AVEO PHARMACEUTICALS INC
Form 10-Q
November 09, 2018

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 September 30, 2018

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.)

One Broadway, 14th Floor, Cambridge, Massachusetts 02142

(Address of Principal Executive Offices) (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 No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 November 8, 2018: 125,346,598

AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2018

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except par value amounts)

(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 20,408	$ 14,949
Marketable securities	—	18,576
Accounts receivable	344	402
Insurance recovery (Note 9)	—	15,000
Clinical trial retainers	284	1,027
Other prepaid expenses and other current assets	402	229
Total current assets	21,438	50,183
Other assets	4	15
Total assets	$ 21,442	$ 50,198
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,983	$ 2,436
Accrued clinical trial costs and contract research	7,253	8,321
Other accrued liabilities	3,190	2,458
Loans payable, net of discount	4,256	—
Deferred revenue	1,342	395
Deferred research and development reimbursements	463	901
Estimated settlement liability (Note 9)	—	17,073
Other liabilities (Note 6)	—	540
Total current liabilities	19,487	32,124
Loans payable, net of current portion and discount	14,621	18,477
Deferred revenue	3,414	1,302
Deferred research and development reimbursements	65	222
PIPE Warrant liability (Note 7)	43,157	37,746
Other liabilities (Note 6)	1,090	1,090
Total liabilities	81,834	90,961
Stockholders' deficit:		
Preferred stock, $.001 par value: 5,000 shares authorized at September 30, 2018 and December 31, 2017; no shares issued and outstanding at each of September 30, 2018 and December 31, 2017	—	—
Common stock, $.001 par value: 250,000 shares authorized at September 30,	121	118

2018 and December 31, 2017; 121,539 and 118,325 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively		
Additional paid-in capital	556,314	546,092
Accumulated other comprehensive loss	—	(4)
Accumulated deficit	(616,827)	(586,969)
Total stockholders' deficit	(60,392)	(40,763)
Total liabilities and stockholders' deficit	$ 21,442	$ 50,198

See accompanying notes.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Collaboration and licensing revenue	$2,335	$4,614	$3,651	$7,497
Partnership royalties	132	—	275	—
	2,467	4,614	3,926	7,497
Operating expenses:				
Research and development	5,160	4,666	15,451	19,503
General and administrative	2,719	2,101	8,156	6,734
Settlement costs (Note 9)	—	—	(667)	—
	7,879	6,767	22,940	26,237
Loss from operations	(5,412)	(2,153)	(19,014)	(18,740)
Other expense, net:				
Interest expense, net	(579)	(655)	(1,621)	(1,736)
Change in fair value of PIPE Warrant liability	(16,172)	(23,538)	(6,512)	(47,947)
Other expense, net	(16,751)	(24,193)	(8,133)	(49,683)
Loss before provision for income taxes	(22,163)	(26,346)	(27,147)	(68,423)
Provision for income taxes	—	(51)	—	(101)
Net loss	$(22,163)	$(26,397)	$(27,147)	$(68,524)
Net loss per share - basic and diluted	$(0.18)	$(0.22)	$(0.23)	$(0.67)
Weighted average number of common shares outstanding – basic and diluted	120,138	118,006	119,311	101,754

See accompanying notes.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net loss	$(22,163)	$(26,397)	$(27,147)	$(68,524)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	(1)	4	4	(4)
Comprehensive loss	$(22,164)	$(26,393)	$(27,143)	$(68,528)

See accompanying notes.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss	$(27,147)	$(68,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,888	774
Non-cash interest expense	399	391
Non-cash change in fair value of PIPE Warrant liability	6,512	47,947
Non-cash charge for settlement costs (Note 9)	(667)	—
Amortization of premium and discount on investments	3	36
Changes in operating assets and liabilities:		
Accounts receivable	58	(1,348)
Insurance recovery (Note 9)	15,000	—
Prepaid expenses and other current assets	570	196
Other noncurrent assets	11	787
Accounts payable	547	(245)
Accrued contract research	(1,068)	3,498
Other accrued liabilities	732	90
Settlement liability (Note 9)	(15,000)	—
Deferred revenue	348	(411)
Deferred research and development reimbursements	(595)	1,394
Net cash used in operating activities	(18,409)	(15,415)
Investing activities		
Purchases of marketable securities	(6,733)	(27,793)
Proceeds from maturities and sales of marketable securities	25,312	14,950
Net cash provided by (used in) investing activities	18,579	(12,843)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	1,100	21,294
Proceeds from issuance of common stock to related parties	4,500	3,210
Proceeds from issuance of stock for stock-based compensation arrangements	229	12
Proceeds from issuance of loans payable	—	5,000
Payment of end-of-term loan costs (Note 6)	(540)	—
Net cash provided by financing activities	5,289	29,516
Net increase in cash and cash equivalents	5,459	1,258
Cash and cash equivalents at beginning of period	14,949	15,096
Cash and cash equivalents at end of period	$20,408	$16,354
Supplemental cash flow information		

Cash paid for interest	$1,486	$1,468
Non-Cash Operating Activity		
Increase to deferred revenue due to adoption of ASC Topic 606 - transition adjustment on January 1, 2018	$2,711	$—

See accompanying notes.

AVEO Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

September 30, 2018

(1) Organization

AVEO Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted medicines for oncology and other areas of unmet medical need. The Company's strategy is to retain North American rights to its oncology portfolio while securing partners in development and commercialization outside of North America. The Company is working to develop and commercialize its lead candidate tivozanib in North America as a treatment for advanced or metastatic renal cell carcinoma ("RCC"). On November 5, 2018, the Company announced positive topline results from the primary analysis of the Company's phase 3 trial of tivozanib in the third- and fourth-line treatment of patients with RCC (the "TIVO-3 trial"), a randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib (Nexavar®), an approved therapy, in 351 subjects with RCC. The TIVO-3 trial met its primary endpoint for progression-free survival ("PFS"). The analysis of the secondary endpoint of overall survival ("OS") was not mature at the time of the final PFS analysis. Based on the results of the TIVO-3 trial, together with the previously completed phase 3 trial of tivozanib in the first line treatment of RCC (the "TIVO-1 trial"), the Company plans to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") within approximately six months from its announcement of topline data results of the TIVO-3 trial. The Company has outlicensed tivozanib (FOTIVDA®) for oncological indications in Europe and other territories outside of North America, and it is approved in the European Union, as well as Norway and Iceland, for the first-line treatment of adult patients with RCC and for adult patients who are vascular endothelial growth factor receptor ("VEGFR") and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for RCC. The Company has entered into partnerships to fund the development and commercialization of AV-203 and ficlatuzumab, both clinical stage assets in oncology. The Company is currently seeking a partner to develop the AV-353 platform, a preclinical asset, worldwide for the potential treatment of pulmonary arterial hypertension ("PAH") and oncology. In addition, a new formulation of tivozanib is being explored in ocular conditions. The Company has recently regained the rights to its AV-380 program for the potential treatment of cachexia and is considering a variety of options to advance the program's development.

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.

Liquidity and Going Concern

The Company has financed its operations to date primarily through private placements and public offerings of its common stock and preferred stock, license fees, milestone payments and research and development funding from strategic partners, and loan proceeds. The Company has devoted substantially all of its resources to its drug development efforts, comprising research and development, manufacturing, conducting clinical trials for its product candidates, protecting its intellectual property and general and administrative functions relating to these operations. The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain profitable operations. As of September 30, 2018, the Company had cash, cash equivalents and marketable securities totaling approximately $20.4 million, working capital of $2.0 million and an accumulated deficit of $616.8 million.

The Company is subject to a number of risks, including the need for substantial additional capital for clinical research and product development. As of September 30, 2018, the Company had approximately $20.4 million in cash, cash equivalents and marketable securities. In the fourth quarter of 2018 to-date, the Company sold approximately 3.8 million shares of its common stock pursuant to its sales agreement with Leerink Partners LLC (the "Leerink Sales Agreement") and received approximately $8.4 million in net proceeds. Based on these available cash resources, the Company does not have sufficient cash on hand to support current operations for at least the next twelve months from the date of filing this Quarterly Report on Form 10-Q. This condition raises substantial doubt about the Company's ability to continue as a going concern.

The Company's plans to address this condition include pursuing one or more of the following options to secure additional funding, none of which can be guaranteed or are entirely within the Company's control:

- Earn royalty payments pursuant to the Company's license agreement with EUSA Pharma (UK) Limited (the "EUSA Agreement"). In August 2017, EUSA Pharma (UK) Limited ("EUSA") obtained marketing approval from the European Medicines Agency (the "EMA") for tivozanib (FOTIVDA) for the treatment of RCC.

- Earn milestone payments pursuant to the collaboration and license agreements described in Note 4 or restructure / monetize existing potential milestone and/or royalty payments under those collaboration and license agreements.
- Raise funding through the possible additional sales of the Company's common stock, including public or private equity financings and / or sales of the Company's common stock under the Leerink Sales Agreement, as discussed in Note 7.
- Partner AV-353 to secure potential additional non-dilutive funds and advance development of the AV-353 platform for the potential treatment of PAH.

Pursuant to the EUSA Agreement, the Company is entitled to receive up to an additional $8.0 million in milestone payments of $2.0 million per country upon reimbursement approval for RCC, if any, in each of France, Germany, Italy and Spain, and an additional $2.0 million milestone payment for the grant of marketing approval, if any, in three of the licensed countries outside of the European Union, as mutually agreed by the parties. These milestone payments are subject to the 30% sublicense fee payable to Kyowa Hakko Kirin Co., Ltd. (formerly Kirin Brewery Co., Ltd.) ("KHK") pursuant to the Company's license agreement with KHK (the "KHK Agreement"). The Company is also eligible to receive an additional research and development reimbursement payment from EUSA of 50% of the total costs for the Company's TIVO-3 trial, up to $20.0 million, if EUSA elects to opt-in to that study. This research and development reimbursement payment would not be subject to the 30% sublicense fee payable to KHK, subject to certain limitations. Refer to Note 4 "Collaborations and License Agreements - KHK" for further details.

There can be no assurance that the Company will receive cash proceeds from any of these potential resources or to the extent cash proceeds are received such proceeds would be sufficient to support the Company's current operating plan for at least the next twelve months from the date of filing this Quarterly Report on Form 10-Q.

Pursuant to the requirements of Accounting Standards Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASC 205-40") management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

Under ASC 205-40, the future receipt of potential funding from the Company's collaborators and other resources cannot be considered probable at this time because none of the Company's current plans have been finalized at the time of filing this Quarterly Report on Form 10-Q and the implementation of any such plan is not probable of being effectively implemented as none of the plans are entirely within the Company's control. Accordingly, substantial doubt is deemed to exist about the Company's ability to continue as a going concern within one year after the date these financial statements are issued.

The Company believes that its approximate $20.4 million in cash, cash equivalents and marketable securities at September 30, 2018, along with approximately $8.4 million received in net proceeds from the sale of approximately 3.8 million shares of its common stock pursuant to the Leerink Sales Agreement in the fourth quarter of 2018 to-date, would allow it to fund its planned operations into the second quarter of 2019. This estimate assumes no receipt of additional milestone payments from its partners, no funding from new partnership agreements, no additional equity financings, no debt financings, no additional sales of equity under the Leerink Sales Agreement and no additional sales of equity through the exercise of the outstanding PIPE Warrants or the Settlement Warrants (Refer to Note 7,

Common Stock – Settlement Warrants and Private Placement / PIPE Warrants regarding specific details.). Accordingly, the timing and nature of activities contemplated for the remainder of 2018, 2019 and thereafter will be conducted subject to the availability of sufficient financial resources.

If the Company is unable to obtain sufficient capital to continue to advance its programs, the Company would be forced to delay, reduce or eliminate its research and development programs and any future commercialization efforts.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

(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 U.S. generally accepted accounting principles ("GAAP") 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 GAAP 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 and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018 or any other future period.

The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2018, and for the three months and nine months ended September 30, 2018 and 2017, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes as of December 31, 2017 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, 2017, which was filed with the U.S. Securities and Exchange Commission ("SEC") on March 13, 2018.

(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 promised goods and services, 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 preclinical and clinical material. Payments to the Company under these arrangements typically include one or more of the following: non-refundable, upfront license fees; option exercise fees; funding of research and/or development efforts; milestone payments; and royalties on future product sales.

Collaboration Arrangements Within the Scope of ASC 808, Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and are therefore within the scope of ASC Topic 808, Collaborative Arrangements ("ASC 808"). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements that are deemed to be within the scope of ASC 808, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, Revenue from Contracts with Customers ("ASC 606"). The Company's policy is generally to recognize amounts received from collaborators in connection with joint operating activities that are within the scope of ASC 808 as a reduction in research and development expense.

Arrangements Within the Scope of ASC 606, Revenue from Contracts with Customers

Effective January 1, 2018, the Company adopted ASC 606 using the modified retrospective transition method. Under this method, the Company has recognized the cumulative effect of the adoption as an adjustment to the opening balance of accumulated deficit in the current period condensed consolidated balance sheet. Financial results for reporting periods beginning after January 1, 2018, are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under ASC 605, Revenue Recognition. ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaboration arrangements and leases.

Under ASC 606, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company determines it expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligation(s). As part of the accounting for these

arrangements, the Company must make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

Once a contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period

between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed each of its revenue generating arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of its arrangements.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time based on the use of an output or input method.

Licenses of intellectual property: The terms of the Company's license agreements include the license of functional intellectual property, given the functionality of the intellectual property is not expected to change substantially as a result of the Company's ongoing activities. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the portion of the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises (that is, for licenses that are not distinct from other promised goods and services in an

arrangement), the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Research and development funding: Arrangements that include payment for research and development services are generally considered to have variable consideration. If and when the Company assesses the payment for these services is no longer subject to the constraint on variable consideration, the related revenue is included in the transaction price.

Milestone payments: At the inception of each arrangement that includes non-refundable payments for contingent milestones, including preclinical research and development, clinical development and regulatory, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of the achievement of contingent milestones and the likelihood of a significant reversal of such milestone revenue, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration and licensing revenue in the period of adjustment. This quarterly assessment may result in the recognition of revenue related to a contingent milestone payment before the milestone event has been achieved.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The following table summarizes the total revenues earned in the three months and nine months ended September 30, 2018 and 2017, respectively, by partner (in thousands). Refer to Note 4 Collaborations and License Agreements regarding specific details.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
EUSA	$467	$4,099	$1,926	$4,297
Novartis	—	15	—	1,835
CANbridge	2,000	500	2,000	1,000
Ophthotech	—	—	—	115
Other	—	—	—	250
Total	$2,467	$4,614	$3,926	$7,497

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 internal costs for salaries, bonuses,

benefits, stock-based compensation, facilities, and research-related overhead, and external costs for clinical trials, drug manufacturing and distribution, license fees, consultants and other contracted services.

Warrants Issued in Connection with Private Placement

In May 2016, the Company issued warrants to purchase an aggregate of 17,642,482 shares of common stock in connection with a private placement financing and recorded the warrants as a liability (the "PIPE Warrants"). The Company accounts for warrant instruments that either conditionally or unconditionally obligate the issuer to transfer assets as liabilities regardless of the timing of the redemption feature or price, even though the underlying shares may be classified as permanent or temporary equity. As of September 30, 2018, PIPE Warrants exercisable for 777,201 shares of common stock had been exercised, for approximately $0.8 million in cash proceeds, and PIPE Warrants exercisable for 16,865,281 shares of common stock were outstanding. In July 2017, Hercules Capital Inc. exercised its PIPE Warrants with respect to all 259,067 shares of common stock underlying such PIPE Warrants, and the Company issued Hercules Capital Inc. 259,067 shares of its common stock and received approximately $0.3 million in cash proceeds. In January 2018, PIPE Warrants with respect to 518,134 shares of common stock underlying such PIPE Warrants were exercised, and the Company issued 518,134 shares of its common stock and received approximately $0.5 million in cash proceeds. Refer to Note 7, "Common Stock—Private Placement / PIPE Warrants" for further discussion of the private placement financing.

The PIPE Warrants contain a provision giving the warrant holder the option to receive cash, equal to the fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480, Distinguishing Liabilities from Equity requires that these warrants be classified as a liability and not as equity. Accordingly, the Company recorded a warrant liability in the amount of approximately $9.3 million upon issuance of the PIPE Warrants. The fair value of these warrants has been determined using the Black-Scholes pricing model. These warrants are subject to revaluation at each balance sheet date and any changes in fair value are recorded as a non-cash gain or (loss) in the Statement of Operations as a component of other income (expense), net until the earlier of their exercise or expiration or upon the completion of a liquidation event. Upon exercise, the PIPE Warrants are subject to revaluation just prior to the date of the warrant exercise and any changes in fair value are recorded as a non-cash gain or (loss) in the Statement of Operations as a component of other income (expense), net and the corresponding reduction in the PIPE Warrant liability is recorded as additional paid-in capital in the Balance Sheet as a component of stockholder's equity.

The Company recorded non-cash losses of approximately $16.2 million and $6.5 million in the three months and nine months ended September 30, 2018, respectively, and non-cash losses of approximately $23.5 million and $47.9 million in the three months and nine months ended September 30, 2017, respectively, in its Statement of Operations attributable to the increases in the fair value of the PIPE Warrant liability that resulted from higher stock prices as of September 30, 2018 and September 30, 2017 relative to prior periods. In the nine months ended September 30, 2018, the Company recorded a reduction in the PIPE Warrant liability, with a corresponding increase to additional paid-in capital, of approximately $1.1 million attributable to PIPE Warrant exercises in the first quarter of 2018.

The following table rolls forward the fair value of the Company's PIPE Warrant liability, the fair value of which is determined by Level 3 inputs for the three months and nine months ended September 30, 2018 (in thousands):

Fair value at January 1, 2018	$37,746
Increase in fair value	1,465
Reduction in warrant liability for PIPE Warrant exercises	(1,101)
Fair value at March 31, 2018	$38,110
Decrease in fair value	(11,125)
Fair value at June 30, 2018	$26,985
Increase in fair value	16,172
Fair value at September 30, 2018	$43,157

The key assumptions used to value the PIPE Warrants were as follows:

	Issuance	December 31, 2017	March 31, 2018	June 30, 2018	September 30, 2018
Expected price volatility	76.25%	84.86%	85.61%	78.27%	78.56%
Expected term (in years)	5.00	3.50	3.25	3.00	2.75
Risk-free interest rates	1.22%	2.09%	2.39%	2.63%	2.88%
Stock price	$ 0.89	$ 2.79	$ 2.90	$ 2.26	$ 3.31

Dividend yield	—	—	—	—	—

Class Action Settlement and Settlement Warrants

In December 2017, the Company entered into a binding memorandum of understanding (the "MOU") with class representatives Bob Levine and William Windham (the "Plaintiffs"), regarding the settlement of a securities class action lawsuit (the "Class Action") that had been filed in 2013 and was pending in the United States District Court for the District of Massachusetts (the "District Court") against the Company and certain of the Company's former officers (Tuan Ha-Ngoc, David Johnston, and William Slichenmyer, together, the "Individual Defendants"), In re AVEO Pharmaceuticals, Inc. Securities Litigation et al., No. 1:13-cv-11157-DJC. As previously disclosed, the Class Action was purportedly brought on behalf of stockholders who purchased the Company's common stock between May 16, 2012 and May 1, 2013 (the "Class").

In December 2017, upon entering into the MOU, the Company's liability related to this settlement became estimable and probable. Accordingly, the Company recorded an estimated $17.1 million contingent liability, including $15.0 million for the cash portion of the settlement with a corresponding insurance recovery for the 100% portion to be paid directly by certain of the Company's insurance carriers, and an approximate $2.1 million estimate for the fair value on December 31, 2017 of 2.0 million warrants to purchase shares of its common stock that the Company agreed to issue the Class (the "Settlement Warrants"), with a corresponding non-cash charge to the Statement of Operations as a component of operating expense. The Settlement Warrants are

exercisable for a one-year period from their date of issue at an exercise price equal to the closing price on December 22, 2017, the trading day prior to the execution of the MOU, which was $3.00 per share.

The settlement was subject to the execution of a definitive settlement agreement, notice to the Class, and final approval of the District Court and became effective on the date (the "Effective Date") on which all of the following conditions occurred: (a) a final judgment containing the requisite release of claims had been entered by the District Court; (b) no appeal was pending with respect to the final judgment; (c) the final judgment had not been reversed, modified, vacated or amended; (d) the time to file any appeal from the final judgment had expired without the filing of an appeal or an order dismissing the appeal or affirming the final judgment had been entered, and any time to file a further appeal (including a writ of certiorari or for reconsideration of the appeal) had expired; and (e) the MOU and any settlement agreement with respect to the claims released in the final judgment had not expired or been terminated.

In January 2018, the Company entered into a definitive stipulation of settlement agreement (the "Stipulation"). In February 2018, the District Court preliminarily approved the Stipulation, following which the insurance carriers funded the settlement escrow account related to the $15.0 million cash portion of the settlement. On May 30, 2018, the District Court approved the Stipulation in its order of final approval and final judgment (the "Final Judgment"). Upon the conclusion of a 30-day appeal period, the Effective Date was deemed to be June 29, 2018. Pursuant to the Final Judgment, all claims against the Company were released upon the Effective Date. In addition, pursuant to the Stipulation, the Company has no interest in the settlement escrow account subsequent to the Effective Date. Accordingly, the $15.0 million contingent liability associated with the cash portion of the settlement and the corresponding insurance recovery were eliminated on the Effective Date. The Company had agreed to use its best efforts to issue and deliver the Settlement Warrants within ten business days following the Effective Date. On July 16, 2018, the Company issued and delivered the Settlement Warrants in accordance with the Stipulation and filed a corresponding shelf registration statement, File No. (333-226190) to register the shares of common stock underlying the Settlement Warrants which was declared effective by the SEC on July 25, 2018.

Refer to Note 9, "Legal Proceedings" for further discussion of the Class Action settlement.

The estimated fair value of the Settlement Warrants was determined using the Black-Scholes pricing model. The estimated fair value of the Settlement Warrants was subject to revaluation at each balance sheet date and any changes in fair value were recorded as a non-cash gain or (loss) in the Statement of Operations as a component of operating expenses until the Settlement Warrants were issued. In addition, the fair value of the Settlement Warrants on June 30, 2018 was determined based on the estimated fair value of the Settlement Warrants at the time of issuance. The Company recorded non-cash gains of approximately $0.7 million during the nine months ended September 30, 2018 in its Statement of Operations attributable to the decrease in the fair value of the Settlement Warrants prior to their issuance that principally resulted from a lower volatility rate relative to prior periods. In July 2018, upon the issuance of the Settlement Warrants, the Company reclassified the approximate $1.4 million value of the Settlement Warrants from a liability to stockholders equity as a component of additional paid-in-capital based upon the terms of the warrant agreement and, accordingly, the approximate $1.4 million contingent liability on the Company's balance sheet as of June 30, 2018 associated with the warrant portion of the settlement was eliminated.

The key assumptions used to estimate the fair value the Settlement Warrants were as follows:

	December 31, 2017	March 31, 2018	June 30, 2018
Expected price volatility	101.52%	96.01%	62.74%

Expected term (in years)	1.00	1.00	1.00
Risk-free interest rates	1.76%	2.09%	2.37%
Stock price	$ 2.79	$ 2.90	$ 2.90
Dividend yield	—	—	—

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase and an investment in a U.S. government money market fund to be cash equivalents. Changes in the balance of cash and cash equivalents may be affected by changes in investment portfolio maturities, as well as actual cash disbursements to fund operations.

The Company’s cash is deposited in highly-rated financial institutions in the United States. The Company invests in U.S. government money market funds, high-grade, short-term commercial paper, corporate bonds and other U.S. government agency securities, which management believes are subject to minimal credit and market risk. The carrying values of the Company’s cash and cash equivalents approximate fair value due to their short-term maturities.

The Company does not have any restricted cash balances.

Marketable Securities

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 invests in high-grade corporate obligations, including commercial paper, and U.S. government and government agency obligations that are classified as available-for-sale. Since these securities are available to fund current operations they are classified as current assets on the consolidated balance sheets.

Marketable securities are stated at fair value, including accrued interest, with their unrealized gains and losses included as a component of accumulated other comprehensive income or loss, which is a separate component of stockholders' equity. The fair value of these securities is based on quoted prices and observable inputs on a recurring basis. The cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity, with such amortization and accretion recorded as a component of interest expense, net. Realized gains and losses are determined on the specific identification method. Unrealized gains and losses are included in other comprehensive loss until realized, at which point they would be recorded as a component of interest expense, net.

Below is a summary of cash, cash equivalents and marketable securities at September 30, 2018 and December 31, 2017 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
September 30, 2018				
Cash and cash equivalents:				
Cash and money market funds	$ 15,360	$ —	$ —	$15,360
Corporate debt securities	3,051	—	—	3,051
U.S. government agency securities	1,997	—	—	1,997
Total cash, cash equivalents and marketable securities	$ 20,408	$ —	$ —	$20,408
December 31, 2017:				
Cash and cash equivalents:				
Cash and money market funds	$ 14,949	$ —	$ —	$14,949
Total cash and cash equivalents	14,949	—	—	14,949
Marketable securities:				
Corporate debt securities due within 1 year	$ 17,074	$ 1	$ (5)	$17,070
U.S. government agency securities due within 1 year	1,506	—	—	1,506
Total marketable securities	$ 18,580	$ 1	$ (5)	$18,576
Total cash, cash equivalents and marketable securities	$ 33,529	$ 1	$ (5)	$33,525

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 highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company's investment strategy is

focused on capital preservation. The Company invests in instruments that meet the high credit quality standards outlined in the Company's investment policy. This policy also limits the amount of credit exposure to any one issue or type of instrument.

The Company's accounts receivable primarily consists of amounts due to the Company from licensees and collaborators. The Company has not experienced any material losses related to accounts receivable from individual licensees or collaborators.

Fair Value Measurements

The fair value of the Company's financial assets and liabilities reflects the Company's estimate of amounts that it would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from sources independent from the Company) and to minimize the use of unobservable inputs (the Company's assumptions about how market participants would price assets and

liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3: Unobservable inputs based on the Company's assessment of the assumptions that market participants would use in pricing the asset or liability.

Financial assets and liabilities are classified in their entirety within the fair value hierarchy based on the lowest level of input that is significant to the fair value measurement. The Company measures the fair value of its marketable securities by taking into consideration valuations obtained from third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker-dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities and other observable inputs.

As of September 30, 2018, the Company's financial assets valued based on Level 1 inputs consisted of cash and cash equivalents in a U.S. government money market fund and its financial assets valued based on Level 2 inputs consisted of high-grade corporate debt securities, including commercial paper, and U.S. government agency securities. During the three months and nine months ended September 30, 2018, the Company did not have any transfers of financial assets between Levels 1 and 2.

As of September 30, 2018, the Company's financial liability that was recorded at fair value consisted of the PIPE Warrant liability.

The fair value of the Company's loans payable at September 30, 2018 approximates its carrying value, computed pursuant to a discounted cash flow technique using a market interest rate and is considered a Level 3 fair value measurement. The effective interest rate, which reflects the current market rate, considers the fair value of the warrants issued in connection with the loan, loan issuance costs and the deferred financing charge.

The following table summarizes the assets and liabilities measured at fair value on a recurring basis at September 30, 2018 and December 31, 2017 (in thousands):

	Fair Value Measurements as of September 30, 2018			
	Level 1	Level 2	Level 3	Total
Financial assets carried at fair value:				
Cash and money market funds	$15,360	$—	$—	$15,360

Corporate debt securities	—	3,051	—	3,051
U.S. government agency securities	—	1,997	—	1,997
Total cash, cash equivalents and marketable securities	$15,360	$5,048	$—	$20,408
Financial liabilities carried at fair value:				
Total PIPE Warrant liability	$—	$—	$43,157	$43,157

	Fair Value Measurements as of December 31, 2017			
	Level 1	Level 2	Level 3	Total
Financial assets carried at fair value:				