$ 45,290
Marketable securities	24,485	6,011
Accounts receivable	5,149	487
Prepaid expenses and other current assets	7,532	1,306
Total current assets	108,813	53,094
Property and equipment, net	4,022	4,197
Other assets	396	1,946
Restricted cash	607	607
Total assets	$ 113,838	$ 59,844
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 7,302	$ 7,491
Accrued expenses	5,625	7,389
Loans payable, net of discount	7,633	7,467
Deferred revenue	13,415	11,782
Deferred rent	206	176
Total current liabilities	34,181	34,305
Loans payable, net of current portion and discount	10,275	12,278
Deferred revenue, net of current portion	21,035	23,320
Deferred rent, net of current portion	753	819
Other liabilities	1,253	1,249
Warrants to purchase convertible preferred stock		1,459
Commitments and contingencies		
Convertible preferred stock, $.001 par value: 80,624 and no shares authorized at December 31, 2009 and March 31, 2010, respectively; 75,917 shares issued and outstanding at December 31, 2009 and no shares outstanding at March 31, 2010		156,705
Stockholders equity (deficit):		
Preferred Stock, $.001 par value: 5,000 shares and no shares authorized at March 31, 2010 and December 31, 2009, respectively; no shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively		
	30	2

Common stock, $.001 par value: 100,000 and 25,500 shares authorized at March 31, 2010 and December 31, 2009, respectively; 29,904 and 1,641 shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively		
Additional paid-in capital	238,395	7,432
Accumulated other comprehensive income	19	
Accumulated deficit	(192,103)	(177,725)
Total stockholders equity (deficit)	46,341	(170,291)
Total liabilities and stockholders equity (deficit)	$ 113,838	$ 59,844

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)

	For the Three Months Ended March 31,	
	2010	2009
Collaboration revenue	$ 10,881	$ 3,670
Operating expenses:		
Research and development	22,618	9,729
General and administrative	2,753	2,571
	25,371	12,300
Loss from operations	(14,490)	(8,630)
Other income and expense:		
Other income (expense), net	712	(62)
Interest expense	(607)	(743)
Interest income	7	28
Other income (expense), net	112	(777)
Net loss	$ (14,378)	$ (9,407)
Net loss per share basic and diluted	$ (2.27)	$ (5.92)
Weighted-average number of common shares used in net loss per share basic and diluted	6,340	1,590

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)

	For the Three Months Ended March 31,	
	2010	**2009**
Operating activities		
Net loss	$ (14,378)	$ (9,407)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	325	326
Stock-based compensation	816	492
Noncash interest expense	138	203
Noncash deferred rent	(37)	(34)
Loss on disposal of property and equipment	1	
Remeasurement of warrants to purchase convertible preferred stock	(713)	62
Amortization of premium on investments	11	41
Changes in operating assets and liabilities:		
Accounts receivable	(4,662)	1,991
Prepaid expenses and other current assets	(6,228)	(357)
Other noncurrent assets	1,550	(118)
Accounts payable	(189)	(625)
Accrued expenses	(1,764)	(84)
Deferred revenue	(652)	12,796
Other liabilities	4	
Net cash (used in) provided by operating activities	(25,778)	5,286
Investing activities		
Purchases of property and equipment	(150)	(428)
Purchases of marketable securities	(24,465)	(19,960)
Proceeds from maturities and sales of marketable securities	6,000	10,500
Net cash used in investing activities	(18,615)	(9,888)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	72,229	
Proceeds from issuance of convertible preferred stock, net of issuance costs		21,770
Proceeds from exercise of stock options	495	15
Principal payments on loans payable	(1,974)	(421)
Net cash provided by financing activities	70,750	21,364
Net increase in cash and cash equivalents	26,357	16,762
Cash and cash equivalents at beginning of period	45,290	20,814
Cash and cash equivalents at end of period	$ 71,647	$ 37,576

Supplemental cash flow and noncash investing and financing activities

Cash paid for interest	$ 484	$ 543
Cash paid for income taxes		

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

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) Organization

AVEO Pharmaceuticals, Inc. (the Company) is a drug discovery and development company focused on the discovery and development of novel, targeted cancer therapeutics. As used throughout these unaudited, condensed consolidated financial statements, the terms AVEO, we, us, and our refer to the business of AVEO Pharmaceuticals, Inc. and its subsidiaries.

(2) Basis of Presentation

These condensed consolidated financial statements include the accounts of the Company and its majority-owned subsidiary. We have 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 accompanying condensed consolidated financial statements have been included. Interim results for the three months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2010 or any other future period.

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2010, and for the three months ended March 31, 2010 and 2009, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2009 have been derived from our audited financial statements. For further information, refer to the consolidated financial statements and accompanying footnotes included in the final prospectus relating to our initial public offering filed with the Securities and Exchange Commission (SEC) on March 12, 2010.

(3) Significant Accounting Policies

Basic and Diluted Earnings (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. Preferred shares are not included in the calculation of net loss per share until their conversion to common shares. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common stock equivalent shares 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 antidilutive. Accordingly, basic and diluted net loss per common share is the same.

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

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

	For the Three Months Ended March 31, (in thousands)	
	2010	2009
Weighted average options outstanding	3,492	2,936
Weighted average warrants outstanding	182	194
	3,674	3,130

Stock-Based Compensation

The fair value of all awards is recognized in the Company s statements of operations on a straight-line basis over their requisite service periods based on their grant fair values as calculated using the measurement and recognition provisions of Accounting Standards Codification ASC Topic 718, *Stock Compensation*. During the three months ended March 31, 2010 and 2009, respectively, the Company recorded the following stock-based compensation expense as a result of the adoption of ASC Topic 718:

	For the Three Months Ended March 31, (in thousands)	
	2010	2009
Research and development	$ 358	$ 313
General and administrative	458	179
Total stock-based compensation expense	$ 816	$ 492

Allocations to research and development expenses and general and administrative expense are based upon the department to which the associated employee reported. No related tax benefits of the stock-based compensation expense have been recognized. Share-based payments issued to non-employees 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.

Revenue Recognition

The Company s revenue is generated primarily through collaborative research and development and licensing agreements. The terms of these agreements typically include payment to the Company of one or more of the following: nonrefundable, up-front license fees; premiums on the sale of convertible preferred stock; milestone payments; and royalties on product sales. In addition, the Company generates revenue through agreements that generally provide for fees for research and development services rendered. These service agreements also contemplate royalty payments to the Company on future sales of its collaborators products. To date, the Company has earned several milestone payments but has not earned royalty revenue as a result of product sales.

For arrangements that include multiple deliverables, the Company identifies separate units of accounting if certain criteria are met. Accordingly, revenues from licensing and collaboration agreements are recognized based on the performance requirements of the agreement.

Nonrefundable up-front fees, where the Company has ongoing involvement or performance obligations, are recorded as deferred revenue in the balance sheet and amortized on a straight-line basis into collaboration revenue in the statements of operations over the term of the performance obligations.

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

Payments or reimbursements resulting from the Company s research and development efforts are recognized as the services are performed and are presented on a gross basis in accordance with the accounting guidance, *Overall Considerations of Reporting Revenue Gross as a Principal*, 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.

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, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required. Revenues from milestones, if they are nonrefundable and deemed substantive, are recognized upon successful accomplishment of the milestones. 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.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets.

Principles of Consolidation

The Company s consolidated financial statements include the Company s accounts and the accounts of the Company s wholly-owned subsidiary, AVEO Pharma Limited. 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, stock-based compensation, facilities, research-related overhead, clinical trial costs, 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 rather than when the payment is made in accordance with the provisions of ASC 730-20-25-13.

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 March 31, 2010 and December 31, 2009 consist of money market funds and commercial paper.

Marketable Securities

The Company uses Financial Accounting Standards Board (FASB) ASC Topic 820, *Fair Value Measurements and Disclosures* (formerly FASB Statement No. 157, *Fair Value Measurements*), to provide guidance for using fair value to measure assets and liabilities. ASC 820 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value but does not expand the use of fair value in any new circumstances. ASC 820 also requires expanded disclosure of the effect on earnings for items measured using unobservable data, establishes a fair value hierarchy that prioritizes the information used to develop those assumptions and requires separate disclosure by level within the fair value hierarchy.

The Company records marketable securities at fair value. ASC 820 establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and 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 U.S. government securities.

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. agency securities, including direct issuance bonds and corporate bonds.

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 valued with Level 3 inputs.

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

The following tables summarize the financial instruments measured at fair value on a recurring basis in the accompanying consolidated balance sheets as of March 31, 2010 and December 31, 2009.

	Fair Value Measurement as of March 31, 2010			
	Level 1	Level 2	Level 3	Total
Cash equivalents:	$ 52,307	$ 11,847	$	$ 64,154
Marketable securities		24,485		24,485
	$ 52,307	$ 36,332	$	$ 88,639

	Fair Value Measurement as of December 31, 2009			
	Level 1	Level 2	Level 3	Total
Marketable securities	$ 6,011	$	$	$ 6,011

The Company s Level 2 securities in 2010 include commercial paper issuances and are valued using third-party pricing sources. These sources generally use interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing.

Marketable securities in 2009 primarily consist of U.S Treasuries, U.S. government agencies securities and corporate debt 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 original maturities at the date of purchase 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 as a component of stockholders deficit 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 months ended March 31, 2010 and 2009.

Available-for-sale securities at March 31, 2010 and December 31, 2009 consist of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
March 31, 2010:				
Corporate debt securities	$ 24,466	$ 19	$	$ 24,485
December 31, 2009:				
U.S. Treasuries	$ 2,003	$	$	$ 2,003
Government agency securities	4,008			4,008
	$ 6,011	$	$	$ 6,011

All marketable securities at March 31, 2010 and December 31 2009 had maturities of one year or less.

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

Concentrations of Credit Risk

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

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

Fair Value of Financial Instruments

The carrying amounts of the Company s financial instruments, which include cash and cash equivalents, marketable securities, accounts payable, warrants and loans payable, approximate their fair values at March 31, 2010 and December 31, 2009.

Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repair costs are charged to expense as incurred.

Long-lived Assets

The Company periodically assesses the impairment of long-lived assets in accordance with ASC Topic 360, *Property, Plant, and Equipment*. 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 has not recognized any impairment losses through March 31, 2010.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Accumulated other comprehensive loss as of March 31, 2010 and 2009 consists entirely of unrealized gains/losses on available-for-sale securities.

	Three Months Ended March 31,	
	2010	2009
	(in thousands)	
Net Loss	$ (14,378)	$ (9,407)
Unrealized gain (loss) on marketable securities	19	(25)
Comprehensive Loss	$ (14,359)	$ (9,432)

Income Taxes

The Company provides for income taxes using the 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.

On January 1, 2009, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty In Income Taxes* (codified within ASC Topic 740, *Income Taxes)*.

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

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 and the Company operates in only one geographic segment.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

New Accounting Pronouncements

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06, *Improving Disclosures about Fair Value Measurements* (ASU 2010-06). This guidance requires the disclosure of separate amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and the reason for such transfers. ASU 2010-06 also requires information related to purchases, sales, issuances, and settlements of Level 3 financial assets and liabilities to be presented separately in the reconciliation of fair value measurements for the period presented. In addition, ASU 2010-06 clarifies existing disclosure guidance with respect to the level of disaggregation for classes of financial assets and liabilities as well as valuation techniques and inputs used for both recurring and nonrecurring fair value measurements of Level 2 and Level 3 assets and liabilities. We have provided the additional required disclosures effective January 1, 2010.

In February 2010, the FASB issued amended guidance on subsequent events. Under this amended guidance, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and we adopted these new requirements upon issuance of this guidance.

In March 2010, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 08-9, Milestone Method of Revenue Recognition (Issue 08-9). The ASU resulting from Issue 08-9 amends ASC 605-28. This guidance concludes that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The guidance is effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this accounting standard is not expected to impact the Company s financial position or results of operations.

(4) Collaborations and License Agreements

Merck & Co., Inc. (Merck)

In November 2003, the Company entered into a license and research collaboration agreement with Merck & Co., Inc. (Merck) to discover and validate oncology targets. Under the agreement, Merck paid the Company an up-front payment of $7.0 million, which was amortized over the period of substantial involvement of 3.5 years, and made research funding payments of approximately $6.0 million over the course of the three-year research program. In April 2005, the Company and Merck expanded the collaboration, and as part of that expansion, the Company received cash payments for an aggregate of $4.0 million, paid in two equal annual installments in each of May 2005 and April 2006. These payments were initially deferred and were amortized to revenue over the remaining period of the Company s substantial involvement, which was through April 2007. In addition, Merck purchased 1,666,667 shares of Series C Convertible Preferred Stock (Series C Preferred Stock) at a per share price of $3.00, resulting in gross proceeds to the Company of approximately $5.0 million. In connection with the initial public offering recently consummated by the Company and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series C Preferred Stock were converted into one share of common stock. In addition, if all development and regulatory milestones are reached with

respect to six molecular targets, potential additional milestone payments could total, in the aggregate, $249.0 million. The Company is also eligible to receive tiered royalties from Merck based on the sales of products that are directed to or use the collaboration targets selected by Merck.

In August 2005, the Company entered into a second license and research collaboration agreement with Merck which provides for the use of the Company s Human Response Platform. Over the course of the collaborative research program,

AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

which has concluded, the Company received approximately $4.5 million in research funding. In addition, Merck purchased 666,667 shares of Series C Preferred Stock, at a per share price of $3.00, resulting in gross proceeds to the Company of approximately $2.0 million. In connection with the initial public offering recently consummated by the Company and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series C Preferred Stock were converted into one share of common stock. If all development and regulatory milestones under the agreement are achieved, potential milestone payments could total, in the aggregate, $4.9 million.

Merck (Formerly Schering-Plough Corporation)

In March 2007, the Company entered into an agreement with Schering-Plough Corporation, through its subsidiary Schering Corporation, acting through its Schering-Plough Research Institute division, under which it granted Schering-Plough (now Merck) exclusive, worldwide rights to develop and commercialize all of the Company s monoclonal antibody antagonists of hepatocyte growth factor (HGF), including AV-299. The Company also granted Merck an exclusive, worldwide license to related biomarkers for diagnostic use. Under the agreement, the Company received an up-front payment of $7.5 million in May 2007, which is being amortized over the Company s period of substantial involvement, or through completion of the first phase 2 proof-of-concept trial for AV-299, which is expected to be in the first half of 2012. In addition, Schering-Plough purchased 4,000,000 shares of Series D Convertible Preferred Stock (Series D Preferred Stock), at a per share price of $2.50, resulting in gross proceeds to the Company of $10.0 million. In connection with the initial public offering recently consummated by the Company and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series D Preferred Stock were converted into one share of common stock. The amount paid for the Series D Preferred Stock represented fair value as it was the same as the amounts paid by unrelated investors in March and April 2007. Merck funded research of $3.0 million per year for the first three years of the agreement. Merck will reimburse development expenses through completion of the first phase 2 proof-of-concept trial for AV-299, unless extended by mutual written agreement of the parties. Milestone payments for the successful development and commercialization of AV-299, if all approvals in multiple indications and all sales milestones are achieved, could total, in the aggregate, $464.0 million. Upon commercialization, the Company is eligible to receive royalties on Merck s net sales of AV-299.

OSI Pharmaceuticals (OSI)

In September 2007, the Company entered into a collaboration and license agreement with OSI Pharmaceuticals, Inc. (OSI), which provides 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. Under the agreement, OSI paid the Company an up-front payment of $7.5 million, which was recorded in deferred revenue and is being amortized over the Company s period of substantial involvement which is now determined to be through July 2011. OSI also paid the Company $2.5 million for the first year of research program funding, which was recorded in deferred revenue and was recognized as revenue over the performance period and, thereafter, made research payments of $625,000 per quarter through July 2009. In addition, OSI purchased 1,833,334 shares of Series C Preferred Stock, at a per share price of $3.00, resulting in gross proceeds to the Company of $5.5 million. The Company determined that the price paid of $3.00 per share by OSI included a premium of $0.50 over the price per share of the Company s Series D Preferred Stock sold in April 2007; accordingly, the Company will recognize the premium of $917,000 as additional license revenue on a straight-line basis over the period of substantial involvement. In connection with the initial public offering recently consummated by the Company and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series C Preferred Stock were converted into one share of common stock.

In July 2009, the Company and OSI expanded the strategic partnership and 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 a Company 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 consideration for such additional rights, under the amended agreement, OSI paid the Company an up-front payment of $5.0 million, which was recorded in deferred revenue and will be amortized over the Company s remaining period of substantial involvement. OSI also agreed to fund research costs through June 30, 2011. In addition, OSI purchased 3,750,000 shares of Series E Convertible Preferred Stock (Series E Preferred Stock), at a per share price of $4.00, resulting in gross proceeds to the Company of $15.0 million. In connection with the initial public offering

recently consummated by the Company and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series E Preferred Stock were converted

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

into one share of common stock. The Company determined that the price of $4.00 per share paid by OSI included a premium of $1.04 per share over the fair value of the Series E Preferred Stock of $2.96 as calculated by the Company in its retrospective stock valuation. The valuation used the Market Approach to estimate the Company s enterprise value and the Probability Weighted Expected Return Method (PWERM) to allocate the enterprise value to each class of the Company s equity securities; accordingly, the Company will recognize the premium of $3,900,000 as additional license revenue on a straight-line basis over the period of substantial involvement.

Under the amended agreement, if all applicable milestones are achieved, payments for the successful achievement of discovery, development and commercialization milestones could total, in the aggregate, over $94.0 million for each target and its associated products. In addition, the Company is eligible to receive up to $27.0 million in milestones for certain deliverables and research milestones. OSI has the option 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 to certain of its tumor models and tumor archives for an option fee. If OSI elects to exercise this option and the Company transfers the relevant technology to OSI, OSI will be required to pay the Company license expansion fees of $25 million. If OSI does not elect to exercise this option, OSI must pay a lesser amount in order to retain its rights to the bioinformatics platform and any new targets. 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 milestone payments earned to date are for selection of targets, delivery of models or delivery of cell lines. These milestones are not considered to be at risk and substantive, therefore, the milestone payments are being deferred and when earned, will be recognized on a straight line basis over the remaining estimated period of substantial involvement.

Biogen Idec International GmbH (Biogen Idec)

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 of the Company s discovery-stage ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases outside of the United States, Canada and Mexico. Under the terms of the agreement, Biogen Idec paid the Company an upfront cash payment of $5.0 million in March 2009, which will be amortized over the Company s period of substantial involvement, defined as the twenty-year patent life of the development candidate. In addition, Biogen Idec purchased 7,500,000 shares of Series E 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 initial public offering recently consummated by the Company and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series E Preferred Stock were converted on into one share of common stock. The Company determined that the price of $4.00 paid by Biogen Idec included a premium of $1.09 per share over the fair value of the Series E Preferred Stock of $2.91 as calculated by the Company in its retrospective stock valuation. The valuation used the Market Approach to estimate the Company s enterprise value and the PWERM to allocate the enterprise value to each class of the Company s equity securities; accordingly, the Company will recognize the premium of $8,175,000 as revenue on a straight-line basis over the period of substantial involvement. The Company received a $5.0 million milestone payment for achievement of the first pre-clinical discovery milestone under the agreement in June 2009 which was not considered at risk and was therefore deferred and is being recognized over the period of substantial involvement. The Company earned the second $5.0 million milestone payment upon selection of a development candidate in March 2010. This milestone was considered substantive and at risk and has been included in revenue for the quarter ended March 31, 2010. The Company could also receive (i) additional pre-clinical discovery and development milestone payments of $5.0 million in the aggregate, and (ii) if Biogen Idec exercises its option to obtain exclusive rights to commercialize ErbB3 antibody products in its territory, an option exercise fee and regulatory milestone payments of $50.0 million in the aggregate.

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 the United States, Canada and Mexico.

Kirin Brewery Co. Ltd. (Kirin)

In December 2006, the Company entered into an exclusive license agreement with Kirin Brewery Co. Ltd. (now Kyowa Hakko Kirin) to research, develop, manufacture and commercialize tivozanib (f/k/a KRN951), pharmaceutical compositions thereof and associated biomarkers in

all territories in the world except for Asia. Upon entering into the license agreement, the Company made a one-time cash payment in the amount of $5.0 million, which the Company accrued in December 2006 as research and development expense and paid in January 2007. In March 2010, the Company made a $10.0 million milestone

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

payment to Kyowa Hakko Kirin in connection with the initial dosing of patients in the Company s phase 3 clinical trial of tivozanib. In addition, the Company may be required to make up to an aggregate of $50.0 million in additional milestone payments upon the achievement of specified regulatory milestones. The Company is also required to pay tiered royalty payments on net sales it makes of tivozanib in its territory. The royalty rates under the agreement range from the low to mid teens as a percentage of the Company s net sales of tivozanib.

The Company also has the right to grant sublicenses under the license agreement, subject to certain restrictions. In the event the Company sublicenses the rights licensed to it as part of the agreement, the Company is required to pay Kyowa Hakko Kirin a specified percentage of any amounts the Company receives from any third party sublicenses, other than amounts it receives in respect of research and development funding or equity investments, subject to certain limitations.

(5) Prepaid Expenses

Prepaid expenses consisted of the following:

	March 31, 2010	December 31, 2009
Prepaid clinical	$ 5,911	$ 389
Prepaid insurance	634	182
Prepaid in-licensing	604	424
Other prepaid expenses and current assets	383	311
	$ 7,532	$ 1,306

(6) Stock-based Compensation

Stock Plans

A summary of the status of the Company s stock incentive plans at March 31, 2010 and changes during the three 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, 2009	3,275,906	$ 4.56		
Granted	398,182	12.24		
Exercised	(284,370)	1.74		
Cancelled	(41,772)	5.91		
Outstanding at March 31, 2010	3,347,946	$ 5.70	7.19	$ 12,522,397

Vested or expected to vest at March 31, 2010	3,214,906	$	5.51	7.10	$ 12,461,004
Exercisable at March 31, 2010	2,063,180	$	3.71	6.15	$ 10,939,717

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 of the three months ended March 31, 2010 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 March 31, 2010. As of March 31, 2010, there was $5,903,068 of total unrecognized stock-based compensation expense related to stock options granted under the plans. The expense is expected to be recognized over a weighted-average period of 2.3 years.

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

Stock-based payments 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. Since the Company completed its initial public offering in March 2010, it did not have sufficient history as a publicly traded company to evaluate its volatility. As such, the Company has used an average of several peer companies volatilities to determine a reasonable estimate of its volatility. For purposes of identifying similar entities, the Company considered characteristics such as industry, length of trading history, market capitalization and similar product pipelines lines. Due to the lack of available quarterly data for these peer companies and insufficient history as a public company, 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.

During the three months ended March 31, 2010 and 2009, respectively, the assumptions used in the Black-Scholes pricing model for new grants were as follows. The Company issued stock options during the three months ended March 31, 2010.

	Three Months Ended March 31,	
	2010	2009
Volatility factor	63.92%	72.04%
Risk-free interest rate	2.92%	1.98%
Dividend yield		
Expected term (in years)	6.25	6.25

The following resolutions were adopted by the Board of Directors on February 2, 2010 and approved by the Company s stockholders on February 11, 2010:

Approval of an amendment of Certificate of Incorporation which increased authorized Common Stock by 1,875,000 shares related to the increase in shares reserved under the 2002 Stock Plan with a corresponding increase in the number of shares not subject to anti-dilution protection under the Preferred Stock terms.

Adoption of the 2010 Employee Stock Purchase Plan pursuant to which the Company may sell up to an aggregate of 250,000 shares of Common Stock.

Adoption of the 2010 Stock Plan, pursuant to which the Company may grant incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards for the purchase of that number of shares of Common Stock equal to the sum of any shares reserved for issuance under the 2002 Stock Plan that remain available for grant under the 2002 Stock Plan immediately prior to the closing of a public offering and any shares of Common Stock subject to awards under the 2002 Stock Plan which expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right, up to a maximum of 2,500,000 shares.

(7) Income Taxes

The Company accounts for income taxes under the provisions of ASC Topic 740, *Income Taxes*. The Company recorded a tax benefit for the year ended December 31, 2009 in the amount of $100,056 representing a current benefit for federal income taxes related to certain refundable credits. The Company has not recorded a federal or state income tax provision or benefit for the three months ended March 31, 2010 and 2009.

As a result of the initial public offering of the Company s common stock in March of 2010, the Company underwent a change in ownership for purposes of Internal Revenue Code Section 382. As a result, the utilization of federal net operating loss carryforwards and research credit carryforwards as of the date of the initial public offering will be subject to an annual

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AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Continued)

(Unaudited)

limitation of $7.5 million based on the value of the Company immediately before the stock offering. The annual limitation is increased by $10.7 million in the first five years after the change in ownership as a result of the Company s built-in-gains. This limitation is not expected to result in the loss of any of these tax attributes during the carryforward period.

(8) Common Stock

Reverse Stock Split

On February 2, 2010, the Company s Board of Directors and on February 11, 2010, the Company s stockholders approved a 1-for-4 reverse stock split of the Company s common stock. All share and per share amounts in the consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

Initial Public Offering

In March 2010, the Company raised $81.0 million in gross proceeds from the sale of 9,000,000 shares of its common stock in an initial public offering at $9.00 per share. The net offering proceeds after deducting approximately $3.1 million in offering related expenses and underwriters discounts were approximately $72.2 million. All outstanding shares of the Company s convertible preferred stock were converted into 18,979,155 shares of common stock upon the completion of the initial public offering.

In connection with the initial public offering, the Company reclassified its liability related to preferred stock warrants into additional paid-in capital as a result of the conversion of warrants to purchase convertible preferred stock into warrants to purchase common stock.

(9) Subsequent Event

In March 2010, the underwriters of the Company s recently completed initial public offering exercised their option to purchase, and in April 2010, the Company closed the sale to such underwriters of, an additional 968,539 shares of common stock at $9.00 per share resulting in gross proceeds to the Company of approximately $8.7 million.

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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 Item 1 of this Quarterly Report for the three months ended March 31, 2010, as well as the audited financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2009, included in our final prospectus dated March 11, 2010 filed with the SEC. 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, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding our results of operations, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as we expect, anticipate, target, project, believe, goals, estimate, potential, predict, may, will, exp intend, 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. We undertake no obligation to revise or update publicly any forward-looking statement for any reason. Readers should carefully review the factors described under the heading Risk Factors in Item 1A of Part II of this Quarterly Report and in Management s Discussion and Analysis of Financial Condition and Results of Operations , as well as in the documents filed by us with the SEC, as they may be amended from time to time, including our final prospectus dated March 11, 2010.

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel cancer therapeutics. Our product candidates are directed against important mechanisms, or targets, known or believed to be involved in cancer. Tivozanib, our lead product candidate, is a highly potent and selective oral inhibitor of the vascular endothelial growth factor, or VEGF, receptors 1, 2 and 3. Our clinical trials of tivozanib to date have demonstrated a favorable safety and efficacy profile for tivozanib. We have completed a successful 272-patient phase 2 clinical trial of tivozanib in patients with advanced renal cell cancer, or RCC. In this trial, we measured, among other things, each patient s progression-free survival, which refers to the period of time that began when a patient entered the clinical trial and ended when either the patient died or the patient s cancer had grown by a specified percentage or spread to a new location in the body. The overall median progression-free survival of patients in the phase 2 clinical trial was 11.8 months. In a retrospective analysis of the subset of 176 patients in our phase 2 clinical trial who had the clear cell type of RCC and who had undergone prior removal of their affected kidney, referred to as a nephrectomy, both of which are inclusion criteria for our phase 3 clinical trial of tivozanib, the median progression-free survival was 14.8 months. The incidence of side effects in the phase 2 clinical trial, such as diarrhea, fatigue, rash, mucositis, stomatitis and hand-foot syndrome, which are commonly associated with other VEGF receptor inhibitors, was notably low, with moderate to severe episodes of these side effects occurring in fewer than two percent of treated patients. In December 2009, we initiated patient screening for our phase 3 clinical trial of tivozanib in patients with advanced RCC, in which we plan to enroll 500 patients, which we refer to as the TIVO-1 study. We commenced enrollment of patients in the TIVO-1 study in February 2010. The TIVO-1 study is a randomized, controlled clinical trial of tivozanib compared to Nexavar (sorafenib) in advanced clear cell RCC patients who have undergone a prior nephrectomy, and who have not received any prior VEGF-targeted therapy. Nexavar is an oral VEGF receptor inhibitor approved for the treatment of RCC. In its phase 3 clinical trial in patients with advanced clear cell RCC, 94% of whom had undergone a prior nephrectomy, Nexavar demonstrated a median progression-free survival of 5.5 months. Progression-free survival is the primary endpoint in the TIVO-1 study. The TIVO-1 study is designed so that a difference in progression-free survival of three months or more between the treatment arms would be statistically significant.

In addition to the TIVO-1 study, we are currently conducting multiple clinical trials of tivozanib including: a phase 1b clinical trial in combination with Torisel (temsirolimus), an approved inhibitor of the receptor known as mammalian target

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of rapamycin, or mTOR, in patients with advanced RCC; a phase 1b clinical trial in combination with the FOLFOX6 chemotherapy regimen in patients with advanced colorectal cancer and other gastrointestinal cancers; a phase 1b clinical trial in combination with paclitaxel in patients with metastatic breast cancer; and a phase 1b clinical trial as a monotherapy in patients with non-small cell lung cancer. We expect that the results of these clinical trials will help to inform our clinical development plans for tivozanib in additional indications. We acquired exclusive rights to develop and commercialize tivozanib worldwide outside of Asia pursuant to a license agreement we entered into with Kirin Brewery Co. Ltd. (now Kyowa Hakko Kirin) in 2006. Under the license agreement, we obtained an exclusive license 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. Kyowa Hakko Kirin has retained rights to tivozanib in Asia. We have obligations to make milestone, royalty and sublicensing revenue payments to Kyowa Hakko Kirin.

In addition to tivozanib, we have a pipeline of monoclonal antibodies derived from our Human Response Platform , a novel method of building preclinical models of human cancer, which are intended to more accurately represent cancer biology in patients. AV-299, our next most advanced product candidate, is an antibody which binds to hepatocyte growth factor, or HGF, thereby blocking its function. Through the use of our Human Response Platform, our scientists have identified the HGF/c-Met pathway as being a significant driver of tumor growth. We have completed a phase 1 clinical trial of AV-299 and expect to initiate a phase 2 clinical trial for non-small cell lung cancer in the first half of 2010. In 2007, we entered into an agreement with Merck (formally Schering-Plough Corporation) under which we granted Merck exclusive worldwide rights to co-develop and commercialize AV-299 and under which Merck funds all development and manufacturing expenses, subject to an agreed-upon budget. Under that agreement, we retain the option to co-promote AV-299 in the United States for the first large market oncology indication for which Merck files for marketing approval in the United States.

Our Human Response Platform was designed to overcome many of the limitations of traditional approaches to modeling human cancer. The traditional method of modeling human cancer uses a model referred to as a xenograft. A xenograft model is created by adapting cells from a human tumor to grow in a petri dish, and then injecting these cells in a mouse, where they grow into tumors. However, the resulting tumors differ from the original tumor in important respects, and, accordingly, xenograft models are often poor predictors of the success of cancer drugs in human clinical trials. In our Human Response Platform, we use patented genetic engineering techniques to grow populations of spontaneous tumors in animals containing human-relevant, cancer-causing mutations and tumor variation 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. We are utilizing this Human Response Platform alone and with our strategic partners to (i) identify and validate target genes which drive tumor growth, (ii) evaluate drugs which can block the function of these targets and (iii) identify biomarkers, which are indicators of drug response and resistance in patients, in an effort to evaluate which patients are most likely to respond favorably to treatment with such drugs.

In addition, we have identified a number of other promising targets for the development of novel cancer therapeutics using our Human Response Platform. We have preclinical antibody discovery programs underway focusing on targets that appear to be important drivers of tumor growth, including the ErbB3 receptor (partnered with Biogen Idec), the RON receptor, the Notch receptors and the Fibroblast Growth Factor receptors.

We have devoted substantially all of our resources to our drug discovery efforts comprising research and development, conducting clinical trials for our product candidates, protecting our intellectual property and the general and administrative support of these operations. We have generated no revenue from product sales and, through March 31, 2010, have principally funded our operations through:

- $97.1 million of non-dilutive capital in the form of license fees, milestone payments and research and development funding received from our strategic partners; and

- $169.6 million of funding from the sale of convertible preferred stock to all of our investors, including $77.5 million of equity sales to our strategic partners.

We have never been profitable and, as of March 31, 2010, we had an accumulated deficit of $192.1 million. We incurred net losses of approximately $14.4 million and $9.4 million in the three months ended March 31, 2010 and 2009, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we advance our product candidates from discovery through preclinical studies and clinical trials to seek regulatory approval and eventual commercialization. We will need additional financing to support our operating activities.

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Financial Obligations Related to the License and Development of Tivozanib

In December 2006, we entered into a license agreement with Kirin Brewery Co. Ltd. (now Kyowa Hakko Kirin) under which we obtained an exclusive license 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. Kyowa Hakko Kirin has retained rights to tivozanib in Asia. Under the license agreement, we obtained exclusive rights in our territory under certain Kyowa Hakko Kirin 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.

Upon entering into the license agreement with Kyowa Hakko Kirin, we made a one-time cash payment in the amount of $5.0 million. We also made a $10.0 milestone payment to Kyowa Hakko Kirin in March 2010 in connection with the initial dosing of patients in our phase 3 clinical trial of tivozanib. In addition, we may be required to make up to an aggregate of $50.0 million in additional milestone payments upon the achievement of specified regulatory milestones. We are also required to pay tiered royalty payments on net sales we make of tivozanib in our territory. The royalty rates under the agreement range from the low to mid teens as a percentage of our net sales of tivozanib. In the event we sublicense the rights licensed to us under the license agreement, we are required to pay Kyowa Hakko Kirin a specified percentage of any amounts we receive from any third party sublicensees, other than amounts we receive in respect of research and development funding or equity investments, subject to certain limitations.

Strategic Partnerships

OSI Pharmaceuticals

In September 2007, we entered into a collaboration and license agreement with OSI Pharmaceuticals, Inc., or OSI. Our strategic partnership with OSI 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. We are currently working with OSI on the development of proprietary target-driven tumor models for use in target validation, drug screening and biomarker identification to support OSI s drug discovery and development activities. The research program portion of our strategic partnership began in October 2007 and will expire at the end of June 2011 unless the agreement is terminated earlier by either party. Under the terms of our agreement, OSI may, but has no obligation to, elect to obtain exclusive rights, with the right to grant sublicenses, under certain aspects of our intellectual property, to research, develop, make, sell and import drug products and associated diagnostics directed to a specified number of targets identified and/or validated under the agreement. OSI has sole responsibility and is required to use commercially reasonable efforts to develop and commercialize drugs and associated diagnostics directed to the targets to which it has obtained rights. 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. Further, as part of our expanded strategic partnership, we granted OSI an option to receive non-exclusive perpetual rights to certain elements of our Human Response Platform and our bioinformatics platform, including the right to obtain certain of our tumor models and tumor archives. If OSI elects to exercise this additional option and we transfer the relevant technology to OSI, OSI will be required to pay us license expansion fees equal to, in the aggregate, $25.0 million.

In September 2007, OSI paid us an up-front payment of $7.5 million, which was recorded in deferred revenue and is being amortized over our period of substantial involvement which is now determined to be through July 2011. OSI also paid us $2.5 million for the first year of research program funding, which was recorded in deferred revenue and was recognized as revenue over the performance period and, thereafter, made sponsored research payments of $625,000 per quarter through July 2009. In addition, OSI purchased 1,833,334 shares of our series C convertible preferred stock, at a per share price of $3.00, resulting in gross proceeds to us of $5.5 million. We determined that the price paid of $3.00 per share by OSI represents a premium of $0.50 over the price per share for shares of our series D convertible preferred stock sold in April 2007; accordingly, we will recognize the premium of $917,000 as additional license revenue on a straight-line basis over the period of substantial involvement. In connection with the initial public offering we recently consummated and the related 1:4 reverse stock split of our common stock, each four shares of outstanding series C convertible preferred stock were converted into one share of common stock.

In July 2009 under the amended agreement, OSI paid us an up-front payment of $5.0 million, which was recorded in deferred revenue and will be amortized over our remaining period of substantial involvement. OSI also agreed to fund research costs through June 30, 2011. In addition, OSI purchased 3,750,000 shares of our series E convertible preferred stock

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at a per share price of $4.00, resulting in gross proceeds to us of $15.0 million. We determined that the price of $4.00 per share paid by OSI represents a premium of $1.04 per share over the fair value of the series E convertible preferred stock of $2.96 as calculated by us in our retrospective stock valuation; accordingly, we will recognize the premium of $3.9 million as additional license revenue on a straight-line basis over the period of substantial involvement. In connection with the initial public offering we recently consummated 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.

Under the amended agreement, if all applicable milestones are achieved, payments for the successful achievement of discovery, development and commercialization milestones under the agreement could total, in the aggregate, over $94.0 million for each target and its associated products.

Biogen Idec

In March 2009, we entered into an exclusive option and license agreement with Biogen Idec International GmbH, a subsidiary of Biogen Idec Inc., which we collectively refer to herein as Biogen Idec, regarding the development and commercialization of our discovery-stage ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases outside of the United States, Canada and Mexico. Under the agreement, we are responsible for developing ErbB3 antibodies through completion of the first phase 2 clinical trial designed in a manner that, if successful, will generate data sufficient to support advancement to a phase 3 clinical trial. Within a specified time period after we complete this phase 2 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 the United States, Canada and Mexico. We retain the exclusive right to commercialize ErbB3 antibody products in the United States, Canada and Mexico.

Under the terms of the agreement, Biogen Idec paid us an upfront cash payment of $5.0 million in March 2009, which will be amortized over our period of substantial involvement once determined. 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 price of $4.00 paid by Biogen Idec includes 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 will recognize the premium of $8.2 million as revenue on a straight-line basis over the period of substantial involvement. In connection with the initial public offering we recently consummated 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 received 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 received in June 2009 is a near term milestone and not considered to be substantive and at risk, the revenue is being amortized as additional license revenue over our period of substantial involvement. We also earned a second $5.0 million milestone payment upon selection of a development candidate in March 2010. This milestone was considered substantive and at risk and has been included in revenue for the quarter ended March 31, 2010. We could also receive (i) a $5 million near-term pre-clinical discovery and development milestone payment, and (ii) if Biogen Idec exercises its option to obtain exclusive rights to commercialize ErbB3 antibody products in its territory, an option exercise fee and regulatory milestone payments of $50.0 million in the aggregate.

Schering-Plough (now Merck)

In March 2007, we entered into an agreement with Schering-Plough Corporation, or Schering-Plough (now Merck & Co., Inc., or Merck), through its subsidiary Schering Corporation, acting through its Schering-Plough Research Institute division, under which we granted Merck exclusive, worldwide rights to develop and commercialize all of our monoclonal antibody antagonists of hepatocyte growth factor, or HGF, including AV-299, for therapeutic and prophylactic use in humans and for veterinary use. We also granted Merck an exclusive, worldwide license to related biomarkers for diagnostic use. Merck has the right to grant sublicenses under the foregoing licensed rights. We have primary responsibility for certain U.S.-related development activities through the first phase 2 proof-of-concept trial for AV-299. Merck will be responsible for clinical development of AV-299 after completion of such proof-of-concept clinical trial. We also are using our Human Response Platform to conduct translational research to guide the clinical development of AV-299. Merck is responsible for all costs related to the clinical development of AV-299 and clinical and commercial manufacturing.

Under the agreement, Merck paid us an up-front payment of $7.5 million in May 2007, which is being amortized over our period of substantial involvement, or through completion of the first proof-of-concept trial which is estimated for this purpose to be to be the first half of 2012. In addition, Merck purchased 4,000,000 shares of our series D convertible preferred stock, at a per share price of $2.50, resulting in gross proceeds to us of $10.0 million. The amount paid for the series D

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convertible preferred stock represented fair value as it was the same as the amounts paid by unrelated investors in March and April 2007. In connection with the initial public offering we recently consummated and the related 1:4 reverse stock split of our common stock, each four shares of outstanding series D convertible preferred stock were converted into one share of common stock.

Milestone payments for the successful development and commercialization of AV-299, if all approvals in multiple indications and all sales milestones are achieved, could total, in the aggregate, $464.0 million. Upon commercialization, we are eligible to receive tiered royalty payments on Merck s net sales of AV-299, which range from low double digits to high teens as a percentage of net sales.

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, and research and development payments received from our strategic partners.

In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and research and development payments in connection with strategic partnerships, and royalties resulting from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestone and other payments received under our strategic partnerships, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales until 2013 at the earliest. 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 Expense

Research and development expense consists 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;
- 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 to employees and non-employees; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development costs as incurred.

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 increase our research and development expenses for the foreseeable future as we seek to complete development of our most advanced product candidate, tivozanib, and to further advance our earlier-stage research and development projects.

We track external development expenses and personnel expense on a program-by-program basis and allocate common expenses, such as scientific consultants and lab supplies, to each program based on the personnel resources

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allocated to each program. Facilities, depreciation, stock-based compensation, research and development management and research and development support services are not allocated and are considered overhead. Below is a summary of our research and development expenses for the three months ended March 31, 2009 and 2010:

	For the Three Months Ended March 31,	
	2010	2009
	(in thousands)	
Tivozanib	$ 14,886	$ 3,362
AV-299	2,055	1,018
AV-203 program	473	407
Platform collaborations	717	667
Antibody pipeline	1,367	1,264
Other research and development	615	621
Overhead	2,505	2,390
Total research and development expenses	$ 22,618	$ 9,729

Tivozanib

We have completed a phase 2 clinical trial and in February 2010 commenced enrollment in a phase 3 clinical trial for tivozanib in advanced RCC. We are also conducting phase 1b clinical trials of tivozanib in various combinations and dosing regimens in advanced RCC and additional solid tumor indications. Future research and development costs for the tivozanib program are not reasonably certain 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, the timing of the regulatory process, and the success of the ongoing phase 3 clinical trial. Our current estimate for the cost of the phase 3 clinical trial program, including the cost of the comparator drug, Nexavar, is approximately $67.0 million. In the first quarter of 2010, we paid Kyowa Hakko Kirin a $10.0 million milestone in connection with the initiation of our phase 3 clinical trial of tivozanib. We may also be required to make up to an aggregate of $50.0 million in milestone payments to Kyowa Hakko Kirin upon the achievement of specified regulatory milestones. Further, we are required to pay tiered royalty payments on net sales we make of tivozanib in our territory, which range from the low to mid teens as a percentage of net sales. In the event we sublicense the rights licensed to us under the license agreement, we are required to pay Kyowa Hakko Kirin a specified percentage of any amounts we receive from any third party sublicensees, other than amounts we receive in respect of research and development funding or equity investments, subject to certain limitations.

AV-299

We have entered into a license agreement related to AV-299 with Merck (formerly Schering Plough) and under the terms of the exclusive worldwide research, development and license agreement, we are responsible for leading the clinical development of AV-299 through completion of the first phase 2 proof-of-concept trial. All expenses related to development are reimbursed by Merck in accordance with an agreed-upon budget. We record revenue and expenses on a gross basis under this arrangement. All future costs of this program are expected to be fully funded by Merck. We have completed a phase 1 clinical trial of AV-299 and expect to commence a phase 2 clinical trial of AV-299 in the first half of 2010.

AV-203 Program

Our AV-203 program is focused on identifying inhibitors of ErbB3 and is currently in preclinical development. 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 the United States, Canada and Mexico. 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 any candidate identified from this program. We selected a development candidate in the first quarter of 2010 for which we earned a $5.0 million milestone payment from Biogen Idec. We expect to commence manufacturing of this candidate in 2010 in preparation for preclinical and human clinical trials.

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Platform Collaborations

We perform research services for third parties using our Human Response Platform. The related expenses, including personnel and related expenses, are captured as a cost of our various agreements with such third parties. Expenses incurred under our existing agreement with OSI Pharmaceuticals are fully supported by the revenue from that agreement.

Antibody Pipeline

We expect that the expenses related to our antibody pipeline will continue to increase as we seek to identify additional targets for preclinical research and additional personnel are added to these projects. Future research and development costs for our antibody pipeline are not reasonably certain because such costs are dependent on a number of variables, including the success of preclinical studies on these antibodies and the identification of other potential candidates across multiple oncology indications.

Other Research and Development

Other research and development includes expenses related to AV-412, a product candidate for which we have decided not to pursue further development, and certain funding related to our Human Response Platform which is not specifically related to a particular product candidate or a specific strategic partnership. AV-412 was the subject of a license agreement with Mitsubishi Pharma Corporation. We terminated the license agreement with Mitsubishi Pharma effective January 26, 2010. The costs to wind down this program are expected to be minimal.

Uncertainties of Estimates Related to Research and Development Expenses

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

At this time, we cannot reasonably estimate or know the nature, specific timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of our product candidates, or the period, if any, in which material net cash inflows may commence from our product candidates. This 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 other product candidate;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain strategic partnerships and the terms and success of those strategic partnerships, if any, including the timing and amount of payments that we might receive from potential 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 discussed above, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates (except for the estimates we have made for the cost of our phase 3 clinical trial of tivozanib) 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 of each product candidate, as well as ongoing assessment of the product candidate s commercial potential. We plan to develop additional product candidates internally which will increase significantly our research and development expenses in future periods. We will need to raise additional capital in the future in order to complete the commercialization of tivozanib and to fund the development of our other product candidates.

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General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, marketing, information technology, legal and human resources 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, auditing and tax services.

We anticipate that our general and administrative expenses will increase for, among others, the following reasons:

- we expect to incur increased general and administrative expenses to support our research and development activities, which we expect to expand as we continue the development of our product candidates;
- we may also begin to incur expenses related to the sales and marketing of our product candidates in anticipation of commercial launch before we receive regulatory approval of a product candidate; and
- we expect our general and administrative expenses to increase as a result of increased payroll, expanded infrastructure and higher consulting, legal, accounting and investor relations costs, and director and officer insurance premiums, associated with being a public company.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and 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.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no significant changes to our critical accounting policies since the beginning of this fiscal year. Our critical accounting policies are described in the Management s Discussion and Analysis of Financial Condition and Results of Operations section of our final prospectus filed pursuant to Rule 424(b) under the Securities Act with the Securities and Exchange Commission, or SEC, on March 12, 2010.

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Results of Operations

Comparison of Three Months Ended March 31, 2010 and 2009

The following table summarizes the results of our operations for each of the three months ended March 31, 2010 and 2009, together with the changes in those items in dollars and as a percentage:

	Three Months Ended March 31,			
	2010	2009	Increase/ (decrease)	%
		(in thousands)		
Revenue	$ 10,881	$ 3,670	$ 7,211	196%
Operating expenses:				
Research and development	22,618	9,729	12,889	132%
General and administrative	2,753	2,571	182	7%
Total operating expenses	25,371	12,300	13,071	106%
Loss from operations	(14,490)	(8,630)	(5,860)	68%
Other income (expense), net	712	(62)	774	(1248)%
Interest income	7	28	(21)	(75)%
Interest expense	(607)	(743)	136	(18)%
Net loss	$ (14,378)	$ (9,407)	$ (4,971)	53%

The following table sets forth revenues for the three months ended March 31, 2010 and 2009:

	Three Months Ended March 31,			
Revenue	**2010**	**2009**	**Increase/ (decrease)**	**%**
		(in thousands)		
Strategic Partner:				
Biogen Idec	$ 5,076	$	$ 5,076	0
OSI Pharmaceuticals	3,002	1,789	1,213	68%
Merck	2,794	1,881	913	49%
Other	9		9	
	$ 10,881	$ 3,670	$ 7,211	196%

Revenue. Revenue for the three months ended March 31, 2010 was $10.9 million compared to $3.7 million for the three months ended March 31, 2009, an increase of approximately $7.2 million or 196%. The increase is attributable to a $5.0 million milestone payment from Biogen Idec earned in March 2010 for selection of the development candidate for our AV-203 program; additional research and development funding from Merck related to the AV-299 program in the amount of $1.2 million; an increase in amortization of deferred revenue associated with the amended OSI Pharmaceuticals agreement in the amount of $0.8 million; an increase in research revenue earned under the OSI Pharmaceuticals agreement of $0.4 million; and an increase of $0.1 million associated with amortization of previously deferred Biogen Idec license revenue which began in the first quarter of 2010. These increases were partially offset by a decrease of $0.3 million in amortization of the deferred revenue under the Merck agreement due to a change in the estimated period of substantial involvement.

Research and development. Research and development expense for the three months ended March 31, 2010 was $22.6 million compared to $9.7 million for the three months ended March 31, 2009, an increase of $12.9 million or 132%. The increase is primarily attributable to a $10.0 milestone payment to Kyowa Hakko Kirin in connection with the initial dosing of patients in our phase 3 clinical trial of tivozanib; an increase in clinical trial costs of $1.3 million resulting primarily from an increase in costs for the phase 3 clinical trial of tivozanib partially offset by a reduction in costs of the phase 2 clinical trial of tivozanib as it winds down; a $0.8 million increase in development costs related to AV-299 which are reimbursed by Merck but recorded on a gross basis; a $0.7 million increase in salaries and benefits mainly due to an increase in personnel primarily

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supporting development activities for tivozanib and our antibody pipeline; a $0.2 million increase in contract manufacturing for tivozanib to support an increasing number of clinical trials; and a $0.1 million increase in licensing costs as a result of licensing third party drug discovery technology. These increases were partially offset by a decrease in spending for toxicology supporting tivozanib of $0.5 million.

Included in research and development expense were stock-based compensation charges of approximately $358,000 and $313,000 for the three months ended March 31, 2010 and 2009, respectively.

General and administrative. General and administrative expense for the three months ended March 31, 2010 was $2.8 million compared to $2.6 million for the three months ended March 31, 2009, an increase of $0.2 million or 7%. The increase is primarily the result of a $0.3 million increase in stock-based compensation expense partially offset by a $0.1 million decrease in salaries and benefits.

Included in general and administrative expense were stock-based compensation charges of approximately $458,000 and $179,000 for the three months ended March 31, 2010 and 2009, respectively.

Other income (expense), net. Other income (expense), net for the three months ended March 31, 2010 was $712,000 compared to ($62,000) for the three months ended March 31, 2009, an increase of $774,000. The increase is largely a result of a decrease in the value of warrants to purchase preferred stock resulting from a decrease in value of the underlying stock.

Interest income. Interest income for the three months ended March 31, 2010 was $7,000 compared to $28,000 for the three months ended March 31, 2009, a decrease of $21,000 or 75%. Although the average cash balances were higher for the three months ended March 31, 2010, interest rates decreased to only slightly above 0% in 2010 causing the decrease in interest income.

Interest expense. Interest expense for the three months ended March 31, 2010 was $0.6 million compared to $0.7 million for the three months ended March 31, 2009, a decrease of $0.1 million or 18%. The decrease is due to a decrease in the average loan balances in 2010.

Liquidity and Capital Resources

We have funded our operations principally through the sale of equity securities sold in connection with our initial public offering, the private placement of equity securities, revenue from strategic partnerships, debt financing and interest income. As of March 31, 2010, we have received gross proceeds of $81.0 million from the sale of common stock in our initial public offering and $169.6 million from the sale of convertible preferred stock, including $32.9 million from the sale of 11,250,000 shares of series E convertible preferred stock in 2009. As of March 31, 2010, we had received an aggregate of $97.1 million in cash from our three agreements with Merck and our agreements with OSI Pharmaceuticals, Biogen Idec, and Eli Lilly and $21.0 million in funding from our debt financing with Hercules Technology Growth Capital, Inc., or Hercules, and Comerica Bank. As of March 31, 2010, we had cash, cash equivalents and marketable securities of approximately $96.1 million. Currently, our funds are invested in money market funds, U.S. Treasuries, U.S. government agencies securities and commercial paper. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	For the Three Months Ended March 31,	
	2010	2009
Net cash provided by (used in) operating activities	$ (25,778)	$ 5,286
Net cash provided by (used in) investing activities	(18,615)	(9,888)
Net cash provided by (used in) financing activities	70,750	21,364
	$ 26,357	$ 16,762

For the three months ended March 31, 2010 our operating activities used cash of $25.8 million. For the three months ended March 31, 2009 our operating activities provided cash of $5.3 million. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. The cash used in operations for the three months ended March 31, 2010 was due primarily to our net loss adjusted for non-cash items and an increase in accounts receivable related to the $5.0 million Biogen Idec milestone earned in March but paid in April, as well as a $6.2 million increase in prepaid expenses primarily associated with an advance payment for purchase of Nexavar, the comparator drug in our phase 3 clinical trial of tivozanib. The cash provided by operating activities for the three months ended March 31, 2009 was primarily the result our net loss adjusted for non-cash items and an increase in deferred revenue of $12.8 million related to the receipt of an upfront license payment and equity premiums from our agreement with Biogen Idec completed in March 2009.

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For the three months ended March 31, 2010 and 2009, our investing activities used cash of $18.6 million, and $9.9 million, respectively. The cash used by investing activities for the three months ended March 31, 2009 and 2010 was primarily the net result of purchases of marketable securities partially offset by maturities in addition to purchases of property and equipment of $0.2 million and $0.4 million, respectively.

For the three months ended March 31, 2010 and 2009, our financing activities provided $70.8 million and $21.4 million, respectively. The cash provided by financing activities in the first quarter of 2010 was due to the sale and issuance of 9,000,000 shares of common stock at a price of $9.00 per share in our initial public offering with net proceeds of $72.2 million and stock option exercises of $0.5 million, offset partially by principal payments on loans payable in the amount of $2.0 million. The cash provided by financing activities in the first quarter of 2009 was due to the sale of 7,500,000 shares of series E convertible preferred stock with net proceeds of $21.8 million, offset partially by the principal payments on loans payable of $0.4 million.

Credit Facilities.

On May 15, 2008, we entered into a $21.0 million financing agreement with Hercules and Comerica Bank. The full amount of the loan was drawn down in 2008. In May 2009, we triggered a provision allowing a six month extension to the original twelve month interest only period. The new loan is now repayable over 48 months beginning June 2008, with the first 18 payments representing interest only. The remaining principal and associated interest is due and payable in equal monthly installments based upon a 30-month amortization schedule. The loan also calls for a deferred charge of 5.95% to be paid upon maturity. The deferred charge of $1.3 million has been recorded as a loan discount and is being amortized to interest expense over the term of the loan using the effective interest rate method. We 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. Interest is payable at a fixed interest rate of 9.75%. The loan is secured by a lien on all of our assets, except for intellectual property and the capital equipment securing our equipment and refinancing lines of credit described below. As of March 31, 2010, the principal balance outstanding was $18.5 million. We began making principal payments in December 2009 with a final loan maturity in May 2012.

In November 2003, we entered into a $7.5 million financing agreement with General Electric Capital Corporation for an equipment capital expenditure line which we refer to as the equipment line and a refinancing line of existing equipment debt which we refer to as the refinancing line. Borrowings under the equipment line are repayable over 54 months, the first six of which were interest only at fixed interest rates ranging from 8.39% to 10.11%, with a 10% end-of-term balloon payment (guaranteed purchase option). The refinancing line has been fully paid. The equipment line is secured by an interest in the specific financed assets. Under the equipment line, there is a requirement to maintain minimum unrestricted cash equal to the greater of $12.0 million or nine months cash burn. In the event we violate the minimum cash requirement, we must provide a letter of credit or security deposit equal to 70% of the outstanding balance under the equipment line. The aggregate principal outstanding under the equipment line and the refinancing line at March 31, 2010 was approximately $21,100 with a final maturity in June 2010. There is no remaining ability to borrow under the equipment line.

Operating Capital Requirements.

Assuming we successfully complete clinical trials and obtain requisite regulatory approvals, we anticipate commercializing our first product in 2013 at the earliest. Therefore, we anticipate that we will continue to generate significant losses for the next several years as we incur expenses to complete our clinical trial programs for tivozanib, build commercial capabilities, develop our antibody pipeline and expand our corporate infrastructure. We believe that our existing cash and cash equivalents, marketable securities, committed research and development funding and milestone payments that we expect to receive under our existing strategic partnership and license agreements, along with payments we believe that we will receive under new strategic partnerships we assume we will enter into under our current projected operating plan, will allow us to fund our operating plan through at least the first half of 2012.

If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we develop additional opportunities to do so, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have 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. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

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;

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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; and

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

Contractual Obligations and Commitments

In March 2010, we made a $10.0 milestone payment to Kyowa Hakko Kirin in connection with the dosing of the first patient in our phase 3 clinical trial of tivozanib. We have also committed to make in the second quarter of 2010 an additional purchase of the comparator drug, Nexavar, which will be used in our phase 3 clinical trial of tivozanib in the amount of $3.0 million. There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our final prospectus filed pursuant to Rule 424(b) under the Securities Act with the Securities and Exchange Commission on March 12, 2010.

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 are exposed to market risk related to changes in interest rates. As of March 31, 2010 and December 31, 2009, we had cash and cash equivalents and marketable securities of $96.1 million and $51.3 million, respectively, consisting of money market funds, U.S. Treasuries, U.S. government agency securities, corporate debt and 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 have 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 and our equipment line obligations bear interest at fixed rates. As a result, we have limited exposure to changes in interest rates on these borrowings.

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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, 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 in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is 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.

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PART II. OTHER INFORMATION

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 forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosure we make in our reports filed with the SEC.

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

We are dependent on the success of our lead drug candidate, tivozanib, which is in phase 3 development.

To date, we have invested a significant portion of our efforts and financial resources in the research and development of tivozanib. We initiated our phase 3 clinical trial for tivozanib in December 2009 and are currently conducting four phase 1b clinical trials, three of which focus on tivozanib in combination with other known anti-cancer agents.

Our near-term prospects, including our ability to finance our company and to generate strategic partnerships and revenues, will depend heavily on the successful development and commercialization of tivozanib. All of our other potential product candidates, with the exception of AV-299, which we have partnered with Merck (formally Schering-Plough), are in the preclinical research stage. The clinical and commercial success of tivozanib will depend on a number of factors, including the following:

- timely enrollment in our phase 3 clinical trial or our other on-going or planned clinical trials, which may be slower than we currently anticipate, potentially resulting in significant delays;
- our ability to demonstrate to the satisfaction of the U.S. Food and Drug Administration, or FDA, or equivalent foreign regulatory agencies, tivozanib s safety and efficacy through current and future clinical trials;
- the prevalence and severity of adverse side effects;
- timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining compliance with all regulatory requirements applicable to the product;
- the availability, relative cost and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our potential strategic partners marketing, sales and distribution strategy and operations;
- the ability of our third-party manufacturers to manufacture clinical trial supplies of our product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;

our ability to successfully launch commercial sales of tivozanib, assuming FDA approval is obtained, whether alone or in collaboration with others;

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our ability to avoid third party patent interference or patent infringement claims;

acceptance of tivozanib as safe and effective by patients, the medical community and third-party payors; and

a continued acceptable safety profile of the product following approval.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to generate revenues through the sale of tivozanib. If we are not successful in commercializing tivozanib, or are significantly delayed in doing so, our business will be materially harmed and the price of our common stock could substantially decline.

Positive results in our phase 2 clinical trial of tivozanib may not be predictive of the results in our phase 3 clinical trial. If the results of our phase 3 clinical trial are not positive, or are not sufficient for approval of tivozanib, our business will be adversely affected.

Positive results in early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier-stage development. Although the results of our phase 2 clinical trial of tivozanib for the treatment of advanced RCC were positive, we cannot assure you that the phase 3 clinical trial for the treatment of advanced RCC will achieve positive results. A number of factors could contribute to a lack of positive results in our phase 3 clinical trial of tivozanib.

For example, in our phase 2 clinical trial, we compared tivozanib to treatment with placebo. In our phase 3 clinical trial, the primary endpoint is a comparison of progression-free survival of patients treated with tivozanib to the progression-free survival of patients treated with Nexavar. Nexavar is a VEGF receptor inhibitor which has been approved by the FDA and the European Medicines Agency, or the EMEA, for the treatment of advanced RCC, as well as the treatment of hepatocellular carcinoma. Based on our discussions with the FDA and the EMEA, we have set the number of patients to be enrolled in the clinical trial at a number sufficient to demonstrate that a difference in progression-free survival of three months or more between the treatment arms would be statistically significant. The FDA has advised us that the results of the phase 3 clinical trial will need to show not only that patients treated with tivozanib have a statistically significant improvement in progression-free survival as compared to patients treated with Nexavar, but also that the improvement in progression-free survival of patients treated with tivozanib is clinically meaningful in the context of the safety of the drug. It is not clear how much of an improvement in progression-free survival will be required in order for it to be deemed clinically meaningful in the context of the safety of the drug. The FDA and other regulatory authorities will have substantial discretion in evaluating the results of our phase 3 clinical trial, including with respect to what constitutes a clinically meaningful improvement in progression-free survival. Overall survival is a secondary endpoint in our phase 3 clinical trial. Based on our discussions with the FDA, we do not expect the FDA to require that we show a statistically significant improvement in overall survival in patients treated with tivozanib in order to obtain approval by the FDA; however, if the overall survival data are not positive it may influence how the FDA and other regulatory authorities interpret other data from our phase 3 clinical trial. We did not gather data on overall survival in our phase 2 clinical trial of tivozanib.

We cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct in order to gain approval to market tivozanib. Prior to approving a new drug, the FDA generally requires that the efficacy of the drug be demonstrated in two adequate and well-controlled clinical trials. In some situations the FDA approves drugs on the basis of a single well-controlled clinical trial. Based on our discussions with the FDA and the EMEA, we believe we will be required to conduct only a single phase 3 clinical trial of tivozanib in advanced RCC. All of the VEGF inhibitor drugs approved by the FDA and the EMEA to date in advanced RCC, including Votrient, which was approved by the FDA in October 2009, have been approved on the basis of a single phase 3 clinical trial. However, if the FDA or EMEA determines that our phase 3 clinical trial results are not statistically significant and do not demonstrate a clinically meaningful benefit and an acceptable safety profile, or if the FDA or EMEA requires us to conduct additional phase 3 clinical trials of tivozanib in order to gain approval, we will incur significant additional development costs, commercialization of tivozanib would be prevented or delayed and our business would be adversely affected.

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If we do not obtain regulatory approval for tivozanib, AV-299 or any other product candidates, our business will be adversely affected.

Tivozanib, AV-299 and any other product candidate we seek to develop will be subject to extensive governmental regulations relating to, among other things, development, clinical trials, manufacturing and commercialization. In order to obtain regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication, and that our production process yields a consistent and stable product. This process can take many years to complete, requiring the expenditure of substantial resources with highly uncertain results. We may never obtain regulatory approval for tivozanib, AV-299 or any other product candidate we may develop.

We have recently completed a phase 2 clinical trial of our lead product candidate, tivozanib, and have initiated a phase 3 clinical trial of tivozanib for the treatment of RCC. We are also conducting phase 1b clinical trials of tivozanib in various combinations and dosing regimens in RCC and additional solid tumor indications, including breast cancer and colorectal cancer. In addition to tivozanib, we have a pipeline of monoclonal antibodies derived from our Human Response Platform, a novel method of building preclinical models of human cancer, which are intended to more accurately represent cancer biology in patients. Our first product candidate derived from our Human Response Platform, AV-299, is expected to enter a phase 2 clinical trial for non-small cell lung cancer in the first half of 2010. The results to date from preclinical studies, our phase 1 and phase 2 clinical trials of tivozanib and our phase 1 clinical trials of AV-299 may not be predictive of results in future preclinical studies and clinical trials. A failure of one or more preclinical or clinical trials can occur at any stage of testing. Moreover, there can be no assurance that we will demonstrate the required safety and efficacy to obtain regulatory approvals for either of these product candidates.

Even though tivozanib has been generally well-tolerated in the limited number of patients who have been treated with it, there is no guarantee that unacceptable side effects or other risks will not occur with the exposure of a larger number of patients. If tivozanib, AV-299 or any other product candidate is not shown to be safe and effective in humans through clinical trials, we 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, as well as the potential need for additional financing, would have a material adverse effect on our business, financial condition and results of operations.

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 clinical testing and potential approval of tivozanib as well as the continued development of AV-299, a key element of our strategy is to discover, develop and commercialize a portfolio of antibody-based products. We are seeking to do so through our internal research programs and intend to explore strategic partnerships for the development of new products. All of our other potential product candidates remain in the discovery and preclinical study stages. 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 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 on 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.

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Any failure or delay in completing clinical trials for our product candidates 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 or halted for many reasons, including:

- 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, or the inability of our strategic partners or licensees, to manufacture or obtain from third parties materials sufficient to complete our preclinical studies and clinical trials;
- 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;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of our product candidates during clinical trials;
- 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. For example, we plan to enroll 500 patients in our phase 3 clinical trial of tivozanib. 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 and the availability of approved effective drugs. There are a number of approved treatments for advanced RCC, including drugs that work by inhibiting the VEGF pathway. The availability of these approved treatments and the requirement in our phase 3 clinical trial that patients not have been treated with drugs that inhibit the VEGF pathway could make it more difficult to enroll patients or could delay enrollment in our phase 3 clinical trial. Moreover, we are aware of a number of ongoing clinical trials in RCC which will compete for eligible patients with our tivozanib clinical trials and may delay enrollment in our clinical trials.

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, 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.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing FDA obligations 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 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 testing, including phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. 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 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 future strategic partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Risks Related to Our Financial Position and Capital Requirements

We have incurred net operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability, which would depress the market price of our common stock.

We have incurred net losses since our inception, including net losses of $44.1 million, $32.5 million and $25.0 million for the years ended December 31, 2009, 2008 and 2007, respectively. As of March 31, 2010, we had an accumulated deficit of $192.1 million. We do not know whether or when we will become profitable. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. Our losses have resulted principally from costs incurred in our discovery and development activities. We anticipate that our operating losses will substantially increase over the next several years as we execute our plan to expand our discovery, research, development and commercialization activities, including the phase 3 clinical development and planned commercialization of our lead product candidate, tivozanib.

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.

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 and preclinical and clinical development of our product candidates. In particular, we initiated a phase 3 clinical trial of tivozanib in December 2009, which will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future developing tivozanib and other new and existing antibody product candidates. These expenditures will include costs associated with research and development, acquiring new technologies, conducting preclinical and clinical trials, obtaining regulatory approvals and manufacturing products, 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 necessary to successfully complete the development and commercialization of our product candidates.

We believe that our existing cash and cash equivalents, marketable securities, committed research and development funding and milestone payments that we expect to receive under our existing strategic partnership and license agreements, along with payments we believe that we will receive under new strategic partnerships we assume we will enter into under our current projected operating plan, will allow us to fund our operating plan through at least the second quarter of 2012. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic partnerships. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

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 development activities for one or more of our product candidates;
- delay, limit, reduce or terminate our research and development activities; 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.

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

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders will be diluted, and the terms 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 and 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. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

A substantial portion of our future revenues may be dependent upon our agreements with OSI Pharmaceuticals, Merck and Biogen Idec.

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 products. We currently expect that a substantial portion of our future revenues may be dependent upon our strategic partnerships with OSI Pharmaceuticals Merck and

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Biogen Idec. Under each of these strategic partnerships, our strategic partners have significant development and commercialization responsibilities with respect to anticipated therapeutics to be developed and sold. If these strategic partners were to terminate their agreements with us, fail to meet their obligations or otherwise decrease their level of efforts, allocation of resources or other commitments under these agreements, our future revenues could be negatively impacted and the development and commercialization of our product candidates would be interrupted. In addition, if OSI, Merck or Biogen Idec do not achieve some or any of the development, regulatory and commercial milestones or if they do not achieve certain net sales thresholds, in each case, 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 these strategic 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 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 beginning on page 44.

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 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. 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 recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current 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 and 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 March 31, 2010, we had $96.1 million of cash, cash equivalents and marketable securities consisting of cash, money market and government obligations. 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 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 the general economic downturn.

Risks Related to Our Business and Industry

Because we have a short operating history, there is a limited amount of information about us upon which you can evaluate our business and prospects.

Our operations began in October 2001 and we have only a limited operating history upon which you can evaluate our business and prospects. In addition, as an early stage company, we have limited experience 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;

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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 and marketing capabilities;

gain market acceptance for our products;

develop and maintain successful strategic relationships; 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.

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. For example, we anticipate that tivozanib, if approved for the treatment of advanced RCC, would compete with angiogenesis inhibitors and mTOR inhibitors that are currently approved for the treatment of advanced RCC, such as Avastin, marketed by Roche Laboratories, Inc., Nexavar, marketed by Onyx Pharmaceuticals, Inc. and Bayer HealthCare AG, Sutent, marketed by Pfizer Inc., Votrient, marketed by GlaxoSmithKline plc, Torisel, marketed by Pfizer, and Afinitor, marketed by Novartis Pharmaceuticals Corporation, and other therapies in development.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. We will not be able to compete successfully unless we successfully:

design and develop products that are superior to other products in the market;

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; 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 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.

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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, particularly Tuan Ha-Ngoc, our Chief Executive Officer, Elan Ezickson, our Chief Business Officer, David Johnston, our Chief Financial Officer, William Slichenmyer, our Chief Medical Officer, and Jeno Gyuris, our Senior Vice President, Head of Research, as well as other senior scientists on our management team. Although none of these individuals has informed us to date that he intends to retire or resign in the near future, the loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our product pipeline, 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. Although we have entered into an employment agreement and a severance and change in control agreement with Tuan Ha-Ngoc, and severance and change in control agreements with each of Elan Ezickson, David Johnston, William Slichenmyer and Jeno Gyuris, these agreements do not provide for a fixed term of service.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms.

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, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners,

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suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. 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 would require significant financial and management resources. Regardless of the merits or eventual outcome, 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;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

the inability to commercialize our product candidates; and

a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies in the amount of $10 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.

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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 no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities.

We have no sales, marketing or distribution experience. To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that tivozanib will be approved. For product candidates such as tivozanib where we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, 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.

Outside of the United States, where appropriate, we may elect in the future to utilize strategic partners or contract sales forces to assist in the commercialization of tivozanib and future 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 tivozanib and AV-299, among physicians, patients, health care payors and, in the cancer market, acceptance by the major operators of cancer clinics.

Even if tivozanib, AV-299 or any other product candidate that we may develop or acquire in the future obtains regulatory approval, the product may not gain market acceptance among physicians, health care 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 tivozanib, as demonstrated in clinical trials;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;

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the results obtained in our phase 3 clinical trial of tivozanib for the treatment of advanced clear cell RCC and the extent to which the results demonstrate that treatment with tivozanib represents a clinically meaningful improvement in care as compared to other available VEGF inhibitors;

the potential and perceived advantages of tivozanib over alternative treatments, including, for example, Avastin, Nexavar, Sutent or Votrient;

the cost of treatment in relation to alternative treatments;

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

the continued projected growth of oncology drug markets;

relative convenience and ease of administration;

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

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

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

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In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care 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 health care in the United States, third-party payors are increasingly attempting to contain health care 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 health care, the increasing influence of health maintenance organizations, additional legislative proposals, as well as country, regional, or local healthcare budget limitations. Thus, 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.

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

We intend to seek approval to market our future products in both the United States and in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

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

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care 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 health care 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 new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals, medical devices, or our product candidates. If reimbursement for our approved product candidates, if any, is substantially less that we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

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Further federal and state proposals and health care 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 the 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 health care 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 a collaboration agreement with Merck related to the development and commercialization of AV-299, our monoclonal antibody antagonist of hepatocyte growth factor, or HGF. Pursuant to the agreement, we have primary responsibility for certain U.S.-related development activities through completion of the first phase 2 clinical trial for AV-299 designed to demonstrate achievement of a primary efficacy endpoint in humans as established by the parties, which we refer to as a proof-of-concept trial. Merck will be responsible for clinical development of AV-299 after completion of the first proof-of-concept trial. We are currently leading the clinical development of AV-299, which includes conducting multiple phase 1 clinical trials and preparing to conduct a phase 2 clinical trial, and we are using our Human Response Platform to conduct translational research to guide the clinical development of AV-299. Merck is responsible for all costs related to the clinical development of AV-299 and clinical and commercial manufacturing, subject to an agreed-upon budget.

We have entered into a strategic partnership with OSI, 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. Key elements of our strategic partnership with OSI include: (1) identifying and validating a pre-agreed number of oncology targets for drug discovery, development and commercialization by OSI, (2) generating target-driven *in vivo* mouse tumor models for use in drug screening and biomarker validation to support OSI s drug discovery and translational research activities, and (3) applying our Human Response Platform to identify genetic profiles that correlate with drug response to compounds in certain of OSI s small molecule drug discovery programs. We are required to devote, and OSI is required to fund, a mutually agreed minimum number of individuals to the research program each year. Under the terms of our agreement, OSI may, but has no obligation to, elect to obtain exclusive rights to certain aspects of our intellectual property to research, develop, make, sell and import drug products and associated diagnostics directed to a specified number of targets identified and/or validated under the strategic partnership. OSI has sole responsibility and is required to use commercially reasonable efforts to develop and commercialize drugs and associated diagnostics directed to the targets to which it has obtained rights.

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We have entered into an exclusive option and license agreement with Biogen Idec regarding the development and commercialization of our ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases outside of the United States, Canada and Mexico. Under the agreement, we are responsible for developing ErbB3 antibodies through completion of the first phase 2 clinical trial designed in a manner that, if successful, will generate data sufficient to support advancement to a phase 3 clinical trial. Within a specified time period after we complete the phase 2 clinical trial and deliver to Biogen Idec a detailed data package containing the results of the trial, Biogen Idec may elect to obtain (1) a co-exclusive (with us) worldwide license under our relevant intellectual property to develop and manufacture ErbB3 antibody products, and (2) an exclusive license under our relevant intellectual property to commercialize ErbB3 antibody products in all countries in the world other than the United States, Canada and Mexico. We will retain an exclusive right to commercialize ErbB3 antibody products in the United States, Canada and Mexico. Until completion of the first phase 2 clinical trial, we are solely responsible for the research, development, and manufacture of ErbB3 antibody(ies) pursuant to a written work plan meeting specific pre-agreed guidelines. We are solely responsible for all expenses incurred through completion of the first phase 2 clinical trial. If Biogen Idec exercises its option to obtain exclusive commercialization rights to ErbB3 products in its territory, then we will be solely responsible, subject to a mutually agreed development plan, budget and the oversight of a joint development committee, for the global development of ErbB3 antibody products, except that Biogen Idec will be solely responsible for ErbB3 antibody product development activities that relate solely to the Biogen Idec territory. We and Biogen Idec will share global development costs (including manufacturing costs to support development) for ErbB3 antibody products equally, except that Biogen Idec will be solely responsible for all development costs associated solely with the development of ErbB3 antibody products for its territory, and we will be solely responsible for all development costs associated solely with the development of ErbB3 antibody products for the United States, Canada and Mexico.

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 their 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.

Our strategic partnership agreements permit our strategic partners wide discretion in deciding which product candidates to advance through the clinical trial process. Under certain of our strategic partnerships, it is possible for the strategic partner 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.

Our strategic partners 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 change the focus of their development and commercialization efforts or pursue higher-priority programs.

Our strategic partners may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial 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. For example, we entered into a strategic partnership with Schering-Plough prior to its merger with Merck. We also entered into agreements with Merck prior to that merger. Although the effect of the merger on our strategic partnerships is unknown, management of the combined company could determine to reduce the efforts and resources that the combined company will apply to its strategic partnerships with us. In addition, the third-party 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.

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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, Merck can terminate its agreement related to AV-299 with us upon 90 days written notice to us or in connection with an insolvency event or material breach 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 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 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 any strategic partner were to breach or terminate its arrangements with us, or if Biogen Idec does not elect to exercise its option to participate in development of our 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 partner 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.

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 future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

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;

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- 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 a small number of 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 one supplier for the active pharmaceutical ingredient for tivozanib. Currently, a separate contract manufacturer manufactures, packages and distributes clinical supplies of tivozanib. While we believe that our existing supplier of active pharmaceutical ingredient or an alternative supplier would be capable of continuing to produce active pharmaceutical ingredient in commercial quantities, we will need to identify a third-party manufacturer capable of providing commercial quantities of drug product. If we are unable to arrange for such a third-party manufacturing source, or fail to do so on commercially reasonable terms, we may not be able to successfully produce and market tivozanib or may be delayed in doing so.

The process for producing AV-299 has been developed and multiple batches of drug substance have been and are continuing to be produced to support clinical trials of AV-299 through phase 2 clinical trials. Our strategic partner Merck is responsible for the continued process development and all manufacturing of AV-299, including for clinical trial and commercial use. If our strategic partner Merck does not complete process development and manufacture of AV-299 as we expect, clinical trials and any commercial production of AV-299 could be adversely affected.

As with tivozanib and AV-299, we also expect to rely upon third parties to produce materials required for the clinical and commercial production of any other product candidates. 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) 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, 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

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we use to manufacture our drugs. Such suppliers may not sell 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 these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, 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.

Although we believe the current manufacturing process for the active pharmaceutical ingredient for tivozanib is adequate to support future development and commercial demand, because of the complex nature of many of our other compounds, our manufacturers may not be able to manufacture such other compounds at a cost or in quantities or in a timely manner necessary to develop and commercialize other 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 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 and having to enter into alternative arrangements would delay introduction of our product candidates to market.

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.

Risks Related to Our Intellectual Property Rights

We could be unsuccessful in obtaining adequate patent protection for one or more of our product candidates.

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

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

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

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

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

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It is also possible that we failed to identify relevant 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 the use of an organic compound that, among other things, inhibits VEGF binding to one of the VEGF receptors. 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 AV-299, 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 future strategic partners were able to obtain a license, the rights may be nonexclusive, 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 certain aspects of our technology platform, or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations of patent infringement or misappropriation of trade secrets, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the patent owner, in order to continue our research and development programs or to market our product(s). It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This could limit our research and development activities, our ability to commercialize certain products, or both.

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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 aspects of our platform technology are protected by patents exclusively licensed from other companies. If the licensors terminate the licenses or fail to maintain or enforce the underlying patents, our competitive position and market share 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 and the Dana-Farber Cancer Institute for our MaSS screen, which is a method of using our models to screen for, and identify, novel targets for new cancer drugs. 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. We have exclusively licensed certain patent rights covering a method of using our inducible cancer models to identify new targets for cancer drugs. 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.

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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 and development activities and our 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 our confidentiality agreements are carefully drafted to protect our proprietary interests. Nevertheless, there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures.

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

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

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

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

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

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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, Congress may pass patent reform legislation. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. 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 would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been, and may continue to be, highly volatile, and could fall below the price you paid.

The trading price of our common stock is likely to continue be highly volatile and could be 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, including Roche s Avastin, Pfizer s Sutent, Onyx s Nexavar, GSK s Votrient and the timing of these introductions or announcements;

actual or anticipated results from and any delays in our clinical trials, including our phase 3 clinical trial of tivozanib, as well as results of regulatory reviews relating to the approval of our product candidates;

the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

announcements by us 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;

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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, securities class-action litigation has often been instituted against companies. Such 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 principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

To our knowledge, as of April 30, 2010, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 24% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after April 30, 2010. Accordingly, these stockholders will be able to exert a significant degree of 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 our control 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 fair market value of our common stock.

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 or lock-up agreements that were entered into with the underwriters of our public offering, 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 trading 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.

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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.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Unregistered Sales of Equity Securities

During the period from January 1, 2010 until March 31, 2010, we:

- issued 67,808 shares of common stock upon option exercises at a weighted-average exercise price of $2.19 per share for an aggregate sale price of approximately $148,000; and
- granted options to purchase 398,182 shares of common stock at an exercise price of $12.24 per share.

The securities described above were issued pursuant to written compensatory plans or arrangements with our employees and directors in reliance on the exemptions provided by either Section 4(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act.

Use of Proceeds from Registered Securities

Our initial public offering of common stock was effected through Registration Statements on Form S-1 (File Nos. 333-163778 and 333-165412), that were declared effective by the SEC on March 11, 2010, which registered an aggregate of 10,350,000 shares of our common stock at an aggregate offering price of approximately $93.2 million. On March 17, 2010, we completed an initial public offering of 9,000,000 shares of our common stock at a price to the public of $9.00 per share and, on April 6, 2010, we closed the sale of an additional 968,539 shares of common stock at a price to the public of $9.00 per share in connection with the underwriters election to exercise their option to purchase an overallotment, for aggregate gross proceeds of $89.7 million. The offering commenced on March 11, 2010 and terminated before the sale of all

of the securities registered in the offering. J.P. Morgan Securities Inc. and Morgan Stanley & Co. Incorporated acted as joint book-running managers for the offering. Leerink Swann LLC acted as lead co-manager and Canaccord Adams Inc. acted as co-manager of the offering. There were no selling stockholders in the offering.

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We paid $6.3 million in underwriting discounts and commissions to the underwriters in connection with the offering. In addition, we incurred additional costs of approximately $3.1 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $9.4 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were approximately $80.3 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of March 31, 2010, we estimate that we have used approximately $11.0 million of the net proceeds from the initial public offering to fund the clinical development of tivozanib and for working capital, capital expenditures and other general corporate purposes, which includes a $10.0 million milestone payment to Kyowa Hakko Kirin in connection with the initial dosing of patients in our phase 3 clinical trial of tivozanib. We have invested the unused proceeds from the offering in short-term interest-bearing, investment grade securities. There has been no material change in our planned use of proceeds from the initial public offering from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on March 12, 2010.

Item 3. DEFAULTS UPON SENIOR SECURITIES.

None.

Item 4. (REMOVED AND RESERVED).

Item 5. OTHER INFORMATION.

On May 11, 2010, the Compensation Committee of our Board of Directors authorized the acceleration of the vesting of 37,500 shares underlying option awards that had been granted in October 2007 at an exercise price of $5.60 per share to our Chief Financial Officer, David Johnston. Such shares became immediately exercisable.

Item 6. EXHIBITS.

The exhibits listed in the Exhibit Index 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: May 13, 2010

BY: /S/ DAVID JOHNSTON
David Johnston

Chief Financial Officer

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EXHIBIT INDEX

Exhibit	Description
3.1(1)	Restated Certificate of Incorporation of the Registrant.
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.
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.
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.
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.

(1) Incorporate by reference from Exhibit 99.1 of the Registrant s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 18, 2010.