AVEO PHARMACEUTICALS IN Form 10-Q May 10, 2016	C
LINHTED CTATES	
UNITED STATES	
SECURITIES AND EXCHANGE	COMMISSION
Washington, DC 20549	
FORM 10-Q	
(Mark One)	
~	JANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
1934 For the quarterly period ended Mar	rch 31, 2016
OR	
oTRANSITION REPORT PURSU 1934	JANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
For the transition period from	to .
Commission file number 001-3465	5
AVEO PHARMACEUTICALS, IN	NC.
(Exact Name of Registrant as Spec	ified in Its Charter)
	Delaware 04-3581650
(State or Other Jurisdiction of (I.R.S. Employer
I One Broadway, 14th Floor, Cambr	ncorporation or Organization) Identification No.) idge, Massachusetts 02142
(Address of Principal Executive Of	fices) (Zip Code)
(617) 588-1960	

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 5, 2016: 58,181,715

AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2016

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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,	December 31,
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$18,056	\$26,634
Marketable securities	5,749	7,501
Restricted cash	4,000	_
Accounts receivable	1,736	4,641
Prepaid expenses and other current assets	1,123	1,600
Total current assets	30,664	40,376
Property and equipment, net	18	23
Other assets	124	143
Total assets	\$30,806	\$40,542
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$340	\$1,425
Accrued expenses	2,843	4,106
Loans payable, net of discount	3,019	2,053
Deferred revenue	660	814
Settlement liability (Note 11)	4,000	4,000
Total current liabilities	10,862	12,398
Loans payable, net of current portion and discount	6,537	7,418
Deferred revenue	2,832	2,881
Other liabilities	660	618
Stockholders' equity:		
Preferred stock, \$.001 par value: 5,000 shares authorized; no shares issued and		
outstanding	_	
Common stock, \$.001 par value: 200,000 shares authorized; 58,182 and 58,182 shares		
issued and outstanding at March 31, 2016 and December 31, 2015, respectively	58	58
Additional paid-in capital	512,594	512,201
Accumulated other comprehensive income (loss)	2	(3)
Accumulated deficit	(502,739)	,
Total stockholders' equity	9,915	17,227
1 7	, -	,

Total liabilities and stockholders' equity

\$30,806 \$40,542

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

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months		
	Ended		
	March 31		
	2016	2015	
Collaboration and licensing revenue	\$1,203	\$134	
Operating expenses:			
Research and development	5,972	2,695	
General and administrative	2,463	3,255	
Restructuring and lease exit	_	4,333	
	8,435	10,283	
Loss from operations	(7,232)	(10,149)	
Other income and expense:			
Other expense, net	(9)	(14)	
Interest expense	(386)	(716)	
Interest income	17	5	
Other expense, net	(378)	(725)	
Loss before provision for income taxes	(7,610)	(10,874)	
Provision for income taxes	(100)		
Net loss	\$(7,710)	\$(10,874)	
Net loss per share basic and diluted	\$(0.13)	\$(0.21)	
Weighted average number of common shares outstanding	58,166	52,638	

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

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three M Ended	onths
	March 3: 2016	1, 2015
Net loss	_010	\$(10,874)
Other comprehensive income (loss):	1 (1)1	, (), , ,
Unrealized gain (loss) on available-for-sale securities	5	
Comprehensive loss	\$(7,705)	\$(10,874)

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

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

Three Months Ended

	March 3 2016	1,		2015		
Operating activities						
Net loss	\$	(7,710)	\$	(10,874)
Adjustments to						
reconcile net loss to						
net cash used in						
operating activities:						
Impairment of						
property and						
equipment					232	
Depreciation and						
amortization		5			4,488	
Accretion		_			199	
Loss on disposal of						
fixed assets		_			(20)
Stock-based						
compensation		390			427	
Non-cash interest						
expense		86			125	
Amortization of						
premium and discount						
on investments		3			14	
Changes in operating						
assets and liabilities:						
Restricted cash		(4,000)		37	
Accounts receivable		2,905			1,394	
Prepaid expenses and						
other current assets		492			337	
Other noncurrent						
assets		19			26	
Accounts payable		(1,085)		(626)
Accrued expenses		(1,263)		(2,900)
Deferred revenue		(203)		(76)
Lease exit obligation		<u> </u>			(3,345)
Deferred rent					(5,200)
Other liabilities		42			(58)
Net cash used in						
operating activities		(10,319)		(15,820)

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Investing activities				
Purchases of				
marketable securities	(5,746)	(6,048)
Proceeds from				
maturities and sales of				
marketable securities	7,500		1,500	
Proceeds from sale of				
property and				
equipment	_		928	
Net cash provided by				
(used in) investing				
activities	1,754		(3,620)
Financing activities				
Proceeds from				
issuance of common				
stock, net of issuance				
costs	_		4,353	
Proceeds from				
exercise of stock				
options and issuance				
of common and				
restricted stock	2		73	
Debt issuance costs	(15)	_	
Principal payments on				
loans payable			(2,757)
Net cash (used by)				
provided by financing				
activities	(13)	1,669	
Net decrease in cash				
and cash equivalents	(8,578)	(17,771)
Cash and cash				
equivalents at				
beginning of period	26,634		52,306	
Cash and cash				
equivalents at end of				
period	\$ 18,056		\$ 34,535	
Supplemental cash				
flow information				
Cash paid for interest	\$ 301		\$ 617	

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

AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) Organization

AVEO Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted therapeutics for oncology and other areas of unmet medical need. The Company's proprietary platform has delivered unique insights into cancer and related disease. The Company's strategy is to leverage these biomarker insights and partner resources to advance the development of its clinical pipeline.

The Company's pipeline of product candidates includes tivozanib, a potent, selective, long half-life vascular endothelial growth factor tyrosine kinase inhibitor of all three vascular endothelial growth factors. In June 2013, the U.S. Food and Drug Administration issued a complete response letter denying the Company's application for approval of the use of tivozanib in first-line treatment of advanced renal cell carcinoma ("RCC"), citing concerns regarding the negative trend in overall survival in the Company's pivotal phase 3 trial. Subject to the availability of sufficient financial resources, the Company is planning to conduct a second phase 3 trial of tivozanib in the third-line treatment of patients with refractory RCC in order to address the overall survival concerns presented in the June 2013 complete response letter from the FDA and to support a request for regulatory approval of tivozanib in the United States as a third-line treatment and as a first-line treatment. The Company is also planning to conduct a phase 1/2 trial of tivozanib in combination with an immune checkpoint (PD-1) inhibitor for the treatment of RCC. The Company is evaluating all options for funding, including partnerships, for the clinical and regulatory advancement of tivozanib as a single agent and in combination. In February 2016, a strategic partner submitted a Marketing Authorization Application for tivozanib with the European Medicines Agency ("EMA") for the treatment of RCC. The application was validated in March 2016, confirming that the submission was complete and that the EMA would initiate its review process. Another strategic partner has submitted a registration dossier for tivozanib with the Ministry of Health of the Russian Federation for the treatment of RCC in December 2015 that was accepted for review in February 2016.

The Company also has a pipeline of monoclonal antibodies, including:

- (i) Ficlatuzumab, a potent anti-HFG antibody that inhibits the activity of the HGF/c-Met pathway and for which the Company has completed a phase 2 clinical trial and has entered into a partnership with Biodesix, Inc. ("Biodesix") to advance clinical development;
- (ii) AV-203, a potent, high affinity inhibitor of ErbB3 function that has demonstrated anti-tumor activity in multiple preclinical models and for which the Company has completed a phase 1 dose escalation trial and has entered into a partnership with CANbridge Life Sciences Ltd. ("CANbridge") to advance clinical development;
- (iii) AV-380, a potent humanized IgG1 inhibitory monoclonal antibody targeting growth differentiating factor-15, or GDF15, a divergent member of the TGF-\(\beta\) family, for the potential treatment or prevention of cachexia, which the Company has licensed to Novartis International Pharmaceutical Ltd. ("Novartis"); and
- (iv) AV-353, a potent inhibitory antibody specific to Notch 3, which has demonstrated an ability in preclinical models to potentially reverse disease phenotype for pulmonary arterial hypertension ("PAH"), and for which the Company is currently seeking a partner to advance development in PAH.

As used throughout these condensed consolidated financial statements, the terms "AVEO," and the "Company" refer to the business of AVEO Pharmaceuticals, Inc. and its two wholly-owned subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation.

The Company has devoted substantially all of its resources to its drug discovery efforts, comprising research and development, conducting clinical trials for its product candidates, protecting its intellectual property and general and administrative functions relating to these operations.

The Company has an accumulated deficit as of March 31, 2016 of approximately \$502.7 million, and is subject to a number of risks including the need for substantial additional capital for research and product development. The Company will need additional funding to support its planned operating activities, and the timing and nature of activities contemplated for 2016 and thereafter will be conducted subject to the availability of sufficient financial resources.

(2) Basis of Presentation

These condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, AVEO Pharma Limited and AVEO Securities Corporation. 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, 2016 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2016 or any other future period.

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2016, and for the three months ended March 31, 2016 and 2015, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes as of December 31, 2015 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, 2015, which was filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2016.

(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 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 and 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 among multiple deliverables.

The Company typically receives non-refundable, up-front 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 development and could eventually contribute to marketing approval by the U.S. Food and Drug Administration ("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 a New Drug Application ("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 current 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.

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 such as salaries and 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.

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, 2016 consisted of money market funds and corporate debt securities maintained by an investment manager totaling \$9.1 million. Cash equivalents at December 31, 2015 consisted of money market funds, U.S. government agency securities and corporate debt securities, including commercial paper, maintained by an investment manager totaling \$16.3 million. The carrying values of the Company's cash equivalent securities approximate fair value due to their short term maturities.

Marketable Securities

Marketable securities at March 31, 2016 consisted of U.S. government agency securities and corporate debt securities, including commercial paper, maintained by an investment manager. Marketable securities at December 31, 2015 consisted of government

agency 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 issuance. 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 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 marketable securities during the three months ended March 31, 2016 and 2015.

Available-for-sale securities at March 31, 2016 and December 31, 2015 consisted of the following:

	Amortized Inrealized			Unrealized		Fair
	Cost Gains (in thousands)		Losses		Value	
March 31, 2016:						
Corporate debt securities (Due within 1 year)	\$4,748	\$	2	\$	_	\$4,750
Government agency securities (Due within 1 year)	999					999
	\$5,747	\$	2	\$		\$5,749
December 31, 2015:						
Corporate debt securities (Due within 1 year)	\$6,504	\$		\$	(3) \$6,501
Government agency securities (Due within 1 year)	1,000					1,000
•	\$7,504	\$		\$	(3	\$7,501

The aggregate unrealized loss for the Company's corporate debt securities was less than \$1,000 as of March 31, 2016.

Marketable securities in an unrealized loss position at December 31, 2015 consisted of the following:

	Aggregate Unreali			ed
	Fair Value Losse (in thousands)			
Corporate debt securities (Due within 1 year)	\$ 4,100	\$	(3)
Government agency securities (Due within 1 year)	1,000			
	\$ 5,100	\$	(3)

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents, marketable securities and accounts receivable. 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 related to cash deposits 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 issuance.

The Company's accounts receivable primarily consist of amounts due to the Company from licensees and collaborators. As of March 31, 2016, the Company had \$1.7 million of receivables outstanding, including \$0.9 million due from CANbridge pursuant to the Company's licensing arrangement for AV-203 (refer to Note 7), \$0.7 million due from Biodesix pursuant to the Company's collaboration arrangement for AV-299 (refer to Note 7) and \$0.2 million due from Astellas pursuant to the Company's former collaboration arrangement for tivozanib. The Company has not experienced any material losses related to receivables from individual licensees or collaborators.

Fair Value Measurements

The Company records cash equivalents and marketable securities at fair value. The accounting standards for fair value measurements establish a hierarchy 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 that are valued utilizing only Level 1 inputs include money market funds.
- ·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 that are valued utilizing Level 2 inputs include U.S. government agency securities and corporate bonds, including commercial paper. These investments have been initially valued at the transaction price and are subsequently valued, at the end of each reporting period, utilizing third party pricing services or other observable market 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 pricing services as of March 31, 2016.
- ·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 measured at fair value on a recurring basis 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 condensed consolidated balance sheets as of March 31, 2016 and December 31, 2015.

Fair Value Measurements of Cash Equivalents and

Marketable Securities as of March 31, 2016 LeveLevel Level 1 2 3 Total