AVEO PHARMACEUTICALS INC
Form 10-Q
May 09, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2012

OR

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

For the transition period from to .

Commission file number 001-34655

AVEO PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3581650**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

75 Sidney Street, Cambridge, Massachusetts 02139

(Address of Principal Executive Offices) (Zip Code)

(617) 299-5000

(Registrant s Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

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

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

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

Number of shares of the registrant s Common Stock, $0.001 par value, outstanding on May 1, 2012: 43,571,982

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AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2012

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except par value amounts)

(Unaudited)

	March 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 73,065	$ 43,506
Marketable securities	151,262	177,622
Accounts receivable	9,489	7,210
Prepaid expenses and other current assets	3,487	6,057
Total current assets	237,303	234,395
Marketable securities	20,505	54,312
Property and equipment, net	6,032	5,471
Other assets	98	121
Restricted cash	751	751
Total assets	$ 264,689	$ 295,050
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 7,555	$ 8,904
Accrued expenses	14,622	14,289
Loans payable, net of discount		8,551
Deferred revenue	1,294	1,294
Other liabilities	1,249	1,249
Deferred rent	329	322
Total current liabilities	25,049	34,609
Loans payable, net of current portion and discount	25,800	15,619
Deferred revenue, net of current portion	19,361	19,684
Deferred rent, net of current portion	334	359
Other liabilities	1,238	1,238
Stockholders equity:		
Preferred stock, $.001 par value: 5,000 shares authorized; no shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively		
Common stock, $.001 par value: 100,000 shares authorized; 43,560 and 43,254 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	44	43
Additional paid-in capital	431,915	429,531
Accumulated other comprehensive income (loss)	60	(167)
Accumulated deficit	(239,112)	(205,866)

Total stockholders equity	192,907	223,541
Total liabilities and stockholders equity	$ 264,689	$ 295,050

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

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Collaboration revenue	$ 860	$ 133,614
Operating expenses:		
Research and development	24,776	38,017
General and administrative	8,983	9,228
	33,759	47,245
Income (loss) from operations	(32,899)	86,369
Other income and expense:		
Other income (expense), net	299	(56)
Interest expense	(845)	(1,012)
Interest income	199	65
Other expense, net	(347)	(1,003)
Net income (loss)	$ (33,246)	$ 85,366
Basic net income (loss) per share		
Net income (loss) per share	$ (0.77)	$ 2.38
Weighted average number of common shares outstanding	43,254	35,781
Diluted net income (loss) per share		
Net income (loss) per share	$ (0.77)	$ 2.28
Weighted average number of common shares and dilutive common share equivalents outstanding	43,254	37,483

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

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Net income (loss)	$ (33,246)	$ 85,366
Other comprehensive income (loss):		
Unrealized gains on available-for-sale securities	231	40
Foreign currency translation adjustment	(4)	
Comprehensive income (loss)	$ (33,019)	$ 85,406

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

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Operating activities		
Net income (loss)	$ (33,246)	$ 85,366
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	546	372
Stock-based compensation	2,202	1,182
Non-cash interest expense	135	269
Amortization of premium on investments	785	668
Changes in operating assets and liabilities:		
Accounts receivable	(2,279)	(7,656)
Prepaid expenses and other current assets	2,565	(9,363)
Other noncurrent assets	23	38
Restricted cash		(97)
Accounts payable	(1,349)	2,577
Accrued expenses	333	26,691
Deferred revenue	(323)	(7,132)
Deferred rent	(18)	(57)
Net cash (used in) provided by operating activities	(30,626)	92,858
Investing activities		
Purchases of property and equipment	(1,107)	(319)
Purchases of marketable securities	(34,074)	(73,284)
Proceeds from maturities and sales of marketable securities	93,687	35,552
Net cash provided by (used in) investing activities	58,506	(38,051)
Financing activities		
Proceeds from exercise of stock options and issuance of common and restricted stock	183	478
Proceeds from refinancing of loans payable	3,672	
Principal payments on loans payable	(2,172)	
Net cash provided by financing activities	1,683	478
Net increase in cash and cash equivalents	29,563	55,285
Effect of exchange rate changes on cash and cash equivalents	(4)	
Cash and cash equivalents at beginning of period	43,506	45,791
Cash and cash equivalents at end of period	$ 73,065	$ 101,076
Supplemental cash flow and noncash investing and financing		
Cash paid for interest	$ 731	$ 744
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), which does business as AVEO Oncology , 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 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 (VEGF) pathway by inhibiting all three VEGF receptors: VEGF receptors 1, 2 and 3. In January 2012, the Company announced top-line 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 renal cell carcinoma (RCC). Based on these results, the Company expects to file a New Drug Application (NDA) seeking U.S. Food and Drug Administration (FDA) approval to commercialize and sell tivozanib during the third quarter of 2012. The Company also has a pipeline of monoclonal antibodies, including ficlatuzumab, 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 condensed consolidated financial statements, the terms AVEO, we, us, and our refer to the business of AVEO Pharmaceuticals, Inc. and its wholly-owned subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation.

(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, 2012 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2012 or any other future period.

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2012, and for the three months ended March 31, 2012 and 2011, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2011 have been derived from the Company s audited financial statements. For further information, refer to the consolidated financial statements and accompanying footnotes included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2011, which was filed with the U.S. Securities and Exchange Commission on March 30, 2012.

(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

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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 deliverable