

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)

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)

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Delaware **04-3581650**
(State or other jurisdiction of **(I.R.S. Employer**
incorporation or organization) **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 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 Smaller reporting company
(Do not check if a 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

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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Table of Contents**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)

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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.

Table of Contents**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.

Table of Contents**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,	2010
	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,

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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 (in thousands)	Unrealized Losses
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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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

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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.

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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.

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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

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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**