AVEO PHARMACEUTICALS INC
Form 10-Q
May 12, 2011
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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, 2011

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)

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

Number of shares of the registrant s Common Stock, $0.001 par value, outstanding on May 1, 2011: 35,931,606

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AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2011

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(in thousands, except par value amounts)

(unaudited)

	March 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 101,076	$ 45,791
Marketable securities	131,511	94,407
Accounts receivable	8,047	391
Prepaid expenses and other current assets	14,221	4,864
Total current assets	254,855	145,453
Property and equipment, net	4,479	4,532
Other assets	418	456
Restricted cash	704	607
Total assets	$ 260,456	$ 151,048
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 11,824	$ 9,247
Accrued expenses	36,812	10,121
Loans payable, net of discount	3,694	5,766
Deferred revenue	5,415	16,693
Deferred rent	239	266
Total current liabilities	57,984	42,093
Loans payable, net of current portion and discount	19,971	17,636
Deferred revenue, net of current portion	20,655	16,509
Deferred rent, net of current portion	523	553
Other liabilities	2,487	2,487
Stockholders equity:		
Preferred stock, $.001 par value: 5,000 shares authorized at March 31, 2011 and December 31, 2010, respectively; no shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively		
Common stock, $.001 par value: 100,000 shares authorized at March 31, 2011 and December 31, 2010, respectively; 35,913 and 35,604 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	36	36
Additional paid-in capital	309,928	308,268
Accumulated other comprehensive income (loss)	20	(20)
Accumulated deficit	(151,148)	(236,514)

Total stockholders equity	158,836	71,770
Total liabilities and stockholders equity	$ 260,456	$ 151,048

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

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Collaboration revenue	$ 133,614	$ 10,881
Operating expenses:		
Research and development	38,017	22,618
General and administrative	9,228	2,753
	47,245	25,371
Income (loss) from operations	86,369	(14,490)
Other income and expense:		
Other (expense) income, net	(56)	712
Interest expense	(1,012)	(607)
Interest income	65	7
Other (expense) income, net	(1,003)	112
Net income (loss)	85,366	(14,378)
Basic net income (loss) per share		
Net income (loss)	$ 2.38	$ (2.27)
Weighted average number of common shares outstanding	35,781	6,340
Diluted net income (loss) per share		
Net income (loss)	$ 2.28	$ (2.27)
Weighted average number of common shares and dilutive common share equivalents outstanding	37,483	6,340

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)

	Three Months Ended March 31,	
	2011	**2010**
Operating activities		
Net income (loss)	$ 85,366	$ (14,378)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	372	325
Stock-based compensation	1,182	816
Non-cash interest expense	269	138
Deferred rent	(57)	(37)
Loss on disposal of property and equipment		1
Remeasurement of warrants to purchase convertible preferred stock		(713)
Amortization of premium on investments	668	11
Changes in operating assets and liabilities:		
Accounts receivable	(7,656)	(4,662)
Prepaid expenses and other current assets	(9,363)	(6,228)
Other noncurrent assets	38	1,550
Restricted cash	(97)	
Accounts payable	2,577	(189)
Accrued expenses	26,691	(1,764)
Other liabilities		4
Deferred revenue	(7,132)	(652)
Net cash provided by (used in) operating activities	92,858	(25,778)
Investing activities		
Purchases of property and equipment	(319)	(150)
Purchases of marketable securities	(73,284)	(24,465)
Proceeds from maturities and sales of marketable securities	35,552	6,000
Net cash used in investing activities	(38,051)	(18,615)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs		72,229
Proceeds from exercise of stock options	478	495
Principal payments on loans payable		(1,974)
Net cash provided by financing activities	478	70,750
Net increase in cash and cash equivalents	55,285	26,357
Cash and cash equivalents at beginning of period	45,791	45,290
Cash and cash equivalents at end of period	$ 101,076	$ 71,647
Supplemental cash flow and noncash investing and financing		
Cash paid for interest	$ 744	$ 484
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 cancer therapeutics company committed to discovering, developing and commercializing targeted cancer therapies to impact patients lives. The Company s product candidates are directed against important mechanisms, or targets, known or believed to be involved in cancer. Tivozanib, the Company s lead product candidate currently in phase 3 clinical development, which the Company recently partnered with Astellas Pharma Inc. and its wholly-owned direct subsidiaries (Astellas), is designed to provide an optimal blockade of the vascular endothelial growth factor, or VEGF, pathway by inhibiting all three VEGF receptors: VEGF receptors 1, 2 and 3. The Company also has a pipeline of monoclonal antibodies, including ficlatuzumab (AV-299), a product candidate that is currently in phase 2 clinical development, derived from its Human Response Platform, a novel method of building preclinical models of human cancer. 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 subsidiary.

(2) Basis of Presentation

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

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2011 or any other future period.

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2011, and for the three months ended March 31, 2011 and 2010, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2010 have been derived from the Company s audited financial statements. For further information, refer to the consolidated financial statements and accompanying footnotes included in its annual report on Form 10-K for the fiscal year ended December 31, 2010, which was filed with the U.S. Securities and Exchange Commission on March 11, 2011.

(3) Significant Accounting Policies

Basic and Diluted Income (Loss) per Common Share

The Company reports earnings per share in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 260, *Earnings Per Share* (ASC 260), which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. Preferred shares are not included in the calculation of net income (loss) per share until their conversion to common shares. Diluted earnings per share is computed by dividing net income 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. Under the treasury stock method, unexercised in-the-money stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period. Share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting are considered participating securities and are included in the calculation of basic and diluted earnings per share. Common stock equivalent shares have not been included in the net loss per share computation because their effect is anti-dilutive.

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Basic and diluted earnings per share for the three months ended March 31, 2011 and 2010 are as follows:

	Three Months Ended March 31, 2011	2010
	(in thousands, except per share data)	
Basic earnings per share		
Net income (loss)	$ 85,366	$ (14,378)
Income allocated to participating securities	(80)	
Income (loss) available to common stockholders	85,286	(14,378)
Basic weighted average common shares outstanding	35,781	6,340
Basic earnings (loss) per share	$ 2.38	$ (2.27)
Diluted earnings per share		
Net income (loss)	$ 85,366	$ (14,378)
Income allocated to participating securities	(73)	
Income (loss) available to common stockholders	85,293	(14,378)
Weighted average common shares outstanding	35,781	6,340
Diluted potential common shares	1,702	
Diluted weighted average common shares and potential common shares	37,483	6,340
Diluted earnings (loss) per share	$ 2.28	$ (2.27)

Stock-Based Compensation

The fair value of all stock-based awards is recognized in the Company s statements of operations on a straight-line basis over their requisite service periods based on their grant date fair values as calculated using the measurement and recognition provisions of FASB ASC Topic 718, *Stock Compensation*. During the three months ended March 31, 2011 and 2010, respectively, the Company recorded the following stock-based compensation expense:

	Three Months Ended March 31, 2011	2010
	(in thousands)	
Research and development	$ 547	$ 358
General and administrative	635	458
	$ 1,182	$ 816

Allocations to research and development expenses and general and administrative expenses are based upon the department to which the associated employee reported. No related tax benefits of the stock-based compensation expense have been recognized. Stock-based awards 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 revenues are generated primarily through collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses, or options to obtain licenses, to the Company s technology, (ii) research and development activities to be performed on behalf of the collaborative partner and (iii) in certain cases,

services in connection with the manufacturing of pre-clinical and clinical material. Payments to the Company under these arrangements typically include one or more of the following: non-refundable, up-front license fees; option exercise fees; funding of research and/or development efforts; milestone payments; and royalties on future product sales.

Effective January 1, 2011, the Company adopted Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends ASC Topic 605-25, *Revenue Recognition Multiple Element Arrangements*. In addition, effective January 1, 2011, the Company adopted ASU No. 2010-17, *Revenue Recognition Milestone Method*. Refer to New Accounting Pronouncements below for additional discussion of these standards and their impact on the Company s accounting for collaborative research, development and commercialization agreements.

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

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

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

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone, 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.

Principles of Consolidation

The Company s condensed 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, manufacturing costs and other contracted services, license fees, and other external costs.

Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made in accordance with the provisions of ASC Topic 730, *Research and Development*.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents at March 31, 2011 and December 31, 2010 consist of money market funds, commercial paper, corporate bonds and U.S. government agency securities.

Marketable Securities

Marketable securities at March 31, 2011 and December 31, 2010 primarily consist of U.S. treasuries, U.S. government agency securities, a foreign government agency security, commercial paper 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

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months. The Company classifies these investments as available-for-sale. Unrealized gains and losses are included in other comprehensive income as a component of stockholders equity 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, 2011 and 2010.

All marketable securities at March 31, 2011 and December 31, 2010 had maturities of one year or less.

Available-for-sale securities at March 31, 2011 and December 31, 2010 consist of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
March 31, 2011:				
Corporate debt securities	$ 103,877	$ 58	$ (47)	$ 103,888
U.S. Treasuries	7,176	3		7,179
Government agency securities	16,351	7		16,358
Foreign government agency security	4,087		(1)	4,086
	$ 131,491	$ 68	$ (48)	$ 131,511
December 31, 2010:				
Corporate debt securities	$ 71,615	$ 19	$ (27)	$ 71,607
U.S. Treasuries	5,178		(1)	5,177
Government agency securities	13,503		(6)	13,497
Foreign government agency security	4,131		(5)	4,126
	$ 94,427	$ 19	$ (39)	$ 94,407

The aggregate fair value of securities in an unrealized loss position for less than 12 months at March 31, 2011 was $61.5 million, representing twenty seven securities. There were no securities that were in an unrealized loss position for greater than 12 months at March 31, 2011. The unrealized loss was caused by a temporary change in the market for those securities. There was no change in the credit risk of the securities. To determine whether an other-than-temporary impairment exists, the Company performs an analysis to assess whether it intends to sell, or whether it would more likely than not be required to sell, the security before the expected recovery of the amortized cost basis. Where the Company intends to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded in the statement of operations as an other-than-temporary impairment charge. When this is not the case, the Company performs additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where the Company does not expect to receive cash flows, based on using a single best estimate, sufficient to recover the amortized cost basis of a security and these are recognized in other income (expense), net.

Marketable securities in an unrealized loss position at March 31, 2011 and December 31, 2010 consists of the following:

	Aggregate Fair Value	Unrealized Losses
	(in thousands)	
March 31, 2011:		
Corporate debt securities due in less than one year	$ 57,365	$ (47)
Foreign government agency security due in less than one year	4,086	(1)
	$ 61,451	$ (48)

	Aggregate Fair Value	Unrealized Losses
	(in thousands)	
December 31, 2010:		
Corporate debt securities due in less than one year	$ 27,536	$ (27)
U.S. Treasury due in less than one year	5,177	(1)
Government agency securities due in less than one year	13,497	(6)
Foreign government agency security due in less than one year	4,126	(5)
	$ 50,336	$ (39)

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Based on consideration of those factors described in the previous paragraph, the Company does not believe an other-than temporary impairment exists with respect to those securities in an unrealized loss position at March 31, 2011.

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.

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

Fair Value Measurements

The carrying amounts of the Company s financial instruments not required to be measured at fair value, which include accounts receivable, accounts payable, and loans payable, approximate their fair values at March 31, 2011 and December 31, 2010.

The Company records cash equivalents, marketable securities and warrants to purchase preferred stock at fair value. ASC Topic 820, *Fair Value Measurements and Disclosures,* establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between fair value measurements based on market data (observable inputs) and those based on the Company s own assumptions (unobservable inputs). The hierarchy consists of three levels:

Level 1 Quoted market prices in active markets for identical assets or liabilities. Assets utilizing Level 1 inputs include 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 government agency securities, including direct issuance bonds, and corporate bonds. These assets are valued using third party pricing sources which generally use interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing.

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.

The following tables summarize the cash equivalents and marketable securities measured at fair value on a recurring basis in the accompanying condensed consolidated balance sheets as of March 31, 2011 and December 31, 2010.

	Fair Value Measurements of Cash Equivalents and Marketable Securities as of March 31, 2011			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents	$ 97,419	$	$	$ 97,419
Marketable securities	7,179	124,332		131,511
	$ 104,598	$ 124,332	$	$ 228,930

	Fair Value Measurements of Cash Equivalents and Marketable Securities as of December 31, 2010			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents	$ 28,767	$ 14,015	$	$ 42,782
Marketable securities	5,177	89,230		94,407
	$ 33,944	$ 103,245	$	$ 137,189

Property and Equipment

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

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Long-lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever changes in business circumstances indicate that the carrying amount of the asset may not be fully recoverable. The Company has not recognized any impairment losses through March 31, 2011.

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 income (loss) as of March 31, 2011 and 2010 consists entirely of unrealized gains(losses) on available-for-sale securities.

	Three months Ended March 31,	
	2011	2010
	(in thousands)	
Net income (loss)	$ 85,366	$ (14,378)
Unrealized gains on marketable securities	40	19
Comprehensive income (loss)	$ 85,406	$ (14,359)

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.

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

Effective January 1, 2011, the Company adopted ASU 2009-13, which amends ASC Topic 605-25 to eliminate the residual method of allocation for multiple-deliverable revenue arrangements and requires that arrangement consideration be allocated at the inception of an arrangement to all deliverables using the relative selling price method. ASU No. 2009-13 also establishes a selling price hierarchy for determining the selling price of a deliverable, which includes: (1) vendor-specific objective evidence (VSOE) if available; (2) third-party evidence (TPE) if VSOE is not available; and (3) estimated selling price if neither VSOE nor TPE is available.

Prior to the adoption of ASU 2009-13, ASC Topic 605-25 required that the fair value of an undelivered item be determined by reference to VSOE or TPE. This was difficult to determine when a deliverable was not individually sold because of its unique features. Prior to the adoption of ASU 2009-13, if the fair value of the undelivered elements in the arrangement was not determinable, then revenue was generally deferred and recognized over the delivery period of the longest deliverable or when fair value was determined for the undelivered elements. The Company has elected to prospectively apply the provisions of ASU 2009-13 to all multiple-deliverable revenue arrangements entered into or materially modified after January 1, 2011. The adoption of ASU 2009-13 had a material impact on the Company s financial position and results of

operations for the three months ended March 31, 2011 as discussed in Note 4, Collaborations and License Agreements.

On January 1, 2011, the Company adopted ASU 2010-17, which codified a method of revenue recognition that has been common practice. 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. Because the Company s revenue recognition policy for milestone payments is generally consistent with ASU 2010-17, the

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adoption of this standard did not have a material effect on the Company s condensed consolidated financial position, results of operations or cash flows for the three months ended March 31, 2011. This standard may impact the Company s accounting for any milestone payments received in future periods.

Subsequent Events

The Company has evaluated all events or transactions that occurred after March 31, 2011 up through the date the Company issued these financial statements.

(4) Collaborations and License Agreements

Astellas Pharma Inc.

On February 16, 2011, the Company, together with its wholly owned subsidiary, entered into a Collaboration and License Agreement with Astellas (the Astellas Agreement), pursuant to which the Company and Astellas will develop and commercialize tivozanib, AVEO s product candidate currently in phase 3 clinical development, for the treatment of a broad range of cancers, including renal cell carcinoma (RCC) and breast and colorectal cancers. Under the terms of the Astellas Agreement, AVEO and Astellas will share responsibility for continued development and commercialization of tivozanib in North America and in Europe under a joint development plan and a joint commercialization plan, respectively. Throughout the rest of the world (the Royalty Territory), excluding Asia, where Kyowa Hakko Kirin (KHK) has retained all development and commercialization rights, Astellas has an exclusive, royalty-bearing license to develop and commercialize tivozanib. The terms of the Astellas Agreement are subject to the Company s obligations to KHK under a license agreement entered into with KHK in 2006 pursuant to which AVEO acquired exclusive rights to develop and commercialize tivozanib worldwide outside of Asia.

The Company will have lead responsibility for formulating the commercialization strategy for North America under the joint commercialization plan, with each of the Company and Astellas responsible for conducting fifty percent (50%) of the sales efforts and medical affairs activities in North America. Astellas will have lead responsibility for commercialization activities in Europe under the joint commercialization plan, with each of the Company and Astellas responsible for conducting fifty percent (50%) of the medical affairs activities in the major European countries. All costs associated with each party s conduct of development and commercialization activities (including clinical manufacturing and commercial manufacturing costs, if any) in North America and Europe, and any resulting profits or losses, will be shared equally between the parties.

Under the Astellas Agreement, the Company received an initial cash payment of $125 million, comprised of a $75 million license fee and $50 million in research and development funding. The Company retained net proceeds of approximately $97.6 million of the initial cash payment from Astellas, after payments to KHK and strategic, legal and financial advisors. The Company is also eligible to receive from Astellas an aggregate of approximately $1.3 billion in potential milestone payments, comprised of (i) up to $575 million in milestone payments upon achievement of specified clinical development and regulatory milestone events, including up to $90 million in milestone payments in connection with specified regulatory filings, and receipt of marketing approvals, for tivozanib to treat RCC in the United States and Europe, and (ii) up to approximately $780 million in milestone payments upon the achievement of specified sales events. In addition, if tivozanib is successfully developed and launched in the Royalty Territory, Astellas will be required to pay to AVEO tiered, double digit royalties on net sales of tivozanib in the Royalty Territory, if any, subject to offsets under certain circumstances. The Company is required to pay KHK low to mid teen royalties on its net sales in North America, and 30% of certain amounts the Company may receive from Astellas in connection with Astellas development and commercialization activities in Europe and the Royalty Territory, including up-front license fees, milestone payments and royalties.

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

The Company is accounting for the joint development and commercialization activities in North America and Europe as a joint risk sharing collaboration in accordance with ASC Topic 808, *Collaborative Arrangements*. Accordingly, the joint development and commercialization activities in North America and Europe were separated from the other deliverables included in the Astellas

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Agreement. In addition, these activities were not deemed to be separate deliverables under the Astellas Agreement, and accordingly, none of the up-front consideration was attributed to the joint development and commercialization activities in North America and Europe.

Payments from Astellas with respect to Astellas share of tivozanib development and commercialization costs incurred by the Company pursuant to the joint development plan are recorded as a reduction to research and development expense and general and administrative expense in the accompanying condensed consolidated financial statements due to the joint risk sharing nature of the activities in North America and Europe. As a result of the cost-sharing provisions in the Astellas Agreement, the Company reduced research and development expense by $6.2 million and general and administrative expense by $0.2 million during the three months ended March 31, 2011. The Company recorded a corresponding receivable of $6.4 million for amounts due from Astellas pursuant to the cost-sharing provisions that is included in accounts receivable on the condensed consolidated balance sheet at March 31, 2011.

Activities under the Astellas Agreement outside of the joint development and commercialization activities in North America and Europe, including the co-exclusive license to develop and commercialize tivozanib in North America and Europe that was delivered prior to the initiation of the collaborative activities in North America and Europe, were evaluated under ASC Topic 605-25 (as amended by ASU 2009-13) to determine if they represented a multiple element revenue arrangement. The Astellas Agreement includes the following deliverables: (1) a co-exclusive license to develop and commercialize tivozanib in North America and Europe (the License Deliverable); (2) a combined deliverable comprised of an exclusive royalty-bearing license to develop and commercialize tivozanib in the Royalty Territory and the Company s obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its development and commercialization of tivozanib in the Royalty Territory (the Royalty Territory Deliverable); and (3) the Company s obligation to supply clinical material to Astellas for development of tivozanib in the Royalty Territory (the Clinical Material Deliverable). All of these deliverables were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting under ASC Topic 605-25. Factors considered in this determination included, among other things, the subject of the licenses and the research and development and commercial capabilities of Astellas.

The Company allocated the up-front consideration of $125 million to the deliverables based on management s best estimate of selling price of each deliverable using the relative selling price method as the Company did not have VSOE or TPE of selling price for such deliverables. The Company s best estimate of selling price considered discounted cash flow models, the key assumptions of which included the market opportunity for commercialization of tivozanib in North America and Europe and the Royalty Territory, the development costs and market opportunity for the expansion of tivozanib into other solid tumor types, and the time to commercialization of tivozanib for all potential oncology indications. The Company allocated up-front consideration of $120.2 million to the License Deliverable and up-front consideration of $4.8 million to the Royalty Territory Deliverable. The relative selling price of the Company s obligation under the Clinical Material Deliverable had *de minimus* value.

The Company recorded the $120.2 million relative selling price of the License Deliverable as collaboration revenue during the three months ended March 31, 2011 upon delivery of the license, and deferred approximately $4.8 million of revenue representing the relative selling price of the Royalty Territory Deliverable. The Company is recording the $4.8 million of revenue attributed to Royalty Territory Deliverable ratably over the Company s period of performance through April 2022, the remaining patent life of tivozanib. The Company recorded approximately $54,000 of revenue during the three months ended March 31, 2011 associated with the Royalty Territory Deliverable.

The Company believes the development and approval milestones that may be received under the Astellas Agreement are consistent with the definition of a milestone included in ASU 2010-17 and, accordingly, the Company will recognize payments related to the achievement of such milestones, if any, as revenue upon receipt. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve each milestone, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone.

The adoption of ASU 2009-13 on January 1, 2011 materially affected the Company s accounting for the Astellas Agreement. Prior to the adoption of ASU 2009-13, the Royalty Territory Deliverable would not have met the criteria to be considered a separate unit of accounting because neither VSOE nor TPE of fair value exists for this deliverable. Accordingly, the entire arrangement consideration of $125 million would have been deferred at the inception of the arrangement and recognized ratably over the Company s period of performance through April 2022, the remaining patent life of tivozanib. If the Astellas Agreement had been accounted for prior to the adoption of ASU 2009-13, the Company would have recognized revenue of $1.4 million during the three months ended March 31, 2011.

Schering-Plough (now Merck)

In March 2007, the Company 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,

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under which the Company granted Merck exclusive, worldwide rights to develop and commercialize all of the Company s monoclonal antibody antagonists of hepatocyte growth factor, or HGF, including ficlatuzumab, for therapeutic and prophylactic use in humans and for veterinary use. The Company also granted Merck an exclusive, worldwide license to related biomarkers for diagnostic use. The Company also conducted translational research using its Human Response Platform to guide the clinical development of ficlatuzumab. Merck was responsible for all costs related to the clinical development of ficlatuzumab and clinical and commercial manufacturing. On September 28, 2010, the Company received notice from Merck of termination of the collaboration agreement effective as of December 27, 2010, at which point the Company became responsible for the performance and funding of all future research, development, manufacturing and commercialization activities for ficlatuzumab.

Under the agreement, Merck paid the Company an up-front payment of $7.5 million in May 2007, which was being amortized over the Company s period of substantial involvement, which was initially estimated to be through completion of the first phase 2 proof-of-concept trial for ficlatuzumab (which was expected to be the first half of 2012), but was adjusted to reflect the termination of the agreement effective on December 27, 2010. In June 2010, the Company earned and received an $8.5 million milestone payment in connection with the enrollment of patients in the Company s phase 2 clinical trial of ficlatuzumab under the agreement. Since the $8.5 million milestone payment earned in June 2010 was considered substantive and at risk, it was included in revenue for the year ended December 31, 2010.

In March 2011, in connection with the transition of responsibility for the ficlatuzumab program from Merck back to the Company, the Company made a $10.2 million payment to Merck for the purchase of a supply of ficlatuzumab to support ongoing clinical studies. The Company has taken title to approximately $1.1 million of this material as of March 31, 2011 and, pursuant to the provisions of ASC Topic 730, has recognized this amount as research and development expense during the three months ended March 31, 2011. The remaining $9.1 million is included as a component of the prepaid expenses and other current assets balance on the condensed consolidated balance sheet at March 31, 2011. This prepaid amount will be recognized as research and development expense when the Company receives the remaining material, which is expected to occur during the second quarter of 2011.

OSI Pharmaceuticals (OSI)

In September 2007, the Company entered into a collaboration and license agreement with OSI Pharmaceuticals, Inc., (a wholly-owned subsidiary of Astellas US Holding Inc., a holding company owned by Astellas Pharma Inc.) or OSI, which 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. 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.

The Company accounts for the OSI arrangement pursuant to ASC Topic 605-25. The deliverables under the arrangement include use of the Company s proprietary *in vivo* models, research and development services provided using 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, translational research related to cancer and other diseases and 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. Since these services were provided using the Company s proprietary technology, management concluded the arrangement should be accounted for as a single unit of accounting.

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, OSI made research payments of $625,000 per quarter through July 2009. In addition, OSI purchased 1,833,334 shares of Series C Convertible 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 Convertible Preferred Stock sold in April 2007; accordingly, the Company is recognizing the premium of $917,000 as additional license revenue on a straight-line basis over the period of substantial involvement.

In consideration for the additional rights provided for pursuant to the July 2009 expanded agreement, OSI paid the Company an up-front payment of $5.0 million, which was recorded in deferred revenue and is being amortized over the Company s remaining period of substantial involvement which is now determined to be July 2011. 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, 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 consummated by the Company in

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March 2010 and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series E Convertible Preferred Stock were converted into one share of common stock. The Company determined that the 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 Convertible 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 is recognizing the premium of $3,900,000 as additional license revenue on a straight-line basis over the period of substantial involvement which is now determined to be July 2011.

Under the July 2009 expanded 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 $3.0 million for certain research milestones, and up to $24.0 million in biomarker related milestones. In March 2011 the Company received $1.5 million related to achieving certain of these research milestones under the agreement. These research milestones are not considered to be at risk and substantive, therefore, the $1.5 million in payments are being deferred and will be recognized on a straight-line basis over the remaining estimated period of substantial involvement which is now determined to be July 2011. 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 milestones earned to date are for selection of targets, delivery of models, delivery of tumor archives or delivery of cell lines.

In November 2010, OSI exercised its option under the July 2009 expanded agreement providing the right for OSI to license certain elements of the Company s proprietary technology platform, including components of the Human Response Platform for the identification/characterization of novel epithelial-mesenchymal transition agents and proprietary patient selection biomarkers, in support of OSI s clinical development programs. The Company did not consider the option granted to OSI in July 2009 as a deliverable as there was significant uncertainty that this option would ultimately be exercised. The Company received $12.5 million upon delivery of the notice of option exercise, and is in the process of transferring the relevant technology to OSI. The remaining $12.5 million will be paid following the successful transfer of the applicable technology, which is expected to be completed in July 2011. The Company has deferred the initial $12.5 million payment, and is recognizing the full $25 million relating to the option exercise by OSI over the technology transfer period.

The Company believes the application of the provisions of ASU 2009-13 to this arrangement would not change the units of accounting under the arrangement or the manner in which the Company recognizes revenue for the arrangement.

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.

The Company accounts for the Biogen Idec arrangement pursuant to ASC Topic 605-25. The deliverables under the arrangement include an option for a co-exclusive, world-wide license to develop and manufacture ErbB3 antibody products and an option for an exclusive license to commercialize ErbB3 antibody products in all countries in the world other than the United States, Canada and Mexico. The Company determined that these deliverables did not have standalone value due to the fact that the program was still in preclinical development and required the Company s experience to advance development of the product. As such, the Company determined that the agreement should be accounted for as one unit of accounting.

Under the terms of the agreement, Biogen Idec paid the Company an upfront cash payment of $5.0 million in March 2009, which is being 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 Convertible Preferred Stock at a per share price of $4.00, resulting in gross proceeds to the Company of $30.0 million. In connection with the initial public offering consummated by the Company in March 2010 and the related 1:4 reverse stock split of the common stock, each four shares of outstanding Series E Convertible Preferred Stock were converted into one share of common stock. The Company determined that the price of $4.00 paid by Biogen Idec included a premium of $1.09 per share over the fair value of the Series E Convertible Preferred Stock of $2.91 as calculated by the Company in its retrospective stock valuation. 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 is recognizing 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 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 was included in revenue for the quarter ended March 31, 2010. The Company

could also receive (i) an additional pre-clinical discovery and development milestone payment of $5.0 million, and (ii) if Biogen Idec exercises its option to obtain exclusive rights to commercialize ErbB3 antibody products in its territory, an

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option exercise fee and regulatory milestone payments of $50.0 million in the aggregate. The Company considers these milestone payments to be consistent with the definition of a milestone included in ASU 2010-17 and, accordingly, will recognize payments related to the achievement of such milestones, if any, as revenue upon receipt. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve each milestone, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone.

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.

The Company believes the application of the provisions of ASU 2009-13 would not change the units of accounting under the arrangement or the manner in which the Company recognizes revenue for the arrangement.

Kirin Brewery Co. Ltd. (KHK)

In December 2006, the Company entered into an exclusive license agreement with Kirin Brewery Co. Ltd. (now Kyowa Hakko Kirin) (KHK) 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 (the KHK Agreement). Upon entering into the KHK Agreement, the Company made a cash payment in the amount of $5.0 million. In March 2010, the Company made a $10.0 million milestone payment to KHK in connection with the dosing of the first patient in the Company s phase 3 clinical trial of tivozanib. 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 KHK 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 KHK Agreement, subject to certain restrictions, and, as previously described, on February 16, 2011, the Company entered into the Astellas Agreement. Pursuant to the KHK Agreement, the Company is required to pay KHK 30% of certain amounts the Company receives under the Astellas Agreement in connection with Astellas development and commercialization activities in Europe and the Royalty Territory, including up-front license fees, milestone payments and royalties the Company may receive from Astellas. The Company is not obligated to make any payments to KHK in respect of research and development funding or equity investments, subject to certain limitations.

The Company recorded $22.5 million of research and development expense in the quarter ended March 31, 2011 associated with a $22.5 million payment due to KHK related to the up-front license payment received under the Astellas Agreement. The payment was made in April 2011 and was included in accrued expenses on the condensed consolidated balance sheet at March 31, 2011.

(5) Prepaid Expenses

Prepaid expenses and other current assets consisted of the following:

	March 31, 2011	December 31, 2010
	(in thousands)	
Prepaid clinical expenses	$ 11,993	$ 2,741
Interest receivable	922	1,092
Prepaid maintenance costs	634	495
Prepaid insurance	160	311
Other prepaid expenses and current assets	512	225
	$ 14,221	$ 4,864

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(6) Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2011	December 31, 2010
	(in thousands)	
License fees	$ 22,500	
Clinical expenses	7,221	$ 5,676
Professional fees	4,430	204
Salaries and benefits	1,846	3,696
Other	815	545
	$ 36,812	$ 10,121

In the first quarter of 2011, the Company recorded a $4.25 million expense related to payments owed to a financial advisor in connection with the consummation of the Astellas Agreement. These amounts had not been paid as of March 31, 2011, and are included in our accrued expenses balance on the condensed consolidated balance sheet at March 31, 2011. These amounts were paid in April 2011.

(7) Loans Payable

On May 15, 2008, the Company entered into a $21.0 million financing agreement with Hercules Technology Growth Capital Inc., or Hercules Technology Growth, and Comerica Bank, referred to as the prior loan agreement. On May 28, 2010, the Company entered into a new loan and security agreement with Hercules Technology II, L.P. and Hercules Technology III, L.P., affiliates of Hercules Technology Growth, referred to as the new loan agreement, pursuant to which the Company received a loan in the aggregate principal amount of $25.0 million and repaid the remaining outstanding principal and interest under the prior loan agreement of $17.4 million. The Company was initially required to repay the aggregate principal balance of the loan that is outstanding under the new loan agreement in 30 equal monthly installments of principal starting on April 1, 2011. However, the new loan agreement provides that such date will be extended under certain circumstances. On April 1, 2011, the Company triggered the first of two possible extensions to the date from which principal payments will be made. The Company is now required to repay the aggregate principal balance of the loan that is outstanding under the new loan agreement in 30 equal monthly installments of principal starting on October 1, 2011. The current portion of loans payable as of March 31, 2011 includes this extension. Per annum interest is payable at the greater of 11.9% and an amount equal to 11.9% plus the prime rate of interest minus 4.75%, provided however, that the per annum interest shall not exceed 15.0%. The Company must make interest payments on the loan each month following the date of borrowing under the new loan agreement. The entire principal balance and all accrued but unpaid interest will be due and payable on March 1, 2014, provided, however, such amounts will be due and payable on a later date under certain circumstances specified in the new loan agreement. The loan is secured by a lien on all of the Company s personal property as of, or acquired after, the date of the new loan agreement, except for intellectual property.

The new loan agreement requires a deferred charge of $1.25 million to be paid in May 2012 related to the termination of the prior loan agreement. The new loan also includes an additional deferred charge of $1.24 million due upon the maturity of the new loan which has been recorded as a loan discount and is being amortized to interest expense over the term of the new loan agreement using the effective interest rate method. The Company recorded a long-term liability for the full amount of the charge since the payment of such amount is not contingent on any future event. The Company incurred approximately $193,000 in loan issuance costs related to the new loan agreement paid directly to the lenders, which have been offset against the loan proceeds as a loan discount. As part of the new loan agreement, the Company issued warrants to the lenders on June 2, 2010 to purchase up to 156,641 shares of the Company s common stock at an exercise price equal to $7.98 per share. These warrants expire seven years from issuance. The Company recorded the relative fair value of the warrants of approximately $780,000 as equity and as a discount to the related loan outstanding and will amortize the value of the discount to interest expense over the term of the loan using the effective interest method. The relative fair value of the warrant was calculated using the Black-Scholes option-pricing model with the following assumptions: volatility of 64.12%, an expected term equal to the contractual life of the warrant (seven years), a risk-free interest rate of 2.81% and no dividend yield. The resulting effective interest rate including the fair value of the warrant, the new loan issuance costs and the deferred charge approximates 16.1%.

The new loan agreement defines events of default, including the occurrence of an event that results in a material adverse effect upon the Company s business operations, properties, assets or condition (financial or otherwise), its ability to perform its obligations under and in accordance with the terms of the new loan agreement, or upon the ability of the lenders to enforce any of their rights or remedies with respect to such obligations, or upon the collateral under the new loan agreement or upon the liens of the lenders on such collateral or upon the priority of such liens. Hercules Technology Growth Capital also received an option, subject to the Company s written consent, not to be unreasonably withheld, to purchase, either with cash or through conversion of outstanding principal under the loan, up to $2.0 million of equity of the Company sold in any sale by the Company to third parties of equity securities resulting in at least $10.0 million in net cash proceeds to the Company, subject to certain exceptions. The Company has evaluated the embedded

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conversion option, and has concluded that it does not need to be bifurcated and separately accounted for. No amount will be recognized for the conversion feature until such time as the conversion feature is exercised and it can be determined whether a beneficial conversion feature exists. As of March 31, 2011, there have been no events of default under the loan. As of March 31, 2011, the principal balance outstanding was $25.0 million.

Future minimum payments under the loans payable outstanding as of March 31, 2011 are as follows:

Years Ending December 31:	
2011(9 months remaining)	$ 4,423
2012	12,860
2013	11,610
2014	4,213
	33,106
Less amount representing interest	(5,619)
Less discount	(1,335)
Less deferred charges	(2,487)
Less current portion	(3,694)
Loans payable, net of current portion and discount	$ 19,971

(8) Stock-based Compensation

Stock Plans

The Company issued stock options and restricted stock awards during the three months ended March 31, 2011.

A summary of the status of the Company s stock option activity at March 31, 2011 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, 2010	3,605,718	$ 6.44		
Granted	443,611	$ 14.13		
Exercised	(240,182)	$ 1.99		
Cancelled	(29,491)	$ 9.84		
Outstanding at March 31, 2011	3,779,656	$ 7.59	7.02	$ 22,247,135
Vested or expected to vest at March 31, 2011	3,639,034	$ 7.39	6.93	$ 22,106,112
Exercisable at March 31, 2011	2,395,732	$ 5.20	5.89	$ 19,475,937

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, 2011 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, 2011. As of March 31, 2011, there was $8.0 million of total unrecognized stock-based compensation expense related to stock options granted under the Company s 2002 Stock Incentive Plan and 2010 Stock Incentive Plan (the plans). The expense is expected to be recognized over a weighted-average period of 2.7

years.

Stock-based awards to employees are required to be measured at fair value. The Company uses the Black-Scholes pricing model in order to calculate the estimated fair value of its stock option grants. This model requires the Company to make assumptions with respect to factors such as volatility, interest rate, dividend yield and term. 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. The Company utilized a weighted average method of using its own data for the quarters that it has been public, along with data it obtained from its peer companies. 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.

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During the three months ended March 31, 2011 and 2010, respectively, the assumptions used in the Black-Scholes pricing model for new grants were as follows:

	Three Months Ended March 31,	
	2011	2010
Volatility factor	65.01%	63.92%
Risk-free interest rate	2.57%	2.92%
Dividend yield		
Expected term (in years)	6.25	6.25

The restricted stock activity for the three months ended March 31, 2011 is as follows:

	Number of Shares	Weighted-Average Exercise Price
Nonvested at December 31, 2010		
Granted	69,000	$ 14.16
Cancelled		
Expired		
Vested/Released		
Nonvested at March 31, 2011	69,000	$ 14.16

As of March 31, 2011, there was $0.7 million of total unrecognized stock-based compensation expense related to restricted stock awards granted under the plans. The expense is expected to be recognized over a weighted-average period of 0.9 years.

On February 15, 2011, the Company s Board of Directors adopted, subject to stockholder approval, amendment no. 1 to the Company s 2010 Stock Incentive Plan to increase the amount of options granted to newly elected Board members, and amendment no. 2 to the Company s 2010 Stock Incentive Plan to increase the number of shares of common stock reserved for issuance under the Company s 2010 Stock Incentive Plan by 3,000,000. Pursuant to amendment no. 2, the number of shares of the Company s common stock reserved for issuance under the 2010 Stock Incentive Plan is the sum of (i) 4,875,000 shares of common stock plus (ii) the number of shares of common stock subject to awards granted under the 2002 Stock Incentive 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 5,500,000 shares.

On April 12, 2011, the Company s board of directors approved an amendment no. 3 to the Company s 2010 Stock Incentive Plan which became effective upon its approval, to include the following provisions:

- restrictions on repricing, within the meaning of the rules of the NASDAQ Stock Market, any stock option or stock appreciation rights, or SARs, award unless such action is approved by the Company s stockholders;
- minimum vesting provisions with respect to certain awards granted under the plan;
- a maximum limit on the aggregate number of shares that may be granted as awards other than options; and
- revised share counting rules that prohibit the recycling of shares that are tendered or withheld to pay the exercise price of an award or to satisfy tax withholding obligations.

(9) Income Taxes

The Company calculates its provision for income taxes on ordinary income based on its projected annual tax rate for the year. As of March 31, 2011, the Company is projecting an ordinary loss for the year ended December 31, 2011 and, since it maintains a full valuation allowance on all of its deferred tax assets, the Company has recorded no income tax provision or benefit in the current quarter.

As a result of the initial public offering of the Company s common stock in March 2010, the Company underwent a change in ownership for purposes of Internal Revenue Code Section 382. As a result, the Company believes 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 limitation based on the value of the Company immediately before the stock offering. The annual limitation will be increased 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.

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(10) 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. The reverse stock split was effected on February 18, 2010. All share and per share amounts in the condensed 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. In March 2010, the underwriters of the 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 additional net proceeds to the Company of approximately $8.1 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.

Private Placement

On October 28, 2010, the Company entered into a definitive agreement with respect to the private placement of 4.5 million shares of its unregistered common stock at $13.50 per share to a group of institutional and accredited investors. The Company completed the private placement on November 3, 2010, resulting in approximately $56.6 million in net proceeds to the Company.

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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 on Form 10-Q for the quarter ended March 31, 2011, as well as the audited consolidated financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2010, included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the Securities and Exchange Commission, or SEC on March 11, 2011. This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements 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 anticipate, target, project, believe, goals, estimate, potential, predict, may, will, expect, might, could, intend, variations of these those terms and similar expressions are intended to identify these forward-looking statements. Readers are cautioned that these forward-looking statements are predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading Risk Factors in Item 1A of Part II and elsewhere in this report.

Overview

We are a cancer therapeutics company committed to discovering, developing and commercializing targeted cancer therapies to impact patients lives. Our product candidates are directed against important mechanisms, or targets, known or believed to be involved in cancer. Tivozanib, our lead product candidate, which we recently partnered with Astellas Pharma Inc., or Astellas, is designed to provide an optimal blockade of the vascular endothelial growth factor, or VEGF, pathway by inhibiting all three VEGF receptors: 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. Final data from the trial show the overall median progression-free survival of patients in the phase 2 clinical trial was 11.7 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 most common treatment-related side effects seen in the phase 2 clinical trial were hypertension (44.9%) and dysphonia, or hoarseness of voice (21.7%). Severe (grade ^{3}/4) hypertension was observed in 11.8% of patients in the trial. Additionally, the incidence of other side effects in the phase 2 clinical trial, which are commonly associated with other VEGF receptor inhibitors, such as diarrhea, rash, mucositis, stomatitis, fatigue, and hand-foot syndrome, was notably low in comparison to clinical trial results of other VEGF receptor inhibitors. Severe (grade ^{3}/4) incidences of these side effects that were considered by the investigator to be possibly related to tivozanib occurred in fewer than two percent of patients. In February 2010, we initiated enrollment in our global, phase 3 clinical trial comparing the efficacy and safety of tivozanib with Nexavar® (sorafenib), an approved therapy, for first-line treatment in RCC, which we refer to as the TIVO-1 study. The TIVO-1 study is being conducted in patients with advanced clear cell RCC who have undergone a prior nephrectomy and who have not received any prior VEGF-targeted therapy. In August 2010, we completed enrollment in the TIVO-1 study with 517 patients. Based upon the current rate of events, we do not anticipate receiving top-line TIVO-1 data until at least the fourth quarter of this year. 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 evaluating tivozanib in multiple clinical trials including: a completed phase 1b clinical trial in combination with Torisel® (temsirolimus), an approved inhibitor of the receptor known as mammalian target 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 gastrointestinal cancers, including colorectal cancer; a recently completed phase 1b clinical trial in combination with Taxol® (paclitaxel) in patients with metastatic breast cancers; a phase 1b clinical trial in combination with Xeloda® (capecitabine), an oral chemotherapeutic agent, in patients with breast and colorectal cancers; a completed phase 1b clinical trial as a monotherapy in patients with non-small cell lung cancer; and a phase 2 clinical trial designed to evaluate biomarkers of tivozanib in patients with RCC. In addition, a phase 1 investigator sponsored clinical trial was completed in which tivozanib was combined with Afinitor® (everolimus), an approved inhibitor of the mTOR receptor, in patients with advanced colorectal cancer. The phase 2 portion of this investigator sponsored trial combining tivozanib with Afinitor is enrolling patients with refractory metastatic colorectal cancer. We expect that the results of these trials will help to inform our clinical development plans for tivozanib as a monotherapy and in combination with other anti-cancer therapies in multiple cancer indications.

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We acquired exclusive rights to develop and commercialize tivozanib worldwide outside of Asia pursuant to a license agreement we entered into with Kirin Brewery Co. Ltd. (now Kyowa Hakko Kirin), or KHK, 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 outside of Asia. KHK has retained all rights to tivozanib in Asia. We have obligations to make milestone and royalty payments to KHK. The royalty rates range from the low to mid teens as a percentage of our net sales of tivozanib. As discussed below under the heading Strategic Partnerships , we recently entered into a strategic collaboration with Astellas in which we have agreed to share responsibility, including all profits and losses, with Astellas for continued development and commercialization of tivozanib in North America and Europe. Throughout the rest of the world, outside of North America, Europe and Asia, we granted Astellas an exclusive, royalty-bearing license to develop and commercialize tivozanib. We are required to pay KHK low to mid teen royalties on our net sales in North America, and 30% of certain amounts we receive in connection with Astellas development and commercialization activities of tivozanib outside of North America and Asia, including certain amounts we received or will receive from Astellas as up-front license fees, milestone payments and royalties.

In addition to tivozanib, we have a pipeline of monoclonal antibodies derived from our proprietary Human Response Platform , a novel method of building preclinical models of human cancer, which are intended to more accurately represent cancer biology in patients. Ficlatuzumab (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 observed that the HGF/c-Met pathway is a significant driver of tumor growth. We have completed a phase 1 clinical trial of ficlatuzumab and initiated a phase 2 clinical trial in patients with non-small cell lung cancer in May 2010. In 2007, we entered into an agreement with Merck and Co., Inc., or Merck (through its subsidiary Schering Corporation), under which we granted Merck exclusive worldwide rights to develop and commercialize ficlatuzumab. Pursuant to the agreement, Merck funded all research, development and manufacturing expenses, subject to an agreed-upon budget, and under which Merck was obligated to pay development milestones to us, and, as applicable, royalties on product sales. On September 28, 2010, we received notice from Merck of termination of the collaboration agreement effective as of December 27, 2010, at which point we became responsible for the performance and funding of all future research, development, manufacturing and commercialization activities for ficlatuzumab.

We have also 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 our third clinical candidate AV-203, which targets the ErbB3 receptor (partnered with Biogen Idec, Inc., or Biogen Idec), as well as programs directed toward the RON receptor, the Notch receptors and the Fibroblast Growth Factor receptors.

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.

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, 2011, have principally funded our operations through:

- $261.9 million of non-dilutive capital in the form of license fees, milestone payments and research and development funding received from our strategic partners;

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

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

$25.0 million of loan proceeds in connection with our loan agreement with Hercules Technology II, L.P. and Hercules Technology III, L.P; and

$60.8 million of gross proceeds from the private placement of 4.5 million shares of our unregistered common stock at $13.50 per share to a group of institutional and accredited investors in November 2010.

We do not have a history of being profitable and, as of March 31, 2011, we had an accumulated deficit of $151.1 million. Although we did generate a net profit of $85.4 million for the three months ended March 31, 2011, we do not expect to be profitable for the year ended December 31, 2011 or the foreseeable future. We incurred net losses of approximately $14.4 million during the three months ended March 31, 2010. We anticipate that we will continue to incur significant operating costs over the next several years as we advance 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, and the continued clinical development of our phase 2 product candidate, ficlatuzumab. We will need additional financing to support our operating activities.

Strategic Partnerships

Kyowa Hakko Kirin

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

Upon entering into the license agreement with KHK, 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 KHK tiered royalty payments on net sales we make of tivozanib in North America. The royalty rates under the agreement range from the low to mid teens as a percentage of our net sales of tivozanib. In connection with the execution of our collaboration agreement with Astellas discussed below, we are required to pay KHK 30% of the license fee received from Astellas as well as certain amounts we may receive from Astellas in connection with Astellas development and commercialization activities outside of North America and Asia related to tivozanib, other than amounts we receive in respect of research and development funding or equity investments, subject to certain limitations.

In connection with our obligation under the license agreement with KHK to pay a certain percentage of sublicense revenue we receive, we incurred expenses of $22.5 million for our payment to KHK related to the up-front license payment received under the collaboration agreement with Astellas. This amount had not been paid as of March 31, 2011, and is included in our accrued expenses balance on the condensed consolidated balance sheet at March 31, 2011. The full amount was paid to KHK in April 2011.

Astellas Pharma Inc.

In February 2011, we entered into a collaboration and license agreement with Astellas and certain of its indirect wholly owned subsidiaries in connection with which we and Astellas will develop and commercialize tivozanib for the treatment of a broad range of cancers, including RCC, and breast and colorectal cancers. Under the terms of the collaboration agreement, we and Astellas will share responsibility for continued development and commercialization of tivozanib in the United States, Mexico and Canada, or North America, and in Europe under the joint development plan and joint commercialization plan, respectively. Throughout the rest of the world (which excludes North America, Europe and Asia), which we refer to as the royalty territory, Astellas has an exclusive, royalty-bearing license to develop and commercialize tivozanib. Our plan to commercialize tivozanib in collaboration with Astellas, as described herein, is subject to our and Astellas s receipt of necessary regulatory approvals from the FDA and foreign regulatory authorities based upon favorable results in clinical trials. There can be no assurance that such approvals will be obtained.

Assuming successful approvals of tivozanib by applicable regulatory agencies, we will hold all marketing authorizations in North America, including any new drug application in the United States, and Astellas will hold all marketing authorizations in the rest of the world, other than

Asia.

Assuming successful approvals of tivozanib by applicable regulatory agencies, we, as the lead commercialization party in North America, will have lead responsibility for formulating the commercialization strategy for North America under the joint commercialization plan, with each of us and Astellas responsible for conducting fifty percent (50%) of the sales efforts and medical affairs activities in North America. Astellas will have lead responsibility for commercialization activities in Europe under the joint

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commercialization plan, and we will be responsible for conducting fifty percent (50%) of the medical affairs activities in the major European countries. All costs associated with each party s conduct of development and commercialization activities (including clinical manufacturing and commercial manufacturing costs, if any) in North America (including any regulatory milestones and royalties associated with tivozanib in North America which may become payable by us to KHK under our license agreement with KHK), and any resulting profits or losses, will be shared equally between the parties. All costs associated with each party s conduct of development and commercialization activities (including clinical manufacturing and commercial manufacturing costs, if any) in Europe, and any resulting profits or losses, will be shared equally between the parties. As between the parties, we will remain responsible for complying with our sublicense revenue sharing obligations, if any, to KHK under our license agreement with KHK in connection with the development and commercialization of tivozanib outside of North America.

We are responsible for manufacturing, through our third party manufacturer, all of Astellas s requirements for tivozanib pursuant to a clinical supply agreement which we have entered into with Astellas, and a commercial supply agreement which the parties are currently negotiating.

Each party is obligated to use commercially reasonable efforts to develop and commercialize tivozanib in each of the United States, Mexico and Canada, including the filing of an NDA in the United States to treat patients with RCC, and to develop and commercialize tivozanib in each European country specified in the agreement. Astellas is also obligated to use commercially reasonable efforts to develop and commercialize tivozanib in each country in the royalty territory.

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

In connection with the agreement, we received an initial cash payment of $125 million, comprised of a $75 million license fee and $50 million in research and development funding, both of which are non-creditable and non-refundable against any amounts due under the collaboration agreement. We retained net proceeds of approximately $97.6 million of the initial cash payment from Astellas, after payments to KHK and strategic, legal and financial advisors. We are also eligible to receive an aggregate of approximately $1.3 billion in potential milestone payments, comprised of (i) up to $575 million in milestone payments upon achievement of specified clinical development and regulatory milestone events, including up to $90 million in milestone payments in connection with specified regulatory filings, and receipt of marketing approvals, for tivozanib to treat RCC in the United States and Europe, and (ii) up to $780 million in milestone payments upon the achievement of specified sales events. In addition, if tivozanib is successfully developed and launched in the royalty territory, Astellas will be required to pay to us tiered, double digit royalties on net sales of tivozanib in the royalty territory, if any, subject to offsets under certain circumstances. We are required to pay KHK low to mid teen royalties on our net sales in North America, and 30% of certain amounts we may receive from Astellas in connection with Astellas development and commercialization activities in Europe and the royalty territory, including up-front license fees, milestone payments and royalties.

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

We are accounting for the joint development and commercialization activities in North America and Europe as a joint risk sharing collaboration in accordance with Accounting Standards Codification (ASC) 808 *Collaborative Arrangements*. Accordingly, the joint development and commercialization activities in North America and Europe were separated from the other deliverables included in the agreement with Astellas. In addition, these activities were not deemed to be separate deliverables under the agreement with Astellas, and accordingly, none of the up-front consideration paid by Astellas under the agreement was attributed to the joint development and commercialization in North America and Europe.

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Payments from Astellas with respect to Astellas share of research and development costs incurred by us are recorded as a reduction to expense due to the joint risk sharing provisions of the agreement in North America and Europe. As a result of the cost-sharing provisions in the agreement with Astellas, we reduced research and development expense by $6.2 million and general and administrative expense by $0.2 million during the three months ended March 31, 2011. We recorded a corresponding receivable of $6.4 million for amounts due from Astellas representing its reimbursement for the cost sharing provisions of the agreement in North America and Europe during the three months ended March 31, 2011 that is included in accounts receivable on the condensed consolidated balance sheet at March 31, 2011.

Activities under the agreement with Astellas outside of the joint development and commercialization activities in North America and Europe were evaluated under ASC 605-25 *Revenue Recognition- Multiple Element Arrangements* to determine if they represented a multiple element revenue arrangement. The agreement with Astellas includes the following deliverables outside of the joint development and commercialization activities in North America and Europe: a co-exclusive license to develop and commercialize tivozanib in North America and Europe, a royalty-bearing license to develop and commercialize tivozanib in the royalty-bearing territory, which includes our obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its development and commercialization of tivozanib in the royalty-bearing territory, and our obligation to supply clinical material to Astellas for development of tivozanib in the royalty-bearing territory. All of these deliverables were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting under ASC Topic 605-25. ASC Topic 605-25 establishes a selling price hierarchy for determining the selling price of a deliverable, which includes: (1) vendor-specific objective evidence if available; (2) third-party evidence if vendor-specific objective evidence is not available; and (3) estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. We allocated the up-front consideration of $125 million to the deliverables based on our best estimate of selling price of each deliverable using the relative selling price method as we did not have vendor specific objective evidence or third party evidence for such deliverables. Our best estimate of selling price considered discounted cash flow models, the key assumptions of which included the market opportunity for commercialization of tivozanib in North America and Europe and in the royalty-bearing territory, the development costs and market opportunity for the expansion of tivozanib into other solid tumor types, and the time to commercialization of tivozanib for all potential oncology indications. We allocated $120.2 million of the up-front consideration from Astellas to the co-exclusive license in North America and Europe and $4.8 million of the up-front consideration from Astellas to the combined deliverable representing a royalty-bearing license to develop and commercialize tivozanib in the royalty-bearing territory along with our obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its use in the royalty-bearing territory. The relative selling price for our obligation to supply clinical material to Astellas for development in the royalty-bearing territory had de minimus value.

We recorded the $120.2 million relative selling price of the co-exclusive license granted in North America and Europe as collaboration revenue during the three months ended March 31, 2011 upon delivery of the license, and deferred approximately $4.8 million of revenue representing the relative selling price of the royalty-bearing license to develop and commercialize tivozanib in the royalty-bearing territory along with AVEO s obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its use in the royalty-bearing territory. We are recording the $4.8 million ratably over our period of performance through April 2022, the remaining patent life of tivozanib. We recorded approximately $54,000 of revenue during the three months ended March 31, 2011 associated with the amortization of the deferred revenue associated with this agreement.

OSI Pharmaceuticals

In September 2007, we entered into a collaboration and license agreement with OSI Pharmaceuticals, Inc., (a wholly-owned subsidiary of Astellas US Holding Inc., a holding company owned by Astellas Pharma Inc.) or OSI. 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, including the right to obtain certain of our tumor models and tumor archives. We did not consider the option granted to OSI in July 2009 as a deliverable as there was significant uncertainty that this option would ultimately be exercised.

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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 represented 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 are recognizing 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 consummated in March 2010 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 is being 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 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 represented 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 are recognizing 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 consummated in March 2010 and the related 1:4 reverse stock split of our common stock, each four shares of outstanding series E convertible preferred stock were converted into one share of common stock.

In November 2010, OSI exercised its option under the July 2009 expansion of the agreement to license certain elements of our proprietary technology platform, including components of the Human Response Platform for the identification/characterization of novel epithelial-mesenchymal transition agents and proprietary patient selection biomarkers, in support of OSI s clinical development programs. We did not consider the option granted to OSI in July 2009 as a deliverable as there was significant uncertainty that this option would ultimately be exercised. In connection with the exercise of the option, OSI is obligated to pay us $25 million in license expansion fees. We received $12.5 million upon delivery of the notice of option exercise, and we are in the process of transferring the relevant technology to OSI. The remaining $12.5 million will be paid following the successful transfer of the applicable technology, which is expected to be completed in July 2011. We have deferred the initial $12.5 million payment, and are recognizing the full $25 million relating to the option exercise by OSI over the period of substantial involvement, which is now determined to be through July 2011.

Under the July 2009 expanded 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. In March 2011, we earned $1.5 million related to deliverables and research milestones under the agreement. In addition, we are eligible to receive up to $1.5 million in milestones for certain deliverables and research milestones, and up to $24.0 million in biomarker related milestones. Upon commercialization of products which were part of the research program under the agreement, we are eligible to receive tiered royalty payments on sales of products by OSI, its affiliates and sublicensees. All milestones earned to date are for selection of targets, delivery of models, delivery of tumor archives or delivery of cell lines. These milestones are not considered to be at risk and substantive, therefore, the milestone payments are being deferred and will be recognized on a straight-line basis over the remaining estimated period of substantial involvement which is now determined to be July 2011.

We believe the application of the provisions of ASU 2009-13 to this arrangement would not change the units of accounting under the arrangement or the manner in which we recognize revenue for the arrangement.

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.

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We account for the Biogen Idec arrangement pursuant to ASC Topic 605-25. The deliverables under the arrangement include an option for a co-exclusive, world-wide license to develop and manufacture ErbB3 antibody products and an option for an exclusive license to commercialize ErbB3antibody products in all countries in the world other than the United States, Canada and Mexico. We determined that these deliverables did not have standalone value due to the fact that the program was still in preclinical development and required our experience to advance development of the product. As such, we determined that the agreement should be accounted for as one unit of accounting.

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

In June 2009, we 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 was 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 was included in revenue for the quarter ended March 31, 2010. We could also receive (i) a $5.0 million 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. We consider these milestone payments to be substantive and at risk so we expect to record revenue upon achievement of these milestones in accordance with ASU 2010-17.

We believe the application of the provisions of ASU 2009-13 to this arrangement would not change the units of accounting under the arrangement or the manner in which we recognize revenue for the arrangement.

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 ficlatuzumab, 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. We also are using our Human Response Platform to conduct translational research to guide the clinical development of ficlatuzumab. Merck was responsible for all costs related to the clinical development of ficlatuzumab and clinical and commercial manufacturing. On September 28, 2010, we received notice from Merck of termination of the collaboration agreement effective as of December 27, 2010, at which point we became responsible for the performance and funding of all future research, development, manufacturing and commercialization activities for ficlatuzumab.

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, which was initially estimated to be through completion of the first phase 2 proof-of-concept trial for ficlatuzumab (which was expected to be the first half of 2012), but has been adjusted to reflect the termination of the agreement effective on December 27, 2010. 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 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 which we consummated in March 2010, 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.

In June 2010, we earned and received an $8.5 million milestone payment in connection with the enrollment of patients in our phase 2 clinical trial of ficlatuzumab under the agreement. Since the $8.5 million milestone payment earned in June 2010 was considered substantive and at risk, it has been included in revenue for the year ended December 31, 2010.

In March 2011, in connection with the transition of responsibility for the ficlatuzumab program from Merck back to us, we made a $10.2 million payment to Merck for the purchase of a supply of ficlatuzumab to support ongoing clinical studies. We have taken title to approximately $1.1 million of this inventory as of March 31, 2011. The remaining $9.1 million is included in the prepaid expenses and other current assets balance on the condensed consolidated balance sheet at March 31, 2011. We expect to receive the remaining inventory during the second quarter of 2011 and will expense this amount to research and development once title has passed to us.

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

- employee-related expenses, which include salaries and benefits;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial materials;
- 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. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Research and development expenses are net of amounts reimbursed under the Astellas Agreement for Astellas share of development and commercialization costs incurred by the Company pursuant to the joint development plan.

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 the ficlatuzumab program and 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 allocated to such 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, 2011 and 2010:

	Three Months Ended March 31,	
	2011	2010
	(in thousands)	
Tivozanib, net of approximately $6.2 million of amounts reimbursed pursuant to the Astellas Agreement during the three months ended March 31, 2011	$ 28,155	$ 14,886
Ficlatuzumab	3,277	2,055
AV-203 program	1,096	473
Platform collaborations	776	717
Antibody pipeline	1,662	1,367
Other research and development	228	615
Overhead	2,823	2,505
Total research and development expenses	$ 38,017	$ 22,618

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Tivozanib

We have completed a phase 2 clinical trial for tivozanib and in August 2010 completed enrollment of our 517-patient phase 3 clinical trial for tivozanib in advanced RCC. We are also conducting phase 1 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. We recently entered into a collaboration and license agreement with Astellas pursuant to which we and Astellas share responsibility for tivozanib, including expenses for continued development and commercialization of tivozanib, in North America and Europe. Astellas is responsible for continued development and commercialization of tivozanib outside of North America, Europe and Asia. All costs associated with each party s conduct of development and commercialization activities in North America and Europe pursuant to a joint development plan, and any resulting profits or losses, will be shared equally between the parties. 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, excluding the effect of our cost sharing arrangement with Astellas. In the first quarter of 2010, we paid KHK 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 KHK upon the achievement of specified regulatory milestones. Further, we are required to pay KHK tiered royalty payments on net sales we make of tivozanib in North America, which range from the low to mid teens as a percentage of net sales. In connection with the execution of our collaboration agreement with Astellas, we are required to pay KHK 30% of the license fee received from Astellas as well as certain amounts we may receive from Astellas in connection with Astellas development and commercialization activities outside of North America and Asia related to tivozanib, other than amounts we receive in respect of research and development funding or equity investments, subject to certain limitations. In the first quarter of 2011, we recorded $22.5 million of expense for amounts owed to KHK related to the up-front license payment received under the collaboration agreement with Astellas. This payment was made to KHK in the second quarter of 2011.

Ficlatuzumab

In March 2007, we entered into a license agreement related to ficlatuzumab with Merck (formerly Schering-Plough) pursuant to which Merck was responsible for all expenses relating to development of ficlatuzumab in accordance with an agreed-upon budget. We recorded revenue and expenses on a gross basis under this arrangement. We are currently conducting phase 1 clinical trials of ficlatuzumab and initiated a phase 2 clinical trial in the second quarter of 2010, for which we earned an $8.5 million milestone payment from Merck. On September 28, 2010, we received from Merck a notice of termination of the collaboration agreement effective as of December 27, 2010, at which point we became responsible for the performance and funding of all future research, development, manufacturing and commercialization activities for ficlatuzumab. In connection with the transition of responsibility for the ficlatuzumab program, we recently purchased supply of ficlatuzumab for $10.2 million to support ongoing clinical trials of ficlatuzumab. We have taken title to approximately $1.1 million of this material as of March 31, 2011 and, pursuant to the provisions of ASC Topic 730, have recognized this amount as research and development expense during the three months ended March 31, 2011. The remaining $9.1 million is included as a component of the prepaid expenses and other current assets balance on the condensed consolidated balance sheet at March 31, 2011. This prepaid amount will be recognized as research and development expense when we receive the remaining material, which is expected to occur during the second quarter of 2011. Due to the unpredictable nature of preclinical and clinical development, we are unable to estimate with any certainty the costs we will incur in the future development of the ficlatuzumab program.

AV-203: Anti-ErbB3 Antibody Program

Our AV-203 program is focused on identifying inhibitors of ErbB3. In 2010, we nominated our lead development candidate, AV-203, which 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. Upon the selection of AV-203 as a development candidate in the first quarter of 2010, we earned a $5.0 million milestone payment from Biogen Idec. We commenced process development for manufacturing of this candidate in September 2010 in preparation for preclinical and human clinical trials.

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Platform Collaborations

We perform research services for OSI Pharmaceuticals using our Human Response Platform. The related expenses, including personnel and related expenses, are captured as a cost of the agreement with OSI Pharmaceuticals. Expenses incurred under the 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. We do not expect to incur further costs for this product candidate.

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, the terms of those strategic partnerships and the success of those strategic partnerships, if any, including the timing and amount of payments that we might receive from strategic partners;
- the emergence of competing technologies and products and other adverse market developments; and
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims.

As a result of the uncertainties 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 significantly increase 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 ficlatuzumab and our other product candidates.

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.

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

- the need to support our research and development activities, which we expect to expand as we continue the development of our product candidates;
- we began 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
- as a result of increased payroll, expanded infrastructure and higher consulting, legal, accounting and investor relations costs, and directors and officers 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.

Income Taxes

We calculate our provision for income taxes on ordinary income based on our projected annual tax rate for the year. As of March 31, 2011, we are projecting an ordinary loss for the year ended December 31, 2011 and since we maintain a full valuation allowance on all of our deferred tax assets, we have recorded no income tax provision or benefit in the current quarter.

Critical Accounting Policies and Significant Judgments and Estimates

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

Revenue Recognition

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

Effective January 1, 2011, we adopted Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends ASC Topic 605-25, *Revenue Recognition Multiple Element Arrangements*. In addition, effective January 1, 2011, we adopted ASU No. 2010-17, *Revenue Recognition Milestone Method.*

When evaluating multiple element arrangements, we consider whether the deliverables under the arrangement represent separate units of accounting. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting,

management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

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

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

At the inception of each agreement that includes milestone payments, we evaluate 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.

Other than with respect to revenue recognition provided under ASU 2009-13 and ASU 2010-17, there have been no other 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 annual report filed with the SEC on March 11, 2011.

Results of Operations

Comparison of Three Months Ended March 31, 2011 and 2010

The following table summarizes the results of our operations for each of the three months ended March 31, 2011 and 2010, together with the changes in those items in dollars and as a percentage:

	Three Months Ended March 31,		Increase/ (decrease)	%
	2011	2010		
	(in thousands)			
Revenue	$ 133,614	$ 10,881	$ 122,733	1,128%
Operating expenses:				
Research and development	38,017	22,618	15,399	68%
General and administrative	9,228	2,753	6,475	235%
Total operating expenses	47,245	25,371	21,874	86%
Income (loss) from operations	86,369	(14,490)	100,859	(696)%
Other (expense) income, net	(56)	712	(768)	(108)%
Interest expense	(1,012)	(607)	(405)	67%
Interest income	65	7	58	829%
Net income (loss)	$ 85,366	$ (14,378)	$ 99,744	(694)%

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The following table sets forth revenue for the three months ended March 31, 2011 and 2010:

Revenue	Three Months Ended March 31, 2011	2010	Increase/ (decrease)	%
		(in thousands)		
Strategic Partner:				
Astellas	$ 120,254		$ 120,254	
OSI Pharmaceuticals	13,120	$ 3,002	10,118	337%
Merck		2,794	(2,794)	(100)%
Biogen Idec	216	5,076	(4,860)	(96)%
Other	24	9	15	167%
	$ 133,614	$ 10,881	$ 122,733	1,128%

Revenue. Revenue for the three months ended March 31, 2011 was $133.6 million compared to $10.9 million for the three months ended March 31, 2010, an increase of approximately $122.7 million or 1,128%. The increase is primarily attributable to $120.3 million in revenue recognized in connection with the Astellas Agreement; and an increase of $10.0 million in revenue primarily related to the recognition of previously deferred revenue related to OSI s option exercise in November 2010 under our research and license agreement. These increases were partially offset by a decrease of $4.9 million in revenue from Biogen Idec primarily due to the recognition of revenue related to a $5.0 million milestone payment earned in March 2010 for selection of the development candidate for our AV-203 program; a decrease of $2.4 million in research and development funding from Merck due to termination of our ficlatuzumab collaboration in December 2010; and a decrease of $0.4 million in milestones earned under the Merck agreement due to the expiration of the research plan, and related funding, in March 2010.

Research and development. Research and development expenses for the three months ended March 31, 2011 were $38.0 million compared to $22.6 million for the three months ended March 31, 2010, an increase of $15.4 million or 68%. The increase is primarily attributable to a net increase in licensing costs of $12.5 million resulting primarily from a $22.5 million expense recorded in connection with our obligations to KHK related to the up-front license payment received under the Astellas Agreement for the first quarter of 2011, compared to a $10.0 million milestone payment to KHK in connection with the initial dosing of patients in our phase 3 clinical trial of tivozanib during the same period last year; an increase in clinical trial costs of $6.2 million resulting primarily from an increase in costs related to the phase 3 clinical trial of tivozanib, as well as costs related to ficlatuzumab that were previously reimbursed by Merck; a $1.2 million increase in salaries, benefits and contract labor mainly due to an increase in personnel primarily supporting development activities for tivozanib; a $0.6 million increase in contract manufacturing for tivozanib to support an increasing number of clinical trials; a $0.4 million increase in consulting costs primarily related to the development of tivozanib; a $0.3 million increase in lab supplies; and a $0.2 million increase in stock based compensation. These increases were partially offset by the reimbursement of $6.2 million of tivozanib development costs pursuant to the Astellas Agreement.

General and administrative. General and administrative expenses for the three months ended March 31, 2011 were $9.2 million compared to $2.8 million for the three months ended March 31, 2010, an increase of $6.5 million or 235%. The increase is primarily the result of a $4.25 million payment to a financial advisor in connection with the consummation of the Astellas Agreement; a $0.7 million increase in legal costs incurred during the first quarter of 2011 primarily due to year end reporting requirements and advice related to the collaboration agreement with Astellas; a $0.6 million increase in salaries and benefits due to an increase in personnel mainly due to an overall increase in hiring; an increase of $0.3 million for costs related to being a public company; a $0.2 million increase in stock-based compensation expense; and an increase in recruiting and relocation costs of $0.1 million.

Other income (expense), net. Other income (expense), net for the three months ended March 31, 2011 was $(56,000) compared to $712,000 for the three months ended March 31, 2010, a decrease of $768,000. The decrease is largely a result of a decrease in the value of warrants to purchase preferred stock resulting from a decrease in the value of the underlying stock; there was no corresponding income for the three months ended March 31, 2011 as the warrants converted to warrants to purchase common stock in connection with our initial public offering in March 2010.

Interest expense. Interest expense for the three months ended March 31, 2011 was $1.0 million compared to $0.6 million for the three months ended March 31, 2010, an increase of $0.4 million or 67%. The increase in interest expense is due to the refinancing of our loan agreement with Hercules Technology Growth in May 2010, resulting in a higher average loan balance outstanding during the three months ended March 31, 2011 compared to the three months ended March 31, 2010.

Interest income. Interest income for the three months ended March 31, 2011 was $65,000 compared to $7,000 for the three months ended March 31, 2010, an increase of $58,000. The increase in interest income is primarily due to an overall higher average cash balance during the three months ended March 31, 2011 compared to the three months ended March 31, 2010.

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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, 2011, we have received gross proceeds of $89.7 million from the sale of common stock in our initial public offering, $60.8 million from our private placement of shares of our common stock to a group of institutional and accredited investors, and $169.6 million from the sale of convertible preferred stock. As of March 31, 2010, we had received an aggregate of $136.9 million in cash from our three agreements with Merck and our agreements with OSI Pharmaceuticals, Biogen Idec, and Eli Lilly, $125.0 million in cash from our collaboration agreement with Astellas, and $25.0 million in funding from our debt financing with Hercules Technology Growth and certain of its affiliates. As of March 31, 2011, we had cash, cash equivalents and marketable securities of approximately $232.6 million. Currently, our funds are invested in money market funds, U.S. government agency securities, a foreign government agency security, U.S. treasuries, corporate debt and commercial paper. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Three Months Ended March 31,	
	2011	2010
Net cash provided by (used in) operating activities	$ 92,858	$ (25,778)
Net cash used in investing activities	(38,051)	(18,615)
Net cash provided by financing activities	478	70,750
	$ 55,285	$ 26,357

For the three months ended March 31, 2011 and 2010, our operating activities provided (used) cash of $92.9 million, and $(25.8) million, respectively. The cash provided by operations for the three months ended March 31, 2011 was due primarily to our net income adjusted for non-cash items and offset by an increase in accrued expenses of $26.7 million primarily due to amounts owed to KHK and a financial advisor in connection with the consummation of the collaboration agreement with Astellas, a $9.4 million increase in prepaid expenses primarily due to ficlatuzumab inventory that was paid for but not fully received as of March 31, 2011, an increase in accounts receivable of $7.7 million primarily due to the reimbursement of development expenses by Astellas, and a decrease in deferred revenue of $7.1 million related to the recognition of previously deferred revenue. 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 2010 but paid in April 2010, 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.

For the three months ended March 31, 2011 and 2010, our investing activities used cash of $38.1 million, and $18.6 million, respectively. The cash used by investing activities for the three months ended March 31, 2011 and 2010 was primarily the net result of purchases of marketable securities partially offset by maturities and sales, in addition to purchases of property and equipment of $0.3 million and $0.2 million, respectively.

For the three months ended March 31, 2011 and 2010, our financing activities provided $0.5 million and $70.8 million, respectively. The cash provided by financing activities for the three months ended March 31, 2011 was due to stock option exercises of $0.5 million. The cash provided by financing activities for the three months ended March 31, 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.

Credit Facilities. On May 15, 2008, we entered into a $21.0 million financing agreement with Hercules Technology Growth and Comerica Bank, referred to as the prior loan agreement. The full amount of the loan was drawn down in 2008. On May 28, 2010, we entered into a new loan and security agreement with Hercules Technology II, L.P. and Hercules Technology III, L.P., affiliates of Hercules Technology Growth, referred to as the new loan agreement, pursuant to which we received a loan in the aggregate principal amount of $25.0 million. In connection with the new loan agreement, we paid off the remaining outstanding principal and interest of $17.4 million under the prior loan agreement. We are required to repay the aggregate principal balance of the loan that is outstanding under the new loan agreement in 30 equal monthly installments of principal starting on October 1, 2011, provided, however, that such date will be extended under certain circumstances specified in the new loan agreement. The new loan agreement requires a deferred charge of $1.25 million to be paid in May 2012 related to the termination of the prior loan agreement. The new loan agreement also includes an obligation to pay an additional deferred charge of $1.24 million due upon the maturity of the loan which has been recorded as a loan discount and is being amortized to interest expense over the term of the new loan agreement 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. Per annum interest is payable at the greater of 11.9% and an amount equal to 11.9% plus the prime rate of interest minus 4.75%, provided however, that the per annum interest shall not exceed 15.0%. We must make interest payments on the loan each month following the date of borrowing under the new loan agreement. The entire principal balance and all accrued but unpaid interest, plus the end of term payment in the amount of approximately $1.24 million, will be due and payable on September 1, 2013, provided, however, such amounts will be due and payable on a later date under certain circumstances specified in the new loan agreement.

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The loan is secured by a lien on all of our personal property, as of, or acquired after, the date of the new loan agreement, except for intellectual property. As of March 31, 2011, the principal balance outstanding was $25.0 million.

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 were 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 aggregate principal outstanding under the equipment line and the refinancing line was fully paid in June 2010. There is no remaining ability to borrow under the equipment line and refinancing line with General Electric Capital Corporation.

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, and 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 2012.

If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we identify additional opportunities to do so, we may seek to sell additional equity or debt securities or obtain 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 amount of our working capital requirements. Our future capital requirements will depend on many factors, including, but not limited to:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

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

Contractual Obligations and Commitments

In connection with our obligation under the license agreement with KHK to pay 30% of sublicense revenue we receive, we incurred expenses of $22.5 million for amounts owed to KHK related to the up-front license payment received under our collaborative agreement with Astellas. This amount had not been paid as of March 31, 2011, and is included in our accrued expenses balance on the condensed consolidated balance sheet at March 31, 2011. The full amount was paid to KHK in April 2011.

We also incurred expenses to financial advisors in connection with our collaborative agreement with Astellas of $4.25 million. This amount had not been paid as of March 31, 2011, and is included in our accrued expenses balance on the condensed consolidated balance sheet at March 31, 2011. The full amount was paid to these financial advisors in April 2011.

On February 28, 2011, we entered into a sublease agreement with Acceleron Pharma, Inc., to sublease 14,214 square feet of office space. The sublease will expire on May 30, 2015. In conjunction with the lease, we entered into a standby letter of credit in the

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amount of $97,129 which will expire on May 31, 2012 subject to automatic extensions for periods of one year related to the term of the sublease. The letter of credit has been collateralized by a money market account held by the bank which issued the letter of credit. This money market account is classified as a component of restricted cash on the condensed consolidated balance sheet at March 31, 2011.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our annual report filed with the SEC on March 11, 2011.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We invest in short-term marketable securities for investment purposes. We are exposed to market risk related to changes in interest rates. As of March 31, 2011 and December 31, 2010, we had cash and cash equivalents and marketable securities of $232.6 million and $140.2 million, respectively, consisting of money market funds, U.S. treasuries, U.S. government agency securities, a foreign government agency security, 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 bears interest at variable rates. In May 2010, we entered into a new loan agreement with affiliates of Hercules Technology Growth pursuant to which we received a loan in the aggregate principal amount of $25.0 million. Per annum interest is payable at the greater of 11.9% and 11.9% plus the prime rate of interest minus 4.75%, not to exceed 15%. As a result of the 15% maximum per annum interest rate under the new loan agreement, we have limited exposure to changes in interest rates on borrowings under this loan. For every 1% increase in prime over 4.75% on the outstanding debt amount as of March 31, 2011, we would have a decrease in future annual cash flows of approximately $235,000 over the next twelve month period.

Item 4. Controls and Procedures.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of March 31, 2011, 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.

There were no changes in our evaluation of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended March 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 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. These risk factors restate and supersede the risk factors set forth under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2010.

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 are currently conducting our phase 3 registration clinical trial for tivozanib, referred to as TIVO-1, as well as a phase 2 clinical trial and phase 1 clinical trials, many 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 revenues, will depend heavily on the successful development and commercialization of tivozanib. All of our other potential product candidates, with the exception of ficlatuzumab, are in the preclinical research stage. The clinical and commercial success of tivozanib will depend on a number of factors, including the following:

- successful completion of our phase 3 clinical trial and timely enrollment in, and completion of, our other on-going or planned clinical trials;
- 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, including without limitation TIVO-1;
- 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 tivozanib;
- the availability, relative cost, safety and efficacy of alternative and competing treatments;
- the effectiveness of our marketing, sales and distribution strategies and operations, and those of Astellas, our strategic collaboration partner for development and commercialization of tivozanib;

the ability of our third-party manufacturers to manufacture clinical trial and commercial supplies of tivozanib and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;

our ability, and the ability of Astellas, to successfully obtain third party reimbursement and generate commercial demand that result in sales of tivozanib, assuming applicable regulatory approvals are obtained;

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, or our strategic partner, will ever be able to generate revenues through the sale of tivozanib. If we, or our strategic partner, 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

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Medicines Agency, or the EMA, for the treatment of advanced RCC, as well as the treatment of hepatocellular carcinoma. Based on our discussions with the FDA and the EMA, we set the number of patients to be enrolled in the clinical trial at a number we expect will be 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 tr