

AVEO PHARMACEUTICALS INC

Form 10-Q

May 10, 2013

Table of Contents

**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, 2013

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number 001-34655

**AVEO PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: AVEO PHARMACEUTICALS INC - Form 10-Q

**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):

Edgar Filing: AVEO PHARMACEUTICALS INC - Form 10-Q

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

Number of shares of the registrant's Common Stock, \$0.001 par value, outstanding on May 1, 2013: 51,885,668

**Table of Contents**

**AVEO PHARMACEUTICALS, INC.**

**FORM 10-Q**

**FOR THE QUARTER ENDED March 31, 2013**

**TABLE OF CONTENTS**

	<b>Page No.</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	<b>3</b>
<b>Item 1. <u>Financial Statements</u></b>	<b>3</b>
<u>Condensed Consolidated Balance Sheets as of March 31, 2013 and December 31, 2012</u>	3
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2013 and 2012</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2013 and 2012</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2013 and 2012</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<b>Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>21</b>
<b>Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	<b>34</b>
<b>Item 4. <u>Controls and Procedures</u></b>	<b>34</b>
<b><u>PART II. OTHER INFORMATION</u></b>	<b>36</b>
<b>Item 1. <u>Legal Proceedings</u></b>	<b>36</b>
<b>Item 1A. <u>Risk Factors</u></b>	<b>36</b>
<b>Item 6. <u>Exhibits</u></b>	<b>56</b>
<u>Signatures</u>	57

**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, 2013	December 31, 2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 85,898	\$ 76,134
Marketable securities	105,736	84,468
Accounts receivable	9,181	20,649
Prepaid expenses and other current assets	9,744	9,430
<b>Total current assets</b>	<b>210,559</b>	<b>190,681</b>
Property and equipment, net	13,331	12,867
Other assets	367	321
Restricted cash	3,558	3,600
<b>Total assets</b>	<b>\$ 227,815</b>	<b>\$ 207,469</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 8,083	\$ 10,628
Accrued expenses	18,067	19,543
Loans payable, net of discount	9,384	6,809
Deferred revenue	1,294	1,294
Deferred rent	918	856
<b>Total current liabilities</b>	<b>37,746</b>	<b>39,130</b>
Loans payable, net of current portion and discount	16,731	19,228
Deferred revenue, net of current portion	18,067	18,391
Deferred rent, net of current portion	12,851	10,544
Other liabilities	1,238	1,238
Stockholders equity:		
Preferred stock, \$.001 par value; 5,000 shares authorized; no shares issued and outstanding		
Common stock, \$.001 par value; 100,000 shares authorized; 51,848 and 43,780 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	52	44
Additional paid-in capital	495,461	439,173
Accumulated other comprehensive income (loss)	14	(19)
Accumulated deficit	(354,345)	(320,260)
<b>Total stockholders equity</b>	<b>141,182</b>	<b>118,938</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 227,815</b>	<b>\$ 207,469</b>

Edgar Filing: AVEO PHARMACEUTICALS INC - Form 10-Q

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)*

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
Collaboration revenue	\$ 323	\$ 860
Operating expenses:		
Research and development	20,962	24,776
General and administrative	12,449	8,983
Restructuring	67	
	33,478	33,759
Loss from operations	(33,155)	(32,899)
Other income and expense:		
Other (expense) income, net	(101)	299
Interest expense	(870)	(845)
Interest income	41	199
Other expense, net	(930)	(347)
Net loss	\$ (34,085)	\$ (33,246)
Net loss per share basic and diluted	\$ (0.69)	\$ (0.77)
Weighted average number of common shares outstanding	49,380	43,254

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

**Table of Contents****AVEO PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Comprehensive Loss****(In thousands)***(Unaudited)*

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
Net loss	\$ (34,085)	\$ (33,246)
Other comprehensive income:		
Unrealized gains on available-for-sale securities	7	231
Foreign currency translation adjustment	26	(4)
Comprehensive loss	\$ (34,052)	\$ (33,019)

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)**

	<b>Three Months Ended March 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Operating activities</b>		
Net loss	\$ (34,085)	\$ (33,246)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	900	546
Net loss on disposal of fixed assets	50	
Stock-based compensation	2,588	2,202
Non-cash interest expense	81	135
Amortization of premium on investments	339	785
Changes in operating assets and liabilities:		
Accounts receivable	11,468	(2,279)
Prepaid expenses and other current assets	(317)	2,565
Other noncurrent assets	(46)	23
Restricted cash	42	
Accounts payable	(2,545)	(1,349)
Accrued expenses	(2,128)	333
Deferred revenue	(324)	(323)
Deferred rent	2,369	(18)
Net cash used in operating activities	(21,608)	(30,626)
<b>Investing activities</b>		
Purchases of property and equipment	(762)	(1,107)
Purchases of marketable securities	(48,951)	(34,074)
Proceeds from maturities and sales of marketable securities	27,351	93,687
Net cash (used in) provided by investing activities	(22,362)	58,506
<b>Financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	53,638	
Proceeds from exercise of stock options and issuance of common and restricted stock	70	183
Proceeds from refinancing of loans payable		3,672
Principal payments on loans payable		(2,172)
Net cash provided by financing activities	53,708	1,683
Net increase in cash and cash equivalents	9,738	29,563
Effect of exchange rate changes on cash and cash equivalents	26	(4)
Cash and cash equivalents at beginning of period	76,134	43,506
Cash and cash equivalents at end of period	\$ 85,898	\$ 73,065
<b>Supplemental cash flow and noncash investing and financing</b>		
Cash paid for interest	\$ 788	\$ 731
Cash paid for income taxes	\$	\$

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



**Table of Contents****AVEO Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements****(Unaudited)****(1) Organization**

AVEO Pharmaceuticals, Inc. (the Company), which does business as AVEO Oncology, 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, which the Company partnered with Astellas Pharma Inc. and its wholly-owned direct subsidiaries (Astellas), is a potent, selective, long half-life inhibitor of all three vascular endothelial growth factor (VEGF) receptors which is designed to optimize VEGF blockade while minimizing off-target toxicities. In 2012, the Company announced detailed data from its global, phase 3 clinical trial comparing the efficacy and safety of tivozanib with Nexavar® (sorafenib), an approved therapy, for first-line treatment in advanced RCC (the TIVO-1 study). On November 27, 2012, the U.S. Food and Drug Administration (the FDA) accepted for filing the Company's New Drug Application, (NDA) for tivozanib with the proposed indication for the treatment of patients with advanced renal cell carcinoma (RCC). On May 2, 2013, the FDA's Oncologic Drugs Advisory Committee (the ODAC), which provides the FDA with independent expert advice and recommendations, reviewed the Company's NDA for tivozanib and voted 13 to 1 that the application for tivozanib did not demonstrate a favorable benefit/risk evaluation for the treatment of advanced RCC in an adequate and well-controlled trial. Furthermore, the ODAC's vote was consistent with the position taken by the FDA at the ODAC meeting. Given the ODAC's determination, as well as the position taken by the FDA at the ODAC meeting, it is now significantly more likely that the FDA will make an adverse determination with respect to the Company's current NDA and there is an increased probability that the FDA will conclude that an additional trial or trials are needed before marketing approval for tivozanib can be granted, if it is granted at all. The FDA's review of the NDA is expected to be complete by July 28, 2013 according to the timelines established by the Prescription Drug User Fee Act (PDUFA). In view of the current FDA-related uncertainties with respect to the NDA for tivozanib to treat advanced RCC, the Company and Astellas, are evaluating the clinical and regulatory path forward for tivozanib, including Astellas' decision as to whether to submit a Marketing Authorization Application (MAA) for RCC to the European Medicines Agency (EMA).

The Company also has a pipeline of monoclonal antibodies, including ficlatuzumab, a product candidate that is currently in phase 2 clinical development, and AV-203, a monoclonal antibody that targets the ErbB3 receptor, which the Company has partnered with Biogen Idec, Inc. Both ficlatuzumab and AV-203 were derived from the Company's Human Response Platform, a novel method of building preclinical models of human cancer. As used throughout these consolidated financial statements, the term AVEO, refers to AVEO Pharmaceuticals, Inc. and its wholly-owned subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation.

The Company has generated an accumulated deficit as of March 31, 2013 of approximately \$354.3 million since inception, and will require substantial additional capital for research and the development of tivozanib, ficlatuzumab, AV-203 and its other antibody programs. The Company believes that its existing cash, cash equivalents, and marketable securities are sufficient to fund its operations through at least the next twelve months.

**(2) Basis of Presentation**

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

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

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2013, and for the three months ended March 31, 2013 and 2012, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2012 have been derived from the Company's audited financial statements. For further information, refer to the consolidated financial statements

## Edgar Filing: AVEO PHARMACEUTICALS INC - Form 10-Q

and accompanying footnotes included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2012, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 11, 2013.

---

**Table of Contents****(3) Significant Accounting Policies*****Revenue Recognition***

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

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

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

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

The Company aggregates its milestones into four categories: (i) clinical and development milestones, (ii) regulatory milestones, (iii) commercial milestones, and (iv) patent-related milestones. Clinical and development milestones are typically achieved when a product candidate advances into a defined phase of clinical research or completes such phase. For example, a milestone payment may be due to the Company upon the

initiation of a phase 3 clinical trial for a new indication, which is the last phase of clinical

**Table of Contents**

development and could eventually contribute to marketing approval by the FDA or other global regulatory authorities. Regulatory milestones are typically achieved upon acceptance of the submission for marketing approval of a product candidate or upon approval to market the product candidate by the FDA or other global regulatory authorities. For example, a milestone payment may be due to the Company upon the FDA's acceptance of an NDA. Commercial milestones are typically achieved when an approved pharmaceutical product reaches certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. Patent-related milestones are typically achieved when a patent application is filed or a patent is issued with respect to certain intellectual property related to the applicable collaboration.

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

***Principles of Consolidation***

The Company's consolidated financial statements include the Company's accounts and the accounts of the Company's wholly-owned subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation. 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 costs of other contracted services, license fees, and other external costs.

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

***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 and cash equivalents at March 31, 2013 and December 31, 2012 consisted of money market funds, asset-backed commercial paper, and corporate debt securities, including commercial paper, maintained by an investment manager.

***Marketable Securities***

Marketable securities at March 31, 2013 consisted of municipal bonds, asset-backed securities, and corporate debt securities, including commercial paper, maintained by an investment manager. Marketable securities at December 31, 2012 consisted of municipal bonds, asset-backed commercial paper, asset-backed securities, and corporate debt securities, including commercial paper, maintained by an investment manager. Credit risk is reduced as a result of the Company's policy to limit the amount invested in any one issue. Marketable securities consist primarily of investments which have expected average maturity dates in excess of three months, but not longer than 24 months. The Company classifies these investments as available-for-sale. Unrealized gains and losses are included in other comprehensive (loss) income until realized. The cost of securities sold is based on the specific identification method. There were no realized gains or losses recognized on the sale or maturity of securities during the three months ended March 31, 2013 and 2012.

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

Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
-------------------	---------------------	----------------------	---------------

(in thousands)

**March 31, 2013:**

Edgar Filing: AVEO PHARMACEUTICALS INC - Form 10-Q

Corporate debt securities	\$ 74,117	\$ 17	\$ (6)	\$ 74,128
Municipal bonds	10,250			10,250
Asset-backed securities	21,355	3		21,358
	\$ 105,722	\$ 20	\$ (6)	\$ 105,736



**Table of Contents**

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
<b>December 31, 2012:</b>				
Corporate debt securities	\$ 58,751	\$ 16	\$ (11)	\$ 58,756
Municipal bonds	10,545			10,545
Asset-backed securities	6,359			6,359
Asset-backed commercial paper	8,806	2		8,808
	\$ 84,461	\$ 18	\$ (11)	\$ 84,468

The aggregate fair value of securities in an unrealized loss position for less than 12 months at March 31, 2013 was \$38.1 million, representing ten securities. There were no securities that were in an unrealized loss position for greater than 12 months at March 31, 2013. The unrealized loss was caused by a temporary change in the market for those securities primarily caused by changes in market interest rates. There was no change in the credit risk of the securities. To determine whether an other-than-temporary impairment exists, the Company performs an analysis to assess whether it intends to sell, or whether it would more likely than not be required to sell, the security before the expected recovery of the amortized cost basis. Where the Company intends to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded in the statement of operations as an other-than-temporary impairment charge. When this is not the case, the Company performs additional analyses on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where the Company does not expect to receive cash flows, based on using a single best estimate, sufficient to recover the amortized cost basis of a security and these are recognized in other income (expense), net.

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

	Aggregate Fair Value	Unrealized Losses
	(in thousands)	
<b>March 31, 2013:</b>		
Corporate debt securities	\$ 32,401	\$ (6)
Asset-backed securities	5,721	
	\$ 38,122	\$ (6)
<b>December 31, 2012:</b>		
Corporate debt securities	\$ 29,806	\$ (11)
Asset-backed securities	6,359	
	\$ 36,165	\$ (11)

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, 2013.

**Concentrations of Credit Risk**

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

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

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

***Fair Value Measurements***

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

Level 1 Quoted market prices in active markets for identical assets or liabilities. Assets utilizing Level 1 inputs include money market funds.

**Table of Contents**

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

Level 3 Unobservable inputs developed using estimates and assumptions developed by the Company, which reflect those that a market participant would use. The Company currently has no assets or liabilities recorded at fair value that utilize Level 3 inputs. The following tables summarize the cash equivalents and marketable securities measured at fair value on a recurring basis in the accompanying consolidated balance sheets as of March 31, 2013 and December 31, 2012.

**Fair Value Measurements of Cash Equivalents and  
Marketable Securities as of March 31, 2013**

	Level 1	Level 2 (in thousands)	Level 3	Total
Cash equivalents	\$ 38,321	\$ 37,300	\$	\$ 75,621
Marketable securities		105,736		105,736
	\$ 38,321	\$ 143,036	\$	\$ 181,357

**Fair Value Measurements of Cash Equivalents and  
Marketable Securities as of December 31, 2012**

	Level 1	Level 2 (in thousands)	Level 3	Total
Cash equivalents	\$ 51,182	\$ 18,121	\$	\$ 69,303
Marketable securities		84,468		84,468
	\$ 51,182	\$ 102,589	\$	\$ 153,771

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

The fair value of the Company's loans payable at March 31, 2013, computed pursuant to a discounted cash flow technique using the effective interest rate under the loan, is \$26.6 million and is considered a level 2 fair value measurement. The effective interest rate considers the fair value of the warrant issued in connection with the loan, loan issuance costs and the deferred charge.

**Property and Equipment**

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

**Long-lived Assets**

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

March 31, 2013.

***Basic and Diluted Loss per Common Share***

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the reporting period. Preferred shares are not included in the calculation of net loss per share until their conversion to common shares. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common stock equivalent shares consist of the incremental common shares issuable upon the exercise of stock options and warrants. Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per common share is the same.

**Table of Contents**

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

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
	<b>(in thousands)</b>	
Weighted average options outstanding	5,393	4,329
Weighted average warrants outstanding	10	10
	5,403	4,339

**Stock-Based Compensation**

The Company applies the provisions of ASC 718, *Compensation-Stock Compensation ( ASC 718 )*, to share-based payments. All awards are 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 ASC 718. During the three months ended March 31, 2013 and 2012, respectively, the Company recorded the following stock-based compensation expense:

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
	<b>(in thousands)</b>	
Research and development	\$ 1,114	\$ 949
General and administrative	1,474	1,253
<b>Total stock-based compensation expense</b>	<b>\$ 2,588</b>	<b>\$ 2,202</b>

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

**Income Taxes**

The Company provides for income taxes using the 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.

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

**Segment and Geographic Information**

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, principally in the United States. The Company has \$1.2 million of gross assets located in the United Kingdom.

**Use of Estimates**

## Edgar Filing: AVEO PHARMACEUTICALS INC - Form 10-Q

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.

### ***Recently Adopted Accounting Pronouncements***

In February 2013, the Financial Accounting Standards Board issued Accounting Standards Update ( ASU ) No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* ( ASU 2013-02 ). This newly issued accounting standard requires an entity to provide information about the amounts reclassified out of

**Table of Contents**

accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where net income (loss) is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income (loss) but only if the amount reclassified is required under U.S. Generally Accepted Accounting Principles ( GAAP ) to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. This ASU is effective for reporting periods beginning after December 15, 2012. The Company adopted this standard in the first quarter of 2013 and presented this information in the condensed consolidated financial statements. The adoption of this standard did not have an impact on the Company's financial position or results of operations.

For a discussion of recent accounting pronouncements adopted by the Company, please refer to Note 2, Significant Accounting Policies, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the SEC on March 11, 2013. The Company did not adopt any new accounting pronouncements during the three months ended March 31, 2013 that had a material effect on the Company's condensed consolidated financial statements.

***Subsequent Events***

The Company has evaluated all events or transactions that occurred after March 31, 2013 through the date the Company issued these financial statements.

**(4) Collaborations and License Agreements*****Astellas Pharma***

On February 16, 2011, the Company, together with its wholly-owned subsidiary AVEO Pharma Limited, entered into a Collaboration and License Agreement with Astellas (the Astellas Agreement ), pursuant to which the Company and Astellas plan to develop and commercialize tivozanib, the Company's product candidate currently in phase 3 clinical development, for the treatment of a broad range of cancers, including RCC, breast and colorectal cancers. For a discussion of recent regulatory developments relating to the planned development and commercialization of tivozanib for its lead indication in advanced RCC, see Footnote 10 Subsequent Events. In view of the FDA-related uncertainties described therein, the Company and Astellas are currently evaluating the clinical and regulatory path forward for tivozanib, including Astellas' decision as to whether to submit a MAA for RCC to the EMA.

Under the terms of the Astellas Agreement, the Company and Astellas share responsibility for continued development and commercialization of tivozanib in the United States, Canada and Mexico ( North America ) and in Europe under a joint development plan and a joint commercialization plan, respectively. Throughout the rest of the world (the Royalty Territory ), excluding Asia, where Kyowa Hakko Kirin ( KHK ) has retained all development and commercialization rights, Astellas has an exclusive, royalty-bearing license to develop and commercialize tivozanib. The terms of the Astellas Agreement are subject to the Company's obligations to KHK under a license agreement entered into with KHK in 2006 pursuant to which the Company acquired exclusive rights to develop and commercialize tivozanib worldwide outside of Asia.

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

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. In December 2012, the Company received a \$15.0 million milestone payment from Astellas in connection with the acceptance by the FDA of the NDA filing for tivozanib. The milestone was considered substantive and revenue was recognized upon achievement of the milestone. The Company is also eligible to receive from Astellas an aggregate of approximately \$1.3 billion in potential future milestone payments, comprised of (i) up to \$85 million in substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to \$475 million in substantive milestone payments upon achievement of specified regulatory milestone events, including up to \$75 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 (iii) up to approximately \$780 million in milestone payments upon the achievement of specified commercial sales events. The first anticipated clinical and development

## Edgar Filing: AVEO PHARMACEUTICALS INC - Form 10-Q

milestone is due to the Company upon initiation of its next phase 3 clinical trial of tivozanib in RCC in combination with another therapeutic, or in breast cancer, colorectal cancer or another indication. The timing of this milestone is uncertain, as the Company has not finalized plans for its future trials, and the Company may need to undertake further trials that do not result in any milestone payments coming due. A potential significant near-term regulatory milestone is acceptance by the EMA of the first filing of a MAA (\$15 million), if Astellas elects to submit a MAA to the EMA. In addition, if tivozanib is successfully developed and launched in the Royalty Territory, Astellas will be required to pay to the Company tiered, double digit royalties on net sales of tivozanib in the Royalty Territory, if any, subject to offsets under certain circumstances. The Company is required to pay KHK low to mid-teen royalties on its net sales in North America, and 30% of certain amounts the Company may receive from Astellas in connection with Astellas' development and commercialization activities in Europe and the Royalty Territory, including up-front license fees, milestone payments and royalties.



**Table of Contents**

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

The Company is accounting for the joint development and commercialization activities in North America and Europe as a joint risk-sharing collaboration in accordance with ASC 808, *Collaborative Arrangements*. In addition, these activities were not deemed to be separate deliverables under the Astellas Agreement.

Payments from Astellas with respect to Astellas's share of tivozanib development and commercialization costs incurred by the Company pursuant to the joint development plan are recorded as a reduction to research and development expense and general and administrative expense in the accompanying consolidated financial statements due to the joint risk-sharing nature of the activities in North America and Europe. As a result of the cost-sharing provisions in the Astellas Agreement, the Company reduced research and development expense by \$6.3 million and \$8.0 million during the three months ended March 31, 2013 and 2012, respectively. The Company also reduced general and administrative expense by \$1.3 million and \$0.6 million during the three months ended March 31, 2013 and 2012, respectively, as a result of the cost-sharing provisions in the Astellas Agreement. The net amount due to the Company from Astellas pursuant to the cost-sharing provisions was \$7.2 million at March 31, 2013.

Activities under the Astellas Agreement outside of the joint development and commercialization activities in North America and Europe, including the co-exclusive license to develop and commercialize tivozanib in North America and Europe that was delivered prior to the initiation of the collaborative activities in North America and Europe, were evaluated under ASC 605-25, *Revenue Recognition - Multiple Element Arrangements* (ASC 605-25) (as amended by ASU 2009-13, *Revenue Recognition* (ASU 2009-13)) to determine if they represented a multiple element revenue arrangement. The Astellas Agreement includes the following deliverables: (1) a co-exclusive license to develop and commercialize tivozanib in North America and Europe (the License Deliverable); (2) a combined deliverable comprised of an exclusive royalty-bearing license to develop and commercialize tivozanib in the Royalty Territory and the Company's obligation to provide access to clinical and regulatory information resulting from the activities in North America and Europe to Astellas for its development and commercialization of tivozanib in the Royalty Territory (the Royalty Territory Deliverable); and (3) the Company's obligation to supply clinical material to Astellas for development of tivozanib in the Royalty Territory (the Clinical Material Deliverable). The License Deliverable is not sublicenseable. Astellas has the right to sublicense the exclusive royalty-bearing license to develop and commercialize tivozanib in the Royalty Territory. The Company's obligation to provide access to clinical and regulatory information as part of the Royalty Territory Deliverable includes the obligation to provide access, upon request, to all clinical data, regulatory filings, safety data and manufacturing data to Astellas for use in the development and commercialization of tivozanib in the Royalty Territory. The Clinical Material Deliverable includes the obligation to supply clinical material to Astellas in accordance with current good manufacturing practices applicable to clinical materials and other relevant regulatory authority requirements, upon request, for the development of tivozanib in the Royalty Territory. All of these deliverables were deemed to have stand-alone value and to meet the criteria to be accounted for as separate units of accounting under ASC 605-25. Factors considered in this determination included, among other things, the subject of the licenses and the research and development and commercial capabilities of Astellas.

The Company allocated the up-front consideration of \$125 million to the deliverables based on management's best estimate of selling price of each deliverable using the relative selling price method as the Company did not have VSOE or TPE of selling price for such deliverables. The Company's best estimate of selling price considered discounted cash flow models, the key assumptions of which included the market opportunity for commercialization of tivozanib in North America and Europe and the Royalty Territory, the probability of successfully developing and commercializing tivozanib, the remaining development costs for tivozanib, and the estimated time to commercialization of tivozanib. The Company's analysis included the following market conditions and entity-specific factors: (a) the specific rights provided under the license to develop and commercialize tivozanib in North America and Europe and the Royalty Territory, (b) the potential indications for tivozanib pursuant to the licenses, (c) the relevant territories for the respective licenses, (d) the stage of development of tivozanib by potential indication and estimated remaining development timelines and costs for each indication, (e) the development risk by indication, (f) the market size by indication, (g) the expected product life of tivozanib assuming commercialization and (h) the competitive environment. More specifically, the Company's discounted cash flow model included an assumption that the Company and Astellas would develop and commercialize tivozanib in North America and Europe as a monotherapy for RCC, and in combination with other known anti-cancer agents for RCC, breast cancer and colorectal cancer. Approximately 70% of the value of tivozanib in the discounted cash flow model was a result of the estimated market

opportunity for tivozanib as a monotherapy for RCC. The market opportunity for commercialization of tivozanib in North America

## Table of Contents

and Europe was generated using a patient-based forecasting approach, with key epidemiological, market penetration, dosing, compliance, length of treatment, and pricing assumptions derived from primary and secondary market research. While the RCC monotherapy opportunity represented the majority of the market opportunity, clinical trials for tivozanib in the breast cancer and colorectal cancer indications were in earlier stages of development and therefore had more development risk and were assigned a lower probability of success relative to the RCC indication, with a longer timeline to potential cash inflows. The probability of successfully developing and commercializing tivozanib in the various indications throughout the world (other than Asia) was estimated based on standard industry averages for similar product candidates being developed for oncology indications. The remaining development costs were estimated based upon budgets and estimated costs for ongoing and planned clinical trials in all contemplated indications. The time to commercialization was based on the Company's estimates, which projected the launch of tivozanib for RCC monotherapy in 2013. The market opportunity for the Royalty Territory was estimated based upon a specified percentage of total projected European sales and costs of tivozanib. The Company believes that this method for estimating market opportunity outside of North America, Europe and Asia is common in the pharmaceuticals industry. The Company utilized a discount rate of 15% in its analysis, representing the weighted average cost of capital derived from returns on equity for comparable companies.

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

The Company allocated up-front consideration of \$120.2 million to the License Deliverable and up-front consideration of \$4.8 million to the Royalty Territory Deliverable. The relative selling price of the Company's obligation under the Clinical Material Deliverable had *de minimis* value.

The Company recorded the \$120.2 million relative selling price of the License Deliverable as collaboration revenue during the three months ended March 31, 2011 upon delivery of the license, and deferred approximately \$4.8 million of revenue representing the relative selling price of the Royalty Territory Deliverable. The Company is recording the \$4.8 million of revenue attributed to the Royalty Territory Deliverable ratably over the Company's period of performance through April 2022, the remaining patent life of tivozanib. The Company estimated the period of performance considering that the Company and Astellas plan to develop tivozanib in several indications outside of RCC, including in breast cancer and colorectal cancer and potentially in other cancer indications. The clinical development of tivozanib in these indications is in earlier stages of development and, as a result, the clinical development timeline is uncertain and is expected to change as the Company obtains additional clinical data in these indications. As a result, the Company estimated the period of performance as the remaining patent life of tivozanib as it represents the longest period over which development of tivozanib could occur. The Company reassesses the period of performance at each reporting period. The Company recorded approximately \$107,000 of revenue associated with the Royalty Territory Deliverable during each of the three month periods ended March 31, 2013 and 2012.

The Company believes the clinical and development and regulatory milestones that may be achieved under the Astellas Agreement are consistent with the definition of a milestone included in ASU 2010-17, *Revenue Recognition - Milestone Method*, and, accordingly, the Company will recognize payments related to the achievement of such milestones, if any, when such milestone is achieved. Factors considered in this determination included scientific and regulatory risks that must be overcome to achieve each milestone, the level of effort and investment required to achieve each milestone, and the monetary value attributed to each milestone. The Company did not recognize any milestone payments under the Astellas arrangement during the three months ended March 31, 2013 or 2012.

### ***Biogen Idec International GmbH***

In March 2009, the Company entered into an exclusive option and license agreement with Biogen Idec International GmbH, a subsidiary of Biogen Idec Inc., collectively referred to herein as "Biogen Idec", regarding the development and commercialization of the Company's discovery-stage ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases outside of North America.

The Company accounts for the Biogen Idec arrangement pursuant to ASC 605-25. The deliverables under the arrangement include an option for a co-exclusive, worldwide license to develop and manufacture ErbB3 antibody products and an option for an exclusive license to commercialize ErbB3 antibody products in all countries in the world other than North America. The Company determined that these deliverables did not have standalone value due to the fact that the program was still in preclinical development and 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 up-front cash payment of \$5.0 million in March 2009, which is being amortized over the Company's 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,



**Table of Contents**

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. Accordingly, the Company is recognizing the premium of \$8.2 million as revenue on a straight-line basis over the period of substantial involvement. The Company earned a \$5.0 million milestone payment for achievement of the first pre-clinical discovery milestone under the agreement in June 2009 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 was included in revenue for the quarter ended March 31, 2010. The Company earned a third \$5.0 million milestone payment based on achieving the GLP toxicology initiation milestone in June 2011. This milestone was considered substantive and was included in revenue for the quarter ended June 30, 2011. The Company could also receive an option exercise fee and regulatory milestone payments of up to \$45.0 million in the aggregate if Biogen Idec exercises its option to obtain exclusive rights to commercialize ErbB3 antibody products in its territory. The first regulatory milestone that the Company may receive pursuant to this agreement of \$25.0 million is due upon the receipt of the first regulatory approval of a licensed product from the EMA. The Company does not expect to achieve this milestone in the near future. The Company did not earn any milestones under the Biogen arrangement during the three months ended March 31, 2013 or 2012.

If Biogen Idec exercises its exclusive option under the agreement, Biogen Idec will pay the Company royalties on Biogen Idec's sales of ErbB3 antibody products in its territory, and the Company will pay Biogen Idec royalties on the Company's sale of ErbB3 antibody products in North America.

Under the agreement, the Company recorded revenue of \$0.2 million for the three months ended March 31, 2013 and 2012, respectively.

***OSI Pharmaceuticals Inc.***

In September 2007, the Company entered into a collaboration and license agreement with OSI Pharmaceuticals, Inc. (a wholly-owned subsidiary of Astellas US Holding Inc., a holding company owned by Astellas Pharma Inc.), or OSI, which provided for the use of the Company's proprietary *in vivo* models by the Company's scientists at its facilities, use of the Company's bioinformatics tools and other target validation and biomarker research to further develop and advance OSI's small molecule drug discovery and translational research related to cancer and other diseases. In July 2009, the Company and OSI expanded the strategic partnership, and the Company granted OSI a non-exclusive license to use the Company's proprietary bioinformatics platform, and non-exclusive perpetual licenses to use bioinformatics data and the Company's proprietary gene index related to a specific target pathway. Further, as part of the expanded strategic partnership, the Company granted OSI an option, exercisable upon payment of an option fee, to receive non-exclusive perpetual rights to certain elements of the Company's Human Response Platform and to use the Company's bioinformatics platform, and the Company granted OSI the right to obtain certain of its tumor models and tumor archives. In November 2010, OSI exercised its option under the July 2009 expanded agreement providing the right for OSI to license certain elements of the Company's proprietary technology platform, including components of the Human Response Platform for the identification/characterization of novel epithelial-mesenchymal transition agents and proprietary patient selection biomarkers, in support of OSI's clinical development programs. The Company received \$12.5 million of upfront payments from OSI and research funding payments on a quarterly basis that were recognized as revenue through July 2011. In addition, OSI purchased 1,833,334 shares of the Company's Series C Convertible Preferred Stock and 3,750,000 shares of the Company's Series E Convertible Preferred Stock that were converted into shares of common stock upon the Company's initial public offering. The Company determined that both equity issuances included a premium, which was recognized as additional license revenue through July 2011. The Company completed the transfer of the relevant technology to OSI in July 2011. The Company recognized \$25.0 million relating to the option exercise by OSI over the technology transfer period, which was completed in July 2011.

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

In March 2011, the Company earned \$1.5 million related to achieving certain of the biomarker-related milestones under the agreement. These milestones were not considered to be substantive; therefore, the \$1.5 million in payments was deferred and was recognized ratably through July 2011. In May 2012, the Company earned a patent-related milestone payment of \$250,000 upon filing of a patent application by OSI, and the Company also earned a clinical and development milestone payment of \$750,000 for commencement by OSI of GLP toxicology studies. Since these milestones were considered substantive, they were recorded as revenue during the year ended December 31, 2012.



**Table of Contents**

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

***Centocor Ortho Biotech***

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

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

As the relative selling price of the RON license and RON Index license (the delivered items) exceeded the up-front consideration attributable to the deliverables of \$7.0 million, the entire up-front payment was recognized as revenue upon delivery of the licenses during the three months ended June 30, 2011.

The Company has not recognized any revenue related to milestones under this arrangement and does not expect to recognize any revenue related to milestones in the future as a result of the termination of the agreement effective December 6, 2012. Under the agreement, the Company received cash payments related to research and development services of \$0.7 million for the three months ended March 31, 2012, and recorded revenue of \$0.5 million for the three months ended March 31, 2012.

***Kirin Brewery***

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

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

Under the KHK Agreement, the Company may be required to (i) make future milestone payments upon the achievement of specified regulatory milestones in the United States, (ii) pay tiered royalty payments on net sales it makes of tivozanib in its territory ranging from the low to mid-teens as a percentage of the Company's net sales of tivozanib, and (iii) pay 30% of certain amounts the Company receives under the Astellas Agreement in connection with Astellas' development and commercialization activities in Europe and the Royalty Territory related to tivozanib, including up-front license fees, milestone payments and royalties the Company may receive from Astellas (including a potential \$4.5 million milestone payable to KHK in connection with the acceptance by the EMA of the filing of a MAA and \$9.0 million to KHK in connection with the EMA granting marketing approval in Europe), other than amounts the Company receives in respect of research and development funding or equity investments, subject to certain limitations.





---

**Table of Contents****(5) Accrued Expenses**

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

	March 31, 2013	December 31, 2012
	(in thousands)	
Clinical expenses	\$ 6,225	\$ 6,688
Salaries and benefits	3,021	6,015
Pre-commercialization expenses		