AVEO PHARMACEUTICALS INC
Form 10-Q
August 07, 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 June 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 (Do not check if a smaller reporting company) 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 August 3, 2018: 119,030,147

AVEO PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2018

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AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except par value amounts)

(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$18,089	$ 14,949
Marketable securities	—	18,576
Accounts receivable	973	402
Insurance recovery (Note 9)	—	15,000
Clinical trial retainers	567	1,027
Other prepaid expenses and other current assets	370	229
Total current assets	19,999	50,183
Other assets	7	15
Total assets	$20,006	$ 50,198
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$2,822	$ 2,436
Accrued clinical trial costs and contract research	6,991	8,321
Other accrued liabilities	1,684	2,458
Loans payable, net of discount	2,388	—
Deferred revenue	1,342	395
Deferred research and development reimbursements	534	901
Estimated settlement liability (Note 9)	1,406	17,073
Other liabilities (Note 6)	—	540
Total current liabilities	17,167	32,124
Loans payable, net of current portion and discount	16,342	18,477
Deferred revenue	3,749	1,302
Deferred research and development reimbursements	118	222
PIPE Warrant liability (Note 7)	26,985	37,746
Other liabilities (Note 6)	1,090	1,090
Total liabilities	65,451	90,961
Stockholders' deficit:		
Preferred stock, $.001 par value: 5,000 shares authorized at June 30, 2018 and December 31, 2017; no shares issued and outstanding at each of June 30, 2018 and December 31, 2017	—	—
Common stock, $.001 par value: 250,000 shares authorized at June 30,	119	118

2018 and December 31, 2017; 118,995 and 118,325 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively		
Additional paid-in capital	549,099	546,092
Accumulated other comprehensive income (loss)	1	(4)
Accumulated deficit	(594,664)	(586,969)
Total stockholders' deficit	(45,445)	(40,763)
Total liabilities and stockholders' deficit	$20,006	$ 50,198

See accompanying notes.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Revenues:				
Collaboration and licensing revenue	$336	$351	$1,316	$2,883
Partnership royalties	97	—	143	—
	433	351	1,459	2,883
Operating expenses:				
Research and development	4,887	6,881	10,291	14,837
General and administrative	2,827	2,302	5,437	4,633
Settlement costs (Note 9)	(709)	—	(667)	—
	7,005	9,183	15,061	19,470
Loss from operations	(6,572)	(8,832)	(13,602)	(16,587)
Other income (expense), net:				
Interest expense, net	(549)	(530)	(1,042)	(1,081)
Change in fair value of PIPE Warrant liability	11,125	(23,925)	9,660	(24,409)
Other income (expense), net	10,576	(24,455)	8,618	(25,490)
Income (loss) before provision for income taxes	4,004	(33,287)	(4,984)	(42,077)
Provision for income taxes	—	—	—	(50)
Net income (loss)	$4,004	$(33,287)	$(4,984)	$(42,127)
Basic net income (loss) per share				
Net income (loss) per share	$0.03	$(0.30)	$(0.04)	$(0.45)
Weighted average number of common shares outstanding	118,940	110,550	118,891	93,493
Diluted net income (loss) per share				
Net income (loss) per share	$(0.06)	$(0.30)	$(0.11)	$(0.45)
Weighted average number of common shares and dilutive common share equivalents outstanding	128,692	110,550	129,372	93,493

See accompanying notes.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(In thousands)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Net income (loss)	$4,004	$(33,287)	$(4,984)	$(42,127)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	5	(3)	5	(8)
Comprehensive income (loss)	$4,009	$(33,290)	$(4,979)	$(42,135)

See accompanying notes.

AVEO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Operating activities		
Net loss	$(4,984)	$(42,127)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,204	483
Non-cash interest expense	253	268
Non-cash change in fair value of PIPE Warrant liability	(9,660)	24,409
Non-cash charge for settlement warrants (Note 9)	(667)	—
Amortization of premium and discount on investments	2	12
Changes in operating assets and liabilities:		
Accounts receivable	(571)	582
Insurance recovery (Note 9)	15,000	—
Prepaid expenses and other current assets	319	372
Other noncurrent assets	8	618
Accounts payable	386	1,175
Accrued contract research	(1,330)	2,245
Other accrued liabilities	(774)	(171)
Settlement liability (Note 9)	(15,000)	—
Deferred revenue	683	(313)
Deferred research and development reimbursements	(471)	—
Net cash used in operating activities	(15,602)	(12,447)
Investing activities		
Purchases of marketable securities	(6,733)	(9,286)
Proceeds from maturities and sales of marketable securities	25,312	8,252
Net cash provided by (used in) investing activities	18,579	(1,034)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	518	21,035
Proceeds from issuance of common stock to related parties	—	3,210
Proceeds from issuance of stock for stock-based compensation arrangements	185	—
Proceeds from issuance of loans payable	—	5,000
Payment of end-of-term debt costs (Note 6)	(540)	—
Net cash provided by financing activities	163	29,245
Net increase in cash and cash equivalents	3,140	15,764
Cash and cash equivalents at beginning of period	14,949	15,096
Cash and cash equivalents at end of period	$18,089	$30,860
Supplemental cash flow information		

Cash paid for interest	$992	$902
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

June 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 renal cell carcinoma ("RCC"). 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 advanced RCC ("aRCC") 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 aRCC. 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"). The Company previously partnered with Novartis International Pharmaceutical Ltd. ("Novartis") to develop the AV-380 program in cachexia and other indications. Effective August 28, 2018 the Company expects to regain the rights to AV-380 and is considering a variety of options to continue the program's development. Refer to Note 4 "Collaborations and License Agreements – Novartis" for further details.

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 June 30, 2018, the Company had cash, cash equivalents and marketable securities totaling approximately $18.1 million, working capital of $2.8 million and an accumulated deficit of $594.7 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 June 30, 2018, the Company had approximately $18.1 million in cash, cash equivalents and marketable securities. 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 aRCC.
- 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 sales agreement (the "Leerink Sales Agreement") with Leerink Partners LLC ("Leerink"), 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 phase 3 study in third-line RCC, 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.

In addition, CANbridge Life Sciences Ltd. ("CANbridge") filed an initial new drug ("IND") application with the China Food and Drug Administration in December 2017 for a clinical study of AV-203 in esophageal squamous cell carcinoma. Pursuant to the Company's collaboration and license agreement with CANbridge (the "CANbridge Agreement"), the Company is entitled to receive a $2.0 million development and regulatory milestone payment upon the receipt of the regulatory approval of this IND application.

There can be no assurance, however, 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 $18.1 million in cash, cash equivalents and marketable securities at June 30, 2018 would allow it to fund its planned operations into the first quarter of 2019. This estimate assumes no receipt of additional milestone payments from its partners, no funding from new partnership agreements, no equity financings, no debt financings, no sales of equity under its 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 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 six months ended June 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 June 30, 2018, and for the three months and six months ended June 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. 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, Revenue from Contracts with Customers ("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 six months ended June 30, 2018 and 2017, respectively, by partner (in thousands). Refer to Note 4 Collaborations and License Agreements regarding specific details.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
EUSA	$433	$99	$1,459	$198
Novartis	—	15	—	1,820
CANbridge	—	—	—	500
Ophthotech	—	87	—	115
Other	—	150	—	250
Total	$433	$351	$1,459	$2,883

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 June 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 gains of approximately $11.1 million and $9.7 million in the three months and six months ended June 30, 2018, respectively, and non-cash losses of approximately $23.9 million and $24.4 million in the three months and six months ended June 30, 2017, respectively, in its Statement of Operations attributable to the increases and decreases in the fair value of the PIPE Warrant liability that resulted from a lower stock price as of June 30, 2018 and a higher stock price as of June 30, 2017 relative to prior periods. In the six months ended June 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 six months ended June 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

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

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

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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. 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 in each of the three months and six months ended June 30, 2018, respectively, in its Statement of Operations attributable to the decrease in the fair value of the Settlement Warrants that principally resulted from a lower volatility rate relative to prior periods.

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 June 30, 2018 and December 31, 2017 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
June 30, 2018				
Cash and cash equivalents:				
Cash and money market funds	$ 15,075	$ —	$ —	$ 15,075
Corporate debt securities	3,013	1	—	3,014
Total cash, cash equivalents and marketable securities	$ 18,088	$ 1	$ —	$ 18,089
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
US 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 June 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. During the three months and six months ended June 30, 2018, the Company did not have any transfers of financial assets between Levels 1 and 2.

As of June 30, 2018, the Company's financial liabilities that were recorded at fair value consisted of warrant liabilities, including the PIPE Warrant liability and estimated fair value of the Settlement Warrants.

The fair value of the Company's loans payable at June 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 June 30, 2018 and December 31, 2017 (in thousands):

	Fair Value Measurements as of June 30, 2018			
	Level 1	Level 2	Level 3	Total
Financial assets carried at fair value:				
Cash and money market funds	$15,075	$—	$—	$15,075
Corporate debt securities	—	3,014	—	$3,014
Total cash, cash equivalents and marketable securities	$15,075	$3,014	$—	$18,089
Financial liabilities carried at fair value:				
PIPE Warrant liability	$—	$—	$26,985	$26,985
Settlement Warrant liability	—	—	1,406	1,406
Total warrant liabilities	$—	$—	$28,391	$28,391

Fair Value Measurements as of

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Financial assets carried at fair value:				
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	$—	$17,070	$—	$17,070
U.S. government agency securities due within 1 year	—	1,506	—	1,506
Total marketable securities	$—	$18,576	$—	$18,576
Total cash, cash equivalents and marketable securities	$14,949	$18,576	$—	$33,525
Financial liabilities carried at fair value:				
PIPE Warrant liability	$—	$—	$37,746	$37,746
Settlement Warrant liability	—	—	2,073	2,073
Total warrant liabilities	$—	$—	$39,819	$39,819

Basic and Diluted Net Income (Loss) per Common Share

Basic net income (loss) per share attributable to AVEO common stockholders is based on the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share attributable to AVEO common stockholders is based on the weighted-average number of common shares outstanding during the period plus additional weighted-average common equivalent shares outstanding during the period when the effect is dilutive. Common equivalent shares include the incremental common shares issuable upon the exercise of the PIPE Warrants, as determined using the treasury stock method, and exclude the incremental common shares issuable upon the exercise of the Settlement Warrants as these warrants were not outstanding as of June 30, 2018. For the three months and six months ended June 30, 2017 diluted net loss per share is the same as basic net loss per share as the inclusion of common stock issuable upon the exercise of the PIPE Warrants and other common equivalent shares, such as stock options, would be anti-dilutive.

The following table summarizes the computation of basic and diluted net income (loss) per share for the three months and six months ended June 30, 2018 and 2017, respectively (in thousands except per share amounts):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Basic net income (loss) attributable to AVEO common stockholders	$4,004	$(33,287)	$(4,984)	$(42,127)
Less: non-cash gains attributable to the change in fair value of the PIPE Warrant liability	(11,125)	—	(9,660)	—
Diluted net income (loss) attributable to AVEO common stockholders	$(7,121)	$(33,287)	$(14,644)	$(42,127)
Weighted-average shares of common stock outstanding	118,940	110,550	118,891	93,493
Dilutive securities:				
Incremental common shares issuable upon the exercise of the PIPE Warrants	9,752	—	10,481	—
Weighted-average shares of common stock outstanding and dilutive securities	128,692	110,550	129,372	93,493
Basic net income (loss) per share	$0.03	$(0.30)	$(0.04)	$(0.45)
Diluted net income (loss) per share	$(0.06)	$(0.30)	$(0.11)	$(0.45)

The following table summarizes outstanding securities not included in the computation of diluted net loss per common share as the effect would have been anti-dilutive for the three months and six months ended June 30, 2018 and 2017, respectively (in thousands):

	Outstanding at June 30,	
	2018	2017
Options outstanding	9,924	6,568
Warrants outstanding	—	19,453
Total	9,924	26,021

Stock-Based Compensation

Under the Company's stock-based compensation programs, the Company periodically grants stock options and restricted stock to employees, directors and nonemployee consultants. The Company also issues shares under an employee stock purchase plan. The fair value of all awards is recognized in the Company's statements of operations over the requisite service period for each award.

Awards that vest as the recipient provides service are expensed on a straight-line basis over the requisite service period. Other awards, such as performance-based awards that vest upon the achievement of specified goals, are expensed using the accelerated attribution method if achievement of the specified goals is considered probable. The Company has also granted awards that vest upon the achievement of market conditions. Per ASC 718 Share-Based Payments, market conditions must be considered in determining the estimated grant-date fair value of share-based payments and the market conditions must be considered in determining

the requisite service period over which compensation cost is recognized. The Company estimates the fair value of the awards with market conditions using a Monte Carlo simulation, which utilizes several assumptions including the risk-free interest rate, the volatility of the Company's stock and the exercise behavior of award recipients. The grant-date fair value of the awards is then recognized over the requisite service period, which represents the derived service period for the awards as determined by the Monte Carlo simulation.

The Company uses the Black-Scholes option pricing model to value its stock option awards without market conditions, which require the Company to make certain assumptions regarding the expected volatility of its common stock price, the expected term of the option grants, the risk-free interest rate and the dividend yield with respect to its common stock. The Company calculates volatility using its historical stock price data. Due to the lack of the Company's own historical data, the Company elected to use the "simplified" method for "plain vanilla" options to estimate the expected term of the Company's stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The Company utilizes a dividend yield of zero based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

The fair value of equity-classified awards to employees and directors are measured at fair value on the date the awards are granted. Awards to nonemployee consultants are recorded at their fair values and are re-measured as of each balance sheet date until the recipient's services are complete. During the three months and six months ended June 30, 2018 and 2017, the Company recorded the following stock-based compensation expense (in thousands):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Research and development	$198	$71	$381	$123
General and administrative	423	205	823	360
Total	$621	$276	$1,204	$483

Stock-based compensation expense is allocated to research and development and general and administrative expense based upon the department of the employee to whom each award was granted. No related tax benefits of the stock-based compensation expense have been recognized.

Income Taxes

The Company provides for income taxes using the asset-liability method. Under this method, deferred tax assets and liabilities are recognized based on differences between financial reporting and tax bases of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company calculates its provision for income taxes on ordinary income based on its projected annual tax rate for the year. Uncertain tax positions are recognized if the position is more-likely-than-not to be sustained upon examination by a tax authority. Unrecognized tax benefits represent tax positions for which reserves have been established. As of June 30, 2018, the Company is forecasting a net loss for the year ended December 31, 2018 and an effective tax rate of 0%. The Company maintains a full valuation allowance on all deferred tax assets.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118"), which allows the recording of provisional amounts during a measurement period not to extend beyond one year of the enactment date. In accordance with SAB 118, the Company determined a provisional amount for the impact on its prior year deferred tax assets and valuation allowance in its prior year financial statements. The Company has not updated the provisional amounts and expects to complete the final assessment of the impact within the measurement period.

Segment and Geographic Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment principally in the United States. As of June 30, 2018, the Company has no net assets located outside of the United States.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant items subject to such estimates and assumptions include revenue recognition, contract research accruals, measurement of the PIPE Warrant liability, estimated settlement liabilities and measurement of stock-based compensation. The Company bases its estimates on historical experience and various other assumptions that management believes to be reasonable under the circumstances. Material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates if past experience or other assumptions do not turn out to be substantially accurate.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in ASC 605 and creates ASC 606. In 2015 and 2016, the FASB issued additional ASUs related to ASC 606 that delayed the effective date of the guidance for annual and interim periods beginning after December 15, 2017 and clarified various aspects of the new revenue guidance. ASC Topic 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract, and requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

On January 1, 2018, the Company adopted ASC 606 using the modified retrospective method and applied the new guidance to the most current period presented with the cumulative effect of changes reflected in the opening balance of accumulated deficit. The Company conducted an analysis with respect to its active revenue arrangements, including those with EUSA, CANbridge and Novartis.

The adoption of ASC 606 resulted in an approximate $2.7 million increase in each of deferred revenue and the accumulated deficit at the transition date. The transition adjustment related solely to the Company's revenue arrangement with EUSA. The transition adjustment resulted from a change to the Company's accounting policy with respect to the recognition of milestone payments as a result of adopting ASC 606. Prior to the adoption of ASC 606, the Company generally recognized milestone payments in their entirety as revenue in the period the payment was earned. However, under ASC 606, milestone payments are considered to be a form of variable consideration that, upon inclusion in the transaction price, is recognized when (or as) the remaining performance obligation(s) are satisfied. Because the Company's performance obligation under the EUSA Agreement was only partially satisfied at January 1, 2018, a milestone payment received under that arrangement prior to the January 1, 2018 transition date has not been fully recognized as revenue as under ASC 606 as of the transition date.

As a result of adopting ASC 606, the Company established a deferred revenue deferred tax asset, in the amount of $0.7 million, and a corresponding offsetting valuation allowance, such that there was not tax impact on the Company's condensed consolidated financial statements as a result of adopting ASC 606.

There was no impact from adopting ASC 606 to the Company's revenue arrangements with CANbridge and Novartis as (i) the Company did not have any unsatisfied performance obligations under the CANbridge Agreement and the Company's license agreement with Novartis (the "Novartis Agreement") upon the adoption of ASC 606 and (ii) the

transaction price under ASC 606 as of the transition date was the same as the arrangement consideration under ASC Topic 605.

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.

The following table summarizes the cumulative effect of the adoption of ASC 606 to the Company's contracts with customers that were not completed as of the January 1, 2018 transition date (in thousands):

	Impact of ASC 606 Adoption on Condensed Consolidated Balance Sheet as of January 1, 2018		
	As reported under ASC Topic 606	Adjustments	Balances without adoption of ASC Topic 606
Deferred revenue, current portion	$1,027	$ 632	$395
Deferred revenue, net of current portion	$3,381	$ 2,079	$1,302
Accumulated deficit	$(589,680)	$ (2,711)	$(586,969)

The following tables summarize the impact of the adoption of ASC 606 to the Company's condensed consolidated financial statements at June 30, 2018 and for the three months and six months ended June 30, 2018 as follows (in thousands, except per share figures):

	Impact of ASC 606 Adoption on Condensed Consolidated Balance Sheet as of June 30, 2018		
	As reported under ASC Topic 606	Adjustments	Balances without adoption of ASC Topic 606
Deferred revenue, current portion	$1,342	$ 947	$395
Deferred revenue, net of current portion	$3,749	$ 2,645	$1,104
Accumulated deficit	$(594,664)	$ (3,592)	$(591,072)

	Impact of ASC 606 Adoption on Condensed Consolidated Statement of Operations and Comprehensive Loss					
	Three Months Ended June 30, 2018			Six Months Ended June 30, 2018		
	As reported under ASC Topic 606	Adjustments	Balances without adoption of ASC Topic 606	As reported under ASC Topic 606	Adjustments	Balances without adoption of ASC Topic 606
Collaboration and licensing revenue	$336	$ 237	$99	$1,316	$ (882)	$2,198
Total revenues	$433	$ 237	$196	$1,459	$ (882)	$2,341
Income (loss) before provision for income taxes	$4,004	$ 237	$3,767	$(4,984)	$ (882)	$(4,102)
Net income (loss) - basic	$4,004	$ 237	$3,767	$(4,984)	$ (882)	$(4,102)

Net income (loss) - diluted	$(7,121)	$ 237	$(7,358)	$(14,644)	$ (882)	$(13,762)
Net income (loss) per share - basic	$0.03	$ —	$0.03	$(0.04)	$ (0.01)	$(0.03)
Net income (loss) per share - diluted	$(0.06)	$ —	$(0.06)	$(0.11)	$ (0.01)	$(0.10)

	Impact of ASC 606 Adoption on Condensed Consolidated Statement of Cash Flows as of June 30, 2018		
	As reported under ASC Topic 606	Adjustments	Balances without adoption of ASC Topic 606
Net loss	$(4,984)	$(882)	$(4,102)
Changes in deferred revenue	$683	$ 882	$(199)

Refer to Note 3 “Significant Accounting Policies – Revenue Recognition” and Note 4 “Collaborations and License Agreements” for further details.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. The new standard also clarifies that an entity should determine each separately identifiable source or use within the cash receipts and cash payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. The Company adopted the new standard upon the required effective date of January 1, 2018. The adoption of this standard did not have a material impact on the Company’s consolidated statements of cash flows.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. The new standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. The new standard is effective for fiscal years, and interim periods within, beginning after December 15, 2017. The Company adopted the new standard effective January 1, 2018. The adoption of this standard did not have a material impact on the Company's consolidated statements of cash flows.

Pending Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which requires lessees to recognize a right-of-use asset and lease liability for most lease arrangements. The new standard is effective for annual reporting periods beginning after December 15, 2018 with early adoption permitted. The Company is currently evaluating the potential changes from this ASU.

In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, which simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new standard is effective for annual reporting periods beginning after December 15, 2018 with early adoption permitted. The Company is currently evaluating the potential changes from this ASU.

(4) Collaborations and License Agreements

Out-License Agreements

CANbridge

On March 16, 2016, the Company entered into the CANbridge Agreement. Under the terms of the CANbridge Agreement, the Company granted CANbridge the exclusive right to develop, manufacture and commercialize AV-203, the Company's proprietary ErbB3 (HER3) inhibitory antibody, for the diagnosis, treatment and prevention of disease in all countries outside of North America (the "CANbridge Licensed Territory"). In addition, CANbridge has the right of first refusal if the Company determines to out-license any North American rights. The parties have both agreed not to develop or commercialize any ErbB3 inhibitory antibody other than AV-203 during the term of the CANbridge Agreement.

Pursuant to the CANbridge Agreement, CANbridge made an upfront payment to the Company of $1.0 million in April 2016, net of $0.1 million of foreign withholding taxes. CANbridge also reimbursed the Company for $1.0 million of certain AV-203 manufacturing costs incurred by the Company prior to entering into the CANbridge Agreement. CANbridge paid this manufacturing reimbursement in two installments of $0.5 million each, one in March 2017 and one in September 2017, net of foreign withholding taxes. In December 2017, CANbridge filed an IND application with the China Food and Drug Administration for a clinical study of AV-203 in esophageal squamous cell carcinoma. The Company is entitled to receive a $2.0 million development and regulatory milestone payment upon the receipt of

the regulatory approval of this IND application. The Company is also eligible to receive up to $40.0 million in potential additional development and regulatory milestone payments and up to $90.0 million in potential commercial milestone payments based on annual net sales of licensed products. Upon commercialization, the Company is eligible to receive a tiered royalty, with a percentage range in the low double-digits, on net sales of approved licensed products. CANbridge's obligation to pay royalties for each licensed product expires on a country-by-country basis on the later of the expiration of patent rights covering such licensed product in such country, the expiration of regulatory data exclusivity in such country and ten years after the first commercial sale of such licensed product in such country. No development and regulatory milestone payments have been earned as of June 30, 2018.

CANbridge is obligated to use commercially reasonable efforts to develop and commercialize AV-203 in each of China, Japan, the United Kingdom, France, Italy, Spain, and Germany. CANbridge has responsibility for all activities and costs associated with the further development, manufacture and commercialization of AV-203 in the CANbridge Licensed Territory, including the clinical development of AV-203 through phase 2 proof-of-concept in esophageal squamous cell carcinoma, after which the Company may elect to contribute to certain worldwide development efforts.

A percentage of any milestone and royalty payments received by the Company pursuant to the CANbridge Agreement, excluding upfront and reimbursement payments, are due to Biogen Idec International GmbH ("Biogen") as a sublicensing fee under the option and license agreement between the Company and Biogen dated March 18, 2009, as amended.

Accounting Analysis Under ASC 606

The Company evaluated the CANbridge Agreement under ASC 606. Based on this evaluation, the Company identified the following promised goods and services at the inception of the CANbridge Agreement: the Company's grant of an exclusive license to develop and commercialize AV-203 in the CANbridge Licensed Territory, including all technical knowledge and data useful in the development and manufacture of AV-203. The Company determined that the license and know-how represented functional intellectual property. The Company concluded its promise to participate on a joint steering committee was immaterial in the context of the contract based on consideration of qualitative and quantitative factors. In making this evaluation the Company considered the specific personnel and time commitment that would be required to provide the joint steering committee services, concluding that the time commitment would be insignificant. Accordingly, the Company determined the CANbridge Agreement contained a single performance obligation related to the exclusive license to develop and commercialized AV-203 that was satisfied at the inception of the arrangement.

The Company determined that the $1.0 million in upfront consideration received upon the execution of the CANbridge Agreement in March 2016 and the $1.0 million reimbursement received in the year ended December 31, 2017 for certain manufacturing costs incurred by the Company prior to the Effective Date constituted the amount of the consideration to be included in the transaction price upon the adoption of ASC 606 on January 1, 2018 and attributed these amounts to the Company's single performance obligation. Because the Company satisfied the single performance obligation at the inception of the contract and had no remaining performance obligations, each of these amounts were recognized upon receipt. None of the development and regulatory milestones have been included in the transaction price, as these milestone amounts are fully constrained. As part of its evaluation of the constraint, the Company considered multiple factors: (i) regulatory approvals are outside of the control of CANbridge, (ii) certain development and regulatory milestones are contingent upon the success of future clinical trials, if any, which is out of the control of CANbridge, and (iii) efforts by CANbridge. Any consideration related to development and regulatory milestones will be recognized when the corresponding milestones are no longer constrained as the Company does not have any ongoing performance obligations. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to CANbridge and therefore are recognized at the later of when the performance obligation is satisfied or the related sales occur. The Company will re-evaluate the transaction price, including its estimated variable consideration for milestones included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Previously, under ASC 605, the Company recognized the $1.0 million in upfront consideration as collaboration and licensing revenue in the first quarter of 2016 upon delivery of the exclusive license, and recognized the two $0.5 million payments by CANbridge for the reimbursement of manufacturing development activities conducted by the Company prior to the Effective Date as collaboration and licensing revenue in each of March 2017 and September 2017, respectively, as the amounts were fixed, determinable and non-refundable, and the Company did not have any further performance obligations. Accordingly, as the timing and amount of revenue recognition for the payments received from CANbridge are the same under ASC 605 and ASC 606, there was no transition adjustment required as of January 1, 2018.

EUSA

In December 2015, the Company entered into the EUSA Agreement, under which the Company granted to EUSA the exclusive, sublicensable right to develop, manufacture and commercialize tivozanib in the territories of Europe (excluding Russia, Ukraine and the Commonwealth of Independent States), Latin America (excluding Mexico), Africa and Australasia (collectively, the "EUSA Licensed Territories") for all diseases and conditions in humans, excluding non-oncologic diseases or conditions of the eye.

EUSA made research and development reimbursement payments to the Company of $2.5 million upon the execution of the EUSA Agreement during the year ended December 31, 2015 and $4.0 million in September 2017 upon its receipt of marketing approval from the EMA in August 2017 for tivozanib (FOTIVDA) for the treatment of aRCC. In September 2017, EUSA elected to opt-in to co-develop the ongoing TiNivo trial. As a result of exercising its opt-in right, EUSA made an additional research and development reimbursement payment to the Company of $2.0 million. This $2.0 million payment was received in October 2017, in advance of the completion of the TiNivo trial, and represents EUSA's approximate 50% share of the total estimated costs of the TiNivo trial. 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 phase 3 study in third-line RCC, up to $20.0 million, if EUSA elects to opt-in to that study.

The Company is entitled to receive milestone payments of $2.0 million per country upon reimbursement approval for RCC, if any, in each of France, Germany, Italy, Spain and the United Kingdom, and an additional $2.0 million for the grant of marketing approval for RCC, if any, in three of the licensed countries outside of the European Union, as mutually agreed by the parties. In February 2018, EUSA obtained reimbursement approval from the National Institute for Health and Care Excellence ("NICE") in the United Kingdom for the first-line treatment of aRCC. Accordingly, the Company earned a $2.0 million milestone payment that was received in March 2018. The Company is also eligible to receive a payment of $2.0 million per indication in

connection with a filing by EUSA with the EMA for marketing approval, if any, for tivozanib for the treatment of each of up to three additional indications and $5.0 million per indication in connection with the EMA's grant of marketing approval for each of up to three additional indications, as well as potentially up to $335.0 million upon EUSA's achievement of certain sales thresholds. The Company is also eligible to receive tiered double-digit royalties on net sales, if any, of licensed products in the EUSA Licensed Territories ranging from a low double digit up to mid-twenty percent depending on the level of annual net sales.

The research and development reimbursement payments under the EUSA Agreement are not subject to the 30% sublicensing payment payable to KHK, subject to certain limitations. The Company, however, would owe KHK 30% of other, non-research and development payments it may receive from EUSA pursuant to the EUSA Agreement, including reimbursement approvals for RCC in up to five specified European Union ("EU") countries, marketing approvals for RCC in three specified non-EU licensed territories, EU marketing approval filings and corresponding marketing approvals by the EMA for up to three additional indications beyond RCC, and sales-based milestones and royalties, as set forth above. The $2.0 million milestone the Company earned in February 2018 upon EUSA's reimbursement approval from the NICE in the UK in first-line aRCC was subject to the 30% KHK sub-license fee, or $0.6 million, which was paid in April 2018.

EUSA is obligated to use commercially reasonable efforts to seek regulatory approval for and commercialize tivozanib throughout the EUSA Licensed Territories in RCC. EUSA has responsibility for all activities and costs associated with the further development, manufacture, regulatory filings and commercialization of tivozanib in the EUSA Licensed Territories.

Accounting Analysis Under ASC 606

Pursuant to ASC Topic 606, the Company identified the following promised goods and services at the inception of the EUSA Agreement: (i) the Company's grant of an exclusive license to develop and commercialize tivozanib in the EUSA Licensed Territories, including the Company's obligation to transfer all technical knowledge and data useful in the development and manufacture of tivozanib; (ii) the Company's obligation to cooperate with EUSA and support its efforts to file for marketing approval in the EUSA Licensed Territories and in its commercialization efforts, (iii) the Company's obligation to provide access to certain regulatory information resulting from the Company's ongoing development activities outside of the EUSA Licensed Territories and (iv) the Company's participation in a joint steering committee. The Company determined that the license to develop and commercialize tivozanib in the EUSA Licensed Territories was not distinct from the other promised goods and services and has accordingly accounted for these items as a single performance obligation. In reaching this conclusion, the Company concluded the remaining promises were essential to EUSA's use of the license.

The Company concluded at contract inception that EUSA's opt-in rights with respect to the TiNivo trial and the TIVO-3 trial did not represent material rights because at contract inception the Company had not yet initiated either trial and the option price (representing approximately 50% of the costs of the respective trial) was proportional to the value attributed to the EUSA Licensed Territories relative to the territorial rights retained by AVEO. Accordingly, the Company accounts for each opt-in as a separate arrangement when such opt-ins occur.

The Company evaluated the promised goods and services at the inception of the EUSA Agreement under ASC 606. Based on this evaluation, the Company determined that $6.5 million in research and development payments by EUSA, including the $2.5 million upfront consideration received upon the execution of the EUSA Agreement in December 2015 and the $4.0 million payment upon the receipt of marketing approval from the EMA for tivozanib (FOTIVDA) for the treatment of aRCC in August 2017, constituted the amount of the consideration that was included

in the transaction price upon the adoption of ASC 606 on January 1, 2018 and attributed this amount to the Company's single performance obligation. None of the remaining regulatory-related milestones have been included in the transaction price as these milestone amounts are fully constrained. As part of its evaluation of the constraint, the Company considered multiple factors: (i) the remaining reimbursement and marketing approvals in RCC are outside of the control of EUSA and vary on a country-by-country basis, (ii) milestones related to the submission filings for EMA approval of tivozanib in up to three additional indications are contingent upon the success of future clinical trials in additional indications, if any, and are outside of the control of EUSA, (iii) milestones related to the marketing approval by the EMA for tivozanib in up to three additional indications are contingent upon the success of the corresponding future clinical trials, if any, and are outside of the control of EUSA, and (iv) efforts by EUSA. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to EUSA and therefore are recognized at the later of when the performance obligation is satisfied (or partially satisfied) or the related sales occur. The Company will re-evaluate the transaction price, including its estimated variable consideration for milestones included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Under ASC 606, the upfront consideration and regulatory milestones included in the transaction price are being recognized as collaboration and licensing revenue over the Company's performance period from contract execution in December 2015 through the remaining patent life of tivozanib in April 2022. Under ASC 606, upon the achievement of a regulatory milestone, the amount that represents the cumulative catch-up for the period from contract execution in December 2015 through the date of the

milestone achievement is recognized as collaboration and licensing revenue, with the balance classified as deferred revenue and recognized as collaboration and licensing revenue over the remainder of the performance period through April 2022.

Previously, under ASC 605, the $2.5 million in upfront consideration was being recognized over the Company's performance period from contract execution in December 2015 through the remaining patent life of tivozanib in April 2022 and, accordingly, did not represent a change under ASC 606.

Previously, under ASC 605, the Company recognized regulatory milestones when they were achieved. The $4.0 million research and development reimbursement payment upon marketing approval by the EMA in aRCC in August 2017 was recognized as revenue in the third quarter of 2017 in accordance with ASC 605-28, Revenue Recognition—Milestone Method, as the underlying milestone was considered to be substantive and, accordingly, did represent a change under ASC 606. The impact of the adoption of ASC 606 on January 1, 2018 resulted in increases of approximately $2.7 million in each of deferred revenue and the accumulated deficit. This amount represents the $4.0 million gross amount of the research and development reimbursement payment for marketing approval by the EMA in aRCC, less the approximate $1.3 million that otherwise would have been recognized as collaboration and licensing revenue related to the cumulative catch-up for the period from contract execution in December 2015 through December 31, 2017, just prior to the adoption of ASC 606.

In November 2017, the Company began earning sales royalties upon EUSA's commencement of the first commercial launch of tivozanib (FOTIVDA) with the initiation of product sales in Germany. The commercial launch expanded to the UK following the reimbursement approval by the NICE in February 2018, to Austria in April 2018 and to Scotland in July 2018. The Company recognized approximately $97,000 and $143,000 in revenue for sales royalties in the three months and six months ended June 30, 2018, respectively.

In the first quarter of 2018, the Company increased the transaction price to $8.5 million to include the $2.0 million milestone for reimbursement approval from the NICE in the UK in first-line aRCC that was achieved in February 2018. Accordingly, the Company recognized approximately $0.7 million in collaboration and licensing revenue for the cumulative catch-up for the period from contract execution in December 2015 through the milestone achievement in February 2018, with the approximate $1.3 million balance classified as deferred revenue that is being recognized as collaboration and licensing revenue over the remainder of the performance period through April 2022. The Company recognized approximately $0.4 million and $0.1 million, respectively, in total revenues under the EUSA Agreement in the three months ended June 30, 2018 and 2017, respectively, and approximately $1.5 million and $0.2 million in the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, there was approximately $5.1 million in total deferred revenue that will continue to be recognized as collaboration and licensing revenue, in the approximate amount of $0.3 million per quarter, over the duration of the Company's performance period through April 2022.

The following table summarizes the revenues earned in connection with the EUSA Agreement under ASC 606 for the three months and six months ended June 30, 2018 (in thousands):

Revenue Type	Date Achieved	Three Months Ended June 30, 2018	Six Months Ended June 30, 2018
Collaboration and Licensing Revenue:			
Amounts in contract liabilities at the beginning of the period:			
Upfront payment	December 2015	$ 99	$ 198
R&D payment - EMA approval in RCC	August 2017	158	316
New amounts in contract liabilities during the current period:			
Milestone - UK reimbursement approval	February 2018	79	802
		$ 336	$ 1,316
Partnership Royalties		97	143
Total		$ 433	$ 1,459

The following table summarizes changes in the Company’s accounts receivable and contract liabilities (deferred revenue) in connection with the EUSA Agreement for the six months ended June 30, 2018 (in thousands):

Contract Assets	Beginning Balance January 1, 2018	Additions	Deductions	Ending Balance June 30, 2018
Accounts Receivable	$18	$ 2,143	$ (2,064)	97

Contract Liabilities	Transaction Price	Date Achieved	Date Paid	Deferred Revenue Beginning Balance January 1, 2018	Additions	Deductions	Ending Balance June 30, 2018
Amounts in contract liabilities at the beginning of the period:							
Upfront payment	$ 2,500	December 2015	December 2015	$1,697	$ —	$ (198)	$1,499
R&D payment - EMA approval in RCC	4,000	August 2017	September 2017	2,711	—	(316)	2,395
New amounts in contract liabilities during the current period:							
Milestone - UK reimbursement approval	2,000	February 2018	March 2018	—	1,316	(119)	1,197
Total	$ 8,500			$4,408	$ 1,316	$ (633)	$5,091

Opt-In to the TiNivo Trial

In September 2017, EUSA elected to opt-in to co-develop the TiNivo trial. As previously described, the Company accounts for each opt-in as a separate arrangement. As a result of EUSA's exercise of its opt-in right, it became an active participant in the ongoing conduct of the TiNivo trial and is able to utilize the resulting data from the TiNivo trial for regulatory and commercial purposes in the EUSA Licensed Territories. Upon the exercise of its opt-in right, EUSA became responsible for funding 50% of the total estimated costs of the TiNivo trial, up to $2.0 million. The Company is accounting for the joint development activities relative to the TiNivo trial as a joint risk-sharing collaboration in accordance with ASC 808 because EUSA is an active participant in the ongoing TiNivo trial and is exposed to significant risk and rewards in connection with the activity. Payments from EUSA with respect to its share of TiNivo trial development costs incurred by the Company pursuant to a joint development plan are recorded as a reduction in research and development expenses due to the joint risk-sharing nature of the activities that is not representative of a vendor-customer relationship. The Company recognized reductions in research and development expenses of approximately $0.2 million and $0 in the three months ended June 30, 2018 and 2017, respectively, and approximately $0.5 million and $0 in the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018,

the Company had recognized approximately $1.3 million in cumulative total reductions in research and development expenses related to EUSA's approximate 50% share of the cumulative study-to-date costs. EUSA paid the $2.0 million maximum amount of cost sharing per the EUSA Agreement in advance of the completion of the trial. The remaining $0.7 million in prepaid cost sharing was classified as deferred research and development reimbursements as of June 30, 2018 and will continue to be recognized as a reduction in research and development expenses as the related TiNivo trial costs are incurred over the duration of the trial.

Novartis

In August 2015, the Company entered into the Novartis Agreement under which the Company granted to Novartis the exclusive right to develop and commercialize AV-380 and the Company's related antibodies worldwide. The Company also granted Novartis an option to purchase the Company's then-existing supply of AV-380 biological drug substance at an undiscounted price. Novartis was responsible under the Novartis Agreement for the development, manufacture and commercialization of the Company's antibodies and any resulting approved therapeutic products.

On June 29, 2018, Novartis notified the Company that it is terminating the Novartis Agreement without cause effective on August 28, 2018. Pursuant to the Novartis Agreement, Novartis' termination without cause triggers, among other things, the termination of all licenses and other rights granted by the Company to Novartis with regard to the AV-380 program, and the grant by Novartis to the Company of an irrevocable, exclusive, fully paid-up license, with a right to sub-license, to any patent rights or know-how controlled by Novartis as of the termination date related to the AV-380 program. Following termination, Novartis also has an obligation to transfer to the Company all preclinical, technical, manufacturing and other data developed by Novartis. The Company has the right to purchase the inventory of AV-380 biological drug substance from Novartis at a price equal to Novartis' cost.

On June 28, 2018, the Company had separately provided Novartis with notice under the Novartis Agreement's dispute resolution provisions of a dispute regarding Novartis' compliance with its diligence obligations with respect to the development of the AV-380 program. If the parties are unable to resolve the dispute at the management level, an arbitration could be commenced. These dispute resolution procedures run in parallel to the termination process.

In connection with entry into the Novartis Agreement, Novartis made a non-refundable upfront payment to the Company of $15.0 million in September 2015. In December 2015, Novartis exercised an option to acquire the Company's inventory of clinical quality, AV-380 biological drug substance and reimbursed the Company approximately $3.5 million for such existing inventory. In February 2017, Novartis agreed to pay the Company $1.8 million out of its future payment obligations, if any, to the Company under the Novartis Agreement. The funds were used to satisfy a $1.8 million time-based milestone obligation that the Company owed to St. Vincent's Hospital Sydney Limited ("St. Vincent's") in March 2017. Novartis will reduce any subsequent payment obligations to the Company by $1.8 million. The Company had been eligible to receive milestone payments and royalties tied to the commencement of clinical trials, to regulatory approvals and to sales of such products upon commercialization. None of the milestones set forth in the Novartis Agreement had been achieved as of June 30, 2018.

Accounting Analysis Under ASC 606

The Company evaluated the Novartis Agreement under ASC 606. Based on this evaluation, the Company identified the following promised goods and services at the inception of the Novartis Agreement: the Company's grant of an exclusive, worldwide license to develop and commercialize the Product, including all technical knowledge and data useful in the development and manufacture of the Product. The Company concluded the license and know-how were functional intellectual property. The Company concluded its promise to provide 90 days of transition assistance was immaterial in the context of the contract based on consideration of qualitative and quantitative factors. In making this evaluation the Company considered the specific personnel and time commitment that would be required to provide any transition services, concluding that the time commitment would be insignificant. The Company also concluded the option to purchase AV-380 drug substance did not represent a material right as the purchase price was undiscounted and thus did not represent a performance obligation but would instead be accounted for as a separate arrangement if and when the option was exercised. Accordingly, the Company determined at inception the agreement contained a single performance obligation related to the exclusive license to develop and commercialize AV-380 that was satisfied at the inception of the arrangement.

The Company determined that the $15.0 million in upfront consideration upon the execution of the Novartis Agreement in August 2015 and the $1.8 million payment in February 2017 constituted the amount of the consideration to be included in the transaction price upon the adoption of ASC 606 on January 1, 2018 and attributed these amounts to the Company's single performance obligation. Because the Company satisfied the single performance obligation at the inception of the contract and had no remaining performance obligations, each of these amounts were recognized upon receipt. None of the clinical, development and regulatory milestones have been included in the transaction price as these milestone amounts were fully constrained.

The Company evaluated Novartis' exercise of its option to purchase AV-380 drug substance in the fourth quarter of 2015 and identified a single performance obligation related to the delivery of AV-380 drug substance. The performance obligation was satisfied in connection with Novartis' exercise of its option and thus the Company recognized the total transaction price of $3.5 million at the time the option was exercised.

Previously, under ASC 605, the Company recognized the $15.0 million in upfront consideration as collaboration and licensing revenue in the third quarter of 2015 and the $1.8 million payment in February 2017 as collaboration and licensing revenue in the first quarter of 2017 as these amounts were fixed, determinable and non-refundable, and there were no undelivered elements. Previously, under ASC 605, the Company recognized the $3.5 million purchase of the Company's inventory of clinical quality, AV-380 biological drug substance as collaboration and licensing revenue in the fourth quarter of 2015 upon the satisfaction of its performance obligation to deliver the AV-380 drug substance. Accordingly, as the timing and amount of revenue recognition for the payments received from Novartis are the same under ASC 605 and ASC 606, there was no transition adjustment required as of January 1, 2018.

Biodesix

In April 2014, the Company entered into a worldwide co-development and collaboration agreement with Biodesix (the "Biodesix Agreement") to develop and commercialize ficlatuzumab, the Company's HGF inhibitory antibody. Under the Biodesix Agreement, the Company granted Biodesix perpetual, non-exclusive rights to certain intellectual property, including all clinical and biomarker data related to ficlatuzumab, to develop and commercialize VeriStrat®, Biodesix's proprietary companion diagnostic test. Biodesix granted the Company perpetual, non-exclusive rights to certain intellectual property, including diagnostic data related to VeriStrat, with respect to the development and commercialization of ficlatuzumab; each license includes the right to sublicense, subject to certain exceptions. Pursuant to a joint development plan, the Company retains primary responsibility for clinical development of ficlatuzumab. In September 2016, the Company and Biodesix announced the termination of a phase 2 proof-of-concept clinical study of ficlatuzumab in which VeriStrat® was used to select clinical trial subjects (the "FOCAL" trial).

Under the Biodesix Agreement, with the exception of the costs incurred for the FOCAL trial, the Company and Biodesix are each required to contribute 50% of all clinical, regulatory, manufacturing and other costs to develop ficlatuzumab. Pursuant to the

Biodesix Agreement, Biodesix was obligated to provide up to $15 million for the FOCAL trial, following which all costs of the FOCAL trial would be shared equally. In connection with the discontinuation of the FOCAL trial on October 14, 2016, the Company and Biodesix amended the Biodesix Agreement. Under the amendment, the Company agreed to share 50% of the shutdown costs for the FOCAL trial after August 1, 2016. In return for bearing these shutdown costs, the Company will be entitled to recover an agreed multiple of the additional costs borne by the Company out of any income Biodesix receives from the partnership in connection with the licensing or commercialization of ficlatuzumab. Following such recovery, the payment structure under the original Biodesix Agreement, which generally provides that the parties share equally in any costs and revenue, will resume without such modification.

In addition, the Company and Biodesix are funding investigator-sponsored clinical trials, including ficlatuzumab in combination with ERBITUX® (cetuximab) in squamous cell carcinoma of the head and neck, ficlatuzumab in combination with Cytosar (cytarabine) in acute myeloid leukemia and ficlatuzumab in combination with nab-paclitaxel and gemcitabine in pancreatic cancer.

Pending marketing approval or the sublicense of ficlatuzumab, and subject to the negotiation of a commercialization agreement, each party would share equally in commercialization profits and losses, subject to the Company's right to be the lead commercialization party.

Prior to the first commercial sale of ficlatuzumab, each party has the right to elect to discontinue participating in further development or commercialization efforts with respect to ficlatuzumab, which is referred to as an "Opt-Out". If either AVEO or Biodesix elects to Opt-Out, with such party referred to as the "Opting-Out Party", then the Opting-Out Party shall not be responsible for any future costs associated with developing and commercializing ficlatuzumab other than any ongoing clinical trials. If AVEO elects to Opt-Out, it will continue to make the existing supply of ficlatuzumab available to Biodesix for the purposes of enabling Biodesix to complete the development of ficlatuzumab, and Biodesix will have the right to commercialize ficlatuzumab. After election of an Opt-Out, the non-opting out party shall have sole decision-making authority with respect to further development and commercialization of ficlatuzumab. Additionally, the Opting-Out Party shall be entitled to receive, if ficlatuzumab is successfully developed and commercialized, a royalty equal to 10% of net sales of ficlatuzumab throughout the world, if any, subject to offsets under certain circumstances.

Prior to any Opt-Out, the parties shall share equally in any payments received from a third-party licensee; provided, however, after any Opt-Out, the Opting-Out Party shall be entitled to receive only a reduced portion of such third-party payments. The agreement will remain in effect until the expiration of all payment obligations between the parties related to development and commercialization of ficlatuzumab, unless earlier terminated.

The Company is accounting for the joint development activities under the Biodesix Agreement as a joint risk-sharing collaboration in accordance with ASC 808 because Biodesix is an active participant in the ongoing development of ficlatuzumab via its participation on a joint steering committee that oversees the development plans for ficlatuzumab and is exposed to significant risk and rewards in connection with the activity based on its obligation to share in the costs, as defined above. Payments from Biodesix with respect to its share of ficlatuzumab development costs incurred by the Company pursuant to a joint development plan are recorded as a reduction in research and development expenses due to the joint risk-sharing nature of the activities that is not representative of a vendor-customer relationship.

The Company records reimbursements from Biodesix for expenses related to these trials and drug manufacturing as a reduction in research and development expense during the period that reimbursable expenses are incurred. As a result of the cost sharing provisions in the Biodesix Agreement, the Company reduced research and development expenses by approximately $44 thousand and $(0.1) million during the three months ended June 30, 2018 and 2017,

respectively, and by approximately $0.2 million in each of the six months ended June 30, 2018 and 2017, respectively. The amount due to the Company from Biodesix pursuant to the cost-sharing provision was approximately $0.2 million as of June 30, 2018.

Astellas Pharma

In February 2011, the Company, together with its wholly-owned subsidiary AVEO Pharma Limited, entered into a collaboration and license agreement (the “Astellas Agreement”) with Astellas Pharma Inc. and certain of its subsidiaries (together, “Astellas”), pursuant to which the Company and Astellas intended to develop and commercialize tivozanib for the treatment of a broad range of cancers. Astellas elected to terminate the agreement effective on August 11, 2014, at which time the tivozanib rights were returned to the Company. In accordance with the Astellas Agreement, committed development costs, including the costs of completing certain tivozanib clinical development activities, continue to be shared equally.

The Company accounts for the joint development and commercialization activities in North America and Europe as a joint risk-sharing collaboration in accordance with ASC 808. Payments from Astellas with respect to Astellas’ share of tivozanib

development and commercialization costs incurred by the Company pursuant to the joint development plan, including the costs of completing certain tivozanib clinical development activities described in the preceding paragraph, were recorded as a reduction to research and development expense and general and administrative expense in the accompanying consolidated financial statements due to the joint risk-sharing nature of the activities in North America and Europe. As a result of cost-sharing provisions in the Astellas Agreement, the Company reduced research and development expenses by approximately $0.1 million and $0 during each of the three-month and six-month periods ended June 30, 2018 and 2017, respectively. The net amount due to the Company from Astellas pursuant to the cost-sharing provisions was $0.4 million at June 30, 2018.

Biogen Idec International GmbH

In March 2009, the Company entered into an exclusive option and license agreement with Biogen regarding the development and commercialization of the Company's discovery-stage ErbB3-targeted antibodies, AV-203, for the potential treatment and diagnosis of cancer and other diseases outside of North America (the "Biogen Agreement"). Under the Biogen Agreement, the Company was responsible for developing ErbB3 antibodies through completion of the first phase 2 clinical trial designed in a manner that, if successful, will generate data sufficient to support advancement to a phase 3 clinical trial.

In March 2014, the Company and Biogen amended the exclusive option and license agreement (the "Biogen Amendment"). Pursuant to the Biogen Amendment, Biogen agreed to the termination of its rights and obligations under the Biogen Agreement, including Biogen's option to (i) obtain a co-exclusive (with AVEO) worldwide license to develop and manufacture ErbB3 targeted antibodies and (ii) obtain exclusive commercialization rights to ErbB3 products in countries in the world other than North America. As a result, AVEO has worldwide rights to AV-203. Pursuant to the Biogen Amendment, the Company was obligated to use reasonable efforts to seek a collaboration partner for the purpose of funding further development and commercialization of ErbB3 targeted antibodies. The Company is also obligated to pay Biogen a percentage of milestone payments received by AVEO from future partnerships after March 28, 2016 and single digit royalty payments on net sales related to the sale of ErbB3 products, if any, up to a cumulative maximum amount of $50.0 million

In March 2016, the Company entered into a collaboration and license agreement for AV-203 with CANbridge, which satisfied its obligation to seek a collaboration partner for the purpose of funding further development and commercialization of ErbB3 targeted antibodies. Refer to "—CANbridge" within this Note 4 for a further description of that arrangement.

In-License Agreements

St. Vincent's

In July 2012, the Company entered into a license agreement with St. Vincent's, under which the Company obtained an exclusive, worldwide sublicensable right to research, develop, manufacture and commercialize products for human therapeutic, preventative and palliative applications that benefit from inhibition or decreased expression or activity of GDF15, which is also referred to as MIC-1 (the "St. Vincent's Agreement"). Under the St. Vincent's Agreement, St. Vincent's also granted the Company non-exclusive rights for certain related diagnostic products and research tools.

In order to sublicense certain necessary intellectual property rights to Novartis in August 2015, the Company amended and restated the St. Vincent's Agreement and made an additional upfront payment to St. Vincent's of $1.5 million. The Company is required to make milestone payments, up to an aggregate total of $16.7 million, upon the earlier of achievement of specified development and regulatory milestones or a specified date for the first indication, and upon the achievement of specified development and regulatory milestones for the second and third indications, for licensed

therapeutic products, some of which payments may be increased by a mid to high double-digit percentage rate for milestones payments made after the Company grants any sublicense, depending on the sublicensed territory. In March 2017, as further described above under the heading "—Novartis," the Company paid a $1.8 million time-based milestone obligation that it owed to St. Vincent's and recognized $1.8 million in research and development expense. In January 2019, the Company will owe an additional $2.3 million time-based milestone obligation to St. Vincent's. The Company will also be required to pay St. Vincent's tiered royalty payments equal to a low-single-digit percentage of any net sales it or its sublicensees make from licensed therapeutic products. The royalty rate escalates within the low-single-digit range during each calendar year based on increasing licensed therapeutic product sales during such calendar year.

Kyowa Hakko Kirin (KHK)

In December 2006, the Company entered into a license agreement with KHK ("KHK Agreement") under which it obtained an exclusive license, with the right to grant sublicenses subject to certain restrictions, to research, develop, manufacture and commercialize tivozanib, pharmaceutical compositions thereof and associated biomarkers in all potential indications. Its exclusive license covers all territories in the world except for Asia and the Middle East, where KHK has retained the rights to tivozanib. Under

the KHK Agreement, the Company obtained exclusive rights in its territory under certain KHK patents, patent applications and know-how related to tivozanib, to research, develop, make, have made, use, import, offer for sale, and sell tivozanib for the diagnosis, prevention and treatment of any and all human diseases and conditions. The Company and KHK each have access to and can benefit from the other party's clinical data and regulatory filings with respect to tivozanib and biomarkers identified in the conduct of activities under the KHK Agreement.

Under the KHK Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize tivozanib in its territory. Prior to the first anniversary of the first post-marketing approval sale of tivozanib in its territory, neither the Company nor any of its subsidiaries has the right to conduct certain clinical trials of, seek marketing approval for or commercialize any other cancer product that also works by inhibiting the activity of a VEGF receptor.

The Company has upfront, milestone and royalty payment obligations to KHK under the KHK Agreement. Upon entering into the KHK Agreement, the Company made an upfront payment in the amount of $5.0 million. In March 2010, the Company made a milestone payment to KHK in the amount of $10.0 million in connection with the dosing of the first patient in the Company's first phase 3 clinical trial of tivozanib (TIVO-1). In December 2012, the Company made a $12.0 million milestone payment to KHK in connection with the acceptance by the U.S. Food and Drug Administration ("FDA") of the Company's 2012 New Drug Application ("NDA") filing for tivozanib. Each milestone under the KHK Agreement is a one-time only payment obligation, accordingly, the Company did not owe KHK another milestone payment in connection with the dosing of the first patient in the Company's TIVO-3 trial, and would not owe a milestone payment to KHK if the Company files an NDA with the FDA following the completion of the TIVO-3 clinical trial. If the Company obtains approval for tivozanib in the United States., the Company would owe KHK a one-time milestone payment of $18.0 million, provided that the Company does not sublicense U.S. rights for tivozanib prior to obtaining a U.S. regulatory approval. If the Company were to sublicense the U.S. rights, the associated U.S. regulatory milestone would be replaced by a specified percentage of sublicensing revenue, as set forth below.

If the Company sublicenses any of its rights to tivozanib to a third party, as it has done with EUSA, the sublicense defines the payment obligations of the sublicensee, which may vary from the milestone and royalty payment obligations under the KHK Agreement relating to rights the Company retains. The Company is required to pay KHK a fixed 30% of amounts the Company receives from its sublicensees, including upfront license fees, milestone payments and royalties, but excluding amounts the Company receives in respect of research and development reimbursement payments or equity investments, subject to certain limitations. Certain research and development reimbursement payments by EUSA, including the $2.5 million upfront payment in December 2015, the $4.0 million payment in September 2017 upon the approval from the EMA of tivozanib (FOTIVDA) and the $2.0 million payment upon EUSA's election in September 2017 to opt-in to co-develop the TiNivo trial were not subject to sublicense revenue payments to KHK. In addition, if EUSA elects to opt-in to the TIVO-3 trial, the additional research and development reimbursement payment from EUSA of 50% of the total trial costs, up to $20.0 million, would also not be subject to a sublicense revenue payment to KHK, subject to certain limitations. The Company would, however, owe KHK 30% of other, non-research and development payments the Company may receive from EUSA pursuant to the EUSA Agreement, including reimbursement approvals for RCC in up to five specified EU countries, marketing approvals for RCC in three specified non-EU licensed territories, EU marketing approval filings and corresponding marketing approvals by the EMA for up to three additional indications beyond RCC, and sales-based milestones and royalties. The $2.0 million milestone the Company earned in February 2018 upon EUSA's reimbursement approval from the NICE in the UK in first-line aRCC was subject to the 30% KHK sub-license fee, or $0.6 million, which was paid in April 2018.

The Company is also required to pay tiered royalty payments on net sales it makes of tivozanib in its North American territory, which range from the low to mid-teens as a percentage of net sales. The royalty rate escalates within this

range based on increasing tivozanib sales. The Company's royalty payment obligations in a particular country in its territory begin on the date of the first commercial sale of tivozanib in that country, and end on the later of 12 years after the date of first commercial sale of tivozanib in that country or the date of the last to expire of the patents covering tivozanib that have been issued in that country.

The KHK Agreement will remain in effect until the expiration of all of the Company's royalty and sublicense revenue obligations to KHK, determined on a product-by-product and country-by-country basis, unless the Company elects to terminate the KHK Agreement earlier. If the Company fails to meet its obligations under the KHK Agreement and is unable to cure such failure within specified time periods, KHK can terminate the KHK Agreement, resulting in a loss of our rights to tivozanib and an obligation to assign or license to KHK any intellectual property or other rights the Company may have in tivozanib, including its regulatory filings, regulatory approvals, patents and trademarks for tivozanib.

(5) Other Accrued Liabilities

Other accrued expenses consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Professional fees	$ 472	$ 844
Compensation and benefits	858	1,325
Other	354	289
Total	$ 1,684	$ 2,458

(6) Loans Payable

On May 28, 2010, the Company entered into a loan and security agreement with Hercules Capital Inc. and certain of its affiliates (the "First Loan Agreement"). The First Loan Agreement was subsequently amended in March 2012 (the "2012 Amendment"), September 2014 (the "2014 Amendment") and May 2016 (the "2016 Amendment"). Amounts borrowed under the 2012 Amendment were repaid in full in 2015. In December 2017, the Company entered an amended and restated loan and security agreement (the "2017 Loan Agreement") with Hercules Funding III, LLC and Hercules Capital, Inc. (collectively "Hercules").

Pursuant to the 2014 Amendment, the Company received additional loan proceeds from Hercules in the amount of $10.0 million and was required to make an end-of-term payment of approximately $0.5 million on January 1, 2018. This payment was made on the first business day of 2018. The Company incurred approximately $0.2 million in loan issuance costs paid directly to Hercules, which were offset against the loan proceeds and are accounted for as a loan discount.

In connection with the 2014 Amendment, the Company issued warrants to the lenders to purchase up to 608,696 shares of the Company's common stock at an exercise price equal to $1.15 per share. The Company recorded the fair value of the warrants of approximately $0.4 million as stockholders' equity and as a discount to the related loan outstanding and is amortizing the value of the discount to interest expense over the term of the loan using the effective interest method. In July 2017, Hercules exercised all 608,696 warrants. Pursuant to the terms of the warrant, Hercules, at their election, exercised the warrants via a non-cash "net share issuance." The Company issued Hercules 369,297 shares of its common stock and did not receive any cash proceeds in connection with the warrant exercise.

Pursuant to the 2016 Amendment, the Company received additional loan proceeds from Hercules, in an aggregate amount of $10.0 million, in installments of $5.0 million in each of May 2016 and June 2017, which increased the aggregate outstanding principal balance under the First Loan Agreement to $20.0 million. The Company is required to make an end-of-term payment totaling $0.3 million on December 1, 2019. The Company incurred approximately $0.1 million in loan issuance costs paid directly to Hercules, which were offset against the loan proceeds and are accounted for as a loan discount. The 2016 Amendment included a financial covenant that required the Company to maintain an unrestricted cash position (defined as cash and liquid cash, including marketable securities) greater than or equal to $10.0 million through the date of completion of the Company's TIVO-3 trial, with results that were satisfactory to Hercules. Principal payments were scheduled to commence on January 1, 2018 and the loan was scheduled to mature on December 1, 2019.

In connection with the 2016 Amendment, the Company issued warrants to Hercules to purchase up to 1,202,117 shares of the Company's common stock at an exercise price equal to $0.87 per share. The Company recorded the fair value of the warrants of approximately $0.7 million as a component of stockholders' equity and as a discount to the related loan outstanding and is amortizing the value of the discount to interest expense over the term of the loan using

the effective interest method. In July 2017, Hercules exercised all 1,202,117 warrants. Pursuant to the terms of the warrant, Hercules, at their election, exercised the warrants via a non-cash “net share issuance.” The Company issued Hercules 846,496 shares of its common stock and did not receive any cash proceeds in connection with the warrant exercise.

In connection with the 2016 Amendment, Hercules also received an option, subject to the Company’s written consent, not to be unreasonably withheld, to purchase, either with cash or through conversion of outstanding principal under the loan, up to $2.0 million of equity of the Company sold in any sale by the Company to third parties of equity securities resulting in at least $10.0 million in net cash proceeds to the Company, subject to certain exceptions.

In connection with the Company’s May 2016 private placement (refer to Note 7, “Common Stock – Private Placement / PIPE Warrants”), Hercules purchased 259,067 units for cash proceeds of $0.2 million to the Company. This purchase was separate from the $2.0 million equity purchase option under the 2016 Amendment. Each unit in the May 2016 private placement included one share of the Company’s common stock and a PIPE Warrant to purchase one share of the Company’s common stock at an exercise price of $1.00 per share. In July 2017, Hercules exercised its PIPE Warrants with respect to all 259,067 shares of common stock underlying such PIPE Warrants. The Company issued Hercules 259,067 shares of its common stock and received approximately $0.3 million in cash proceeds.

In December 2017, the Company entered into the 2017 Loan Agreement to refinance the Company's existing loan facility with Hercules and to retire the $20.0 million in secured debt then-outstanding under the First Loan Agreement. Per the terms of the 2017 Loan Agreement, the new $20.0 million loan facility has a 42-month maturity from closing, no financial covenants, a lower interest rate and an interest-only period of no less than 12 months, which could be extended up to a maximum of 24 months, assuming the achievement of specified milestones relating to the development of tivozanib. Per the 2017 Loan Agreement, Hercules did not receive any additional warrants to purchase shares of the Company's common stock and no longer has the option, subject to the Company's written consent, to participate in its future equity financings up to $2.0 million through the purchase of the Company's common stock either with cash or through the conversion of outstanding principal under the loan.

The loan maturity date has been revised from December 2019 to July 2021. The Company is not required to make principal payments until February 1, 2019, at which time the Company will be required to make 29 equal monthly payments of principal and interest, in the approximate amount of $0.8 million, through July 2021. An additional end-of-term payment of approximately $0.8 million is due on July 1, 2021, which increases the total end-of-term payments under the 2014 Amendment, 2016 Amendment and 2017 Loan Agreement to approximately $1.6 million. The end-of-term payments under the 2014 Amendment, in the approximate amount of $0.5 million, and the 2016 Amendment, in the amount of $0.3 million, continue to be due on their original due dates of January 1, 2018 and December 1, 2019, respectively. The financial covenant per the 2016 Amendment to maintain an unrestricted cash position greater than or equal to $10.0 million through the date of completion of our TIVO-3 trial with results that are satisfactory to Hercules has been removed. Per the 2017 Loan Agreement, the interest rate decreased from 11.9% to 9.45%. In June 2018, the interest rate increased from 9.45% to 9.70% due to the corresponding increase in the prime interest rate. The Company incurred approximately $0.1 million in loan issuance costs paid directly to Hercules, which are accounted for as a loan discount. The 2017 Loan Agreement was accounted for as a loan modification in accordance with ASC 470-50.

The interest-only period could be extended by two 6-month deferrals upon the achievement of specified milestones relating to the development of tivozanib, including (i) on or prior to September 30, 2018, the Company has received positive data with respect to its TIVO-3 trial for the treatment of RCC for patients in the third-line setting which positive data supports the filing for a new drug application with the FDA, subject to confirmation by Hercules at its reasonable discretion, and (ii) on or prior to June 28, 2019, the Company has received approval from the FDA for its tivozanib product for the treatment of RCC for patients in the third-line setting, subject to confirmation by Hercules at its reasonable discretion.

The unamortized discount to be recognized over the remainder of the loan period was approximately $1.3 million and $1.5 million as of June 30, 2018 and December 31, 2017, respectively.

The Company must make interest payments on the loan balance each month it remains outstanding. Per annum interest is payable on the principal balance of the loan each month it remains outstanding at the greater of 9.45% and an amount equal to 9.45% plus the prime rate minus 4.75% as determined daily, provided however, that the per annum interest rate shall not exceed 15.0% (9.70% as of June 30, 2018).

The loans are secured by a lien on all the Company's personal property (other than intellectual property), whether owned or acquired after the date of the First Loan Agreement. The 2017 Loan Agreement defines events of default, including the occurrence of an event that results in a material adverse effect upon the Company's business operations, properties, assets or condition (financial or otherwise), its ability to perform its obligations or upon the ability of the lenders to enforce any of their rights or remedies with respect to such obligations, or upon the collateral under the 2017 Loan Agreement, the related liens or the priority thereof. As of June 30, 2018, the Company was in compliance with all loan covenants, Hercules has not asserted any events of default and the Company does not believe that there has been a material adverse change as defined in the 2017 Loan Agreement.

The Company has determined that the risk of subjective acceleration under the material adverse events clause is remote and therefore has classified the outstanding principal in current and long-term liabilities based on the timing of scheduled principal payments.

Future minimum payments under the loans payable outstanding as of June 30, 2018 are as follows (amounts in thousands):

Year Ending December 31:	
2018 (remaining 6 months)	$985
2019	8,755
2020	9,041
2021	6,104
	24,885
Less amount representing interest	(3,795)
Less unamortized discount	(1,270)
Less deferred charges	(1,090)
Less loans payable current, net of discount	(2,388)
Loans payable, net of current portion and discount	$16,342

(7) Common Stock

Settlement Warrants

On July 16, 2018, the Company issued and delivered 2.0 million Settlement Warrants to purchase shares of its common stock for a one-year period after the date of issuance at an exercise price equal to $3.00 per share. Refer to Note 3, “Significant Accounting Policies - Class Action Settlement and Settlement Warrants” for further discussion.

Sales Agreement with Leerink

In February 2018, the Company entered into the Leerink Sales Agreement, pursuant to which the Company may issue and sell shares of its common stock from time to time up to an aggregate amount of $50.0 million, at its option, through Leerink as its sales agent, with any sales of common stock through Leerink being made by any method that is deemed an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”), or in other transactions pursuant to an effective shelf registration statement on Form S-3. The Company agreed to pay Leerink a commission of up to 3% of the gross proceeds of any sales of common stock pursuant to the Leerink Sales Agreement. At the time of issuance of these financial statements, no shares of the Company’s common stock have been sold under the Leerink Sales Agreement.

On November 30, 2017, the Company filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale of up to $200.0 million of its common stock, preferred stock, debt securities, warrants and/or units (the “2017 Shelf”). The 2017 Shelf (File No. 333-221873) was declared effective by the SEC on December 15, 2017 and was filed to replace the Company’s then existing shelf registration statement, which was terminated.

Public Offering

On March 31, 2017, the Company closed an underwritten public offering of 34,500,000 shares of its common stock, including the exercise in full by the underwriter of its option to purchase 4,500,000 shares, at the public offering price of $0.50 per share for gross proceeds of approximately $17.3 million. Certain of the Company’s executive officers and a director purchased an aggregate of 420,000 shares and an entity affiliated with New Enterprise Associates, a greater

than 5% stockholder of the Company, purchased 6,000,000 shares in this offering at the same public offering price per share as the other investors. The net offering proceeds to the Company were approximately $15.4 million after deducting underwriting discounts and estimated offering expenses payable by the Company.

Private Placement / PIPE Warrants

In May 2016, the Company entered into a securities purchase agreement with a select group of qualified institutional buyers, institutional accredited investors and accredited investors pursuant to which the Company sold 17,642,482 units, at a price of $0.965 per unit, for gross proceeds of approximately $17.0 million. Each unit consisted of one share of the Company's common stock and a warrant to purchase one share of the Company's common stock (the "PIPE Warrants"). The PIPE Warrants have an exercise price of $1.00 per share and are exercisable for a period of five years from the date of issuance. Certain of the Company's directors and executive officers purchased an aggregate of 544,039 units in this offering at the same price as the other investors. The net offering proceeds to the Company were approximately $15.4 million after deducting placement agent fees and other offering expenses payable by the Company. As of June 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 exercised its PIPE Warrants with respect to all 259,067 shares of common stock underlying such PIPE Warrants, and the Company issued Hercules 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.

Sales Agreement with FBR

In February 2015, the Company entered into a sales agreement (the "FBR Sales Agreement") with FBR & Co. and MLV & Co. (together "FBR"), pursuant to which the Company could issue and sell shares of its common stock from time to time up to an aggregate amount of $17.9 million, at the Company's option, through FBR as its sales agent, with any sales of common stock through FBR being made by any method that is deemed an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act or in other transactions pursuant to an effective shelf registration statement on Form S-3. The Company agreed to pay FBR a commission of up to 3% of the gross proceeds of any sales of common stock pursuant to the FBR Sales Agreement.

In June 2017, the Company conducted its final transaction under the FBR Sales Agreement and sold approximately 6.5 million shares pursuant to the FBR Sales Agreement, as amended, resulting in proceeds of approximately $8.8 million, net of commissions and issuance costs. The FBR Sales Agreement has expired.

(8) Stock-based Compensation

Stock Incentive Plan

The Company maintains the 2010 Stock Incentive Plan (the "Plan") for employees, consultants, advisors, and directors, as amended in March 2013, June 2014 and June 2017. The Plan provides for the grant of equity awards such as stock options and restricted stock. In June 2017, the Company amended the Plan to increase the total number of shares reserved under the Plan by 3,500,000 from 8,500,000 shares to 12,000,000 shares. The amendment was adopted by the Board of Directors in February 2017 and approved by stockholders at the Annual Meeting of Stockholders held on June 21, 2017. The Plan provides that the exercise price of incentive stock options cannot be less than 100% of the fair market value of the common stock on the date of the award for participants who own less than 10% of the total combined voting power of stock of the Company and not less than 110% for participants who own more than 10% of the total combined voting power of the stock of the Company. Options and restricted stock granted under the Plan vest over periods as determined by the Board, which generally are equal to four years. Options generally expire ten years from the date of grant. As of June 30, 2018, there were 1,018,065 shares of common stock available for future issuance under the Plan.

The following table summarizes stock option activity during the six months ended June 30, 2018:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual	Aggregate Intrinsic Value

			Term	
Outstanding at January 1, 2018	7,537,958	$ 2.00		
Granted	2,635,115	$ 3.04		
Exercised	(145,617)	$ 1.19		
Forfeited	(103,523)	$ 6.54		
Outstanding at June 30, 2018	9,923,933	$ 2.25	7.76	$7,190,000
Exercisable at June 30, 2018	4,458,925	$ 2.30	6.42	$4,454,000

Stock options to purchase 488,626 shares of common stock contain performance-based milestone conditions, which were not deemed probable of vesting at June 30, 2018.

The aggregate intrinsic value is based upon the Company’s closing stock price of $2.26 on June 29, 2018, the last trading day of the quarter.

The fair value of stock options subject only to service or performance conditions that are granted to employees is estimated on the date of grant using the Black-Scholes option-pricing model using the assumptions noted in the following table:

	Three Months Ended June 30,	
	2018	2017
Volatility factor	81.94% - 86.07%	73.20% - 76.07%
Expected term (in years)	5.50 - 6.25	5.50 - 6.25
Risk-free interest rates	2.85% - 2.85%	1.84% - 1.95%
Dividend yield	—	—

	Six Months Ended June 30,	
	2018	2017
Volatility factor	80.18% - 83.40%	71.82% - 76.07%
Expected term (in years)	5.50 - 6.25	5.50 - 6.25
Risk-free interest rates	2.64% - 2.85%	1.84% - 2.10%
Dividend yield	—	—

The risk-free interest rate is determined based upon the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the options being valued. The Company does not expect to pay dividends in the foreseeable future.

The Company calculates volatility using its historical stock price data. Due to lack of available option activity data, the Company elected to use the "simplified" method for "plain vanilla" options to estimate the expected term of the stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. Based upon these assumptions, the weighted-average grant date fair value of stock options granted during the six months ended June 30, 2018 and 2017 was $2.15 and $0.40, respectively.

On January 1, 2017, the Company adopted ASU No. 2016-09, Compensation–Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting and elected to account for forfeitures as they occur.

Prior to 2017, the Company included an estimate of the value of the awards that would be forfeited in calculating compensation costs, which the Company estimated based upon actual historical forfeitures. The forfeiture estimates were recognized over the requisite service period of the awards on a straight-line basis.

As of June 30, 2018, there was $7.1 million of total unrecognized stock-based compensation expense related to stock options granted to employees under the Plan. The expense is expected to be recognized over a weighted-average period of 2.8 years.

(9) Legal Proceedings

The Company recently settled a consolidated class action lawsuit (the "Class Action"), In re AVEO Pharmaceuticals, Inc. Securities Litigation et al., No. 1:13-cv-11157-DJC, that had been filed in 2013 against the Company and certain of its former officers (Tuan Ha-Ngoc, David N. Johnston, William Slichenmyer, and Ronald DePinho) in the United States District Court for the District of Massachusetts (the "District Court"). The Class Action had been dismissed without prejudice in March 2015, and the lead plaintiffs then filed a second amended complaint bringing similar allegations, but which no longer named Mr. DePinho as a defendant. The Company moved to dismiss again, and the District Court ruled in the Company's favor and dismissed the second amended complaint with prejudice in November 2015. The lead plaintiffs appealed the District Court's decision and also filed a motion to vacate and reconsider the District Court's judgment. In January 2017, the District Court granted the plaintiffs' motion to vacate the dismissal and judgment. In February 2017, the plaintiffs filed a third amended complaint, on behalf of stockholders who purchased common stock between May 16, 2012 and May 1, 2013 (the "Class") alleging claims similar to those alleged in the prior complaints, namely that the Company and certain of the Company's former officers and directors violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the phase 3 trial design and results for the Company's TIVO-1 clinical trial in an effort to lead investors to believe that the drug would receive approval from the FDA. In July 2017, the District Court entered an order referring the case to alternative dispute resolution. The parties mediated during the fall of 2017.

On December 26, 2017, the parties entered into a binding memorandum of understanding (the "MOU") to settle the Class Action. Under the terms of the MOU, the Company agreed to cause certain of the Company's and the individual defendants' insurance carriers to provide the Class with a cash payment of $15.0 million, which included the cash amount of any attorneys' fees or

litigation expenses that the District Court may award. Additionally, the Company agreed to issue to the Class the Settlement Warrants, for the purchase of 2.0 million shares of the Company's common stock, which, subject to certain conditions, are exercisable from the date of issue until the expiration of a one-year period after the date of issue at an exercise price of $3.00 per share, equal to the closing price on December 22, 2017, the trading day prior to the execution of the MOU. On January 29, 2018, the parties entered into a definitive Stipulation of Settlement (the "Stipulation"), which was filed with the District Court on February 2, 2018. On February 8, 2018, the District Court issued an order preliminarily approving the terms of the Stipulation. In February 2018, the insurance carriers funded the settlement escrow account for the $15.0 million cash settlement. On May 30, 2018, the District Court held the Final Approval Hearing and approved the settlement and the plaintiffs' request for attorneys' fees and expenses, subject to the Final Judgment. Upon the conclusion of a standard 30-day appeal period, the Effective Date was deemed to be June 29, 2018. On July 16, 2018, the Company issued and delivered the Settlement Warrants.

The Company evaluates developments in legal proceedings on a quarterly basis. The Company records an accrual for loss contingencies to the extent that the Company concludes that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. 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 warrant portion of the settlement with a corresponding non-cash charge to the Statement of Operations as a component of operating expenses. 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 Company reversed the $15.0 million cash portion of the settlement from both the contingent liability and the corresponding insurance recovery as of the Effective Date. Refer to Note 3, "Significant Accounting Policies - Class Action Settlement and Settlement Warrants" for further discussion.

Also in 2013, the SEC served a subpoena on the Company for documents and information concerning tivozanib, including related communications with the FDA, investors and others. In September 2015, the SEC invited the Company to discuss the settlement of potential claims asserting that the Company violated federal securities laws by omitting to disclose to investors the recommendation by the staff of the FDA on May 11, 2012, that the Company conduct an additional clinical trial with respect to tivozanib. On March 29, 2016, the SEC filed a complaint against the Company and three of its former officers in the District Court alleging that the Company misled investors about its efforts to obtain FDA approval for tivozanib. Without admitting or denying the allegations in the SEC's complaint, the Company consented to the entry of a final judgment pursuant to which the Company paid the SEC a $4.0 million civil penalty to settle the SEC's claims against it. As this settlement was probable and estimable as of December 31, 2015, the Company recorded an estimated settlement liability of $4.0 million and recorded a corresponding loss in the Statement of Operations as a component of operating expenses. On March 31, 2016, the District Court entered a final judgment which (i) approved the settlement; (ii) permanently enjoined the Company from violating Section 17(a) of the Securities Act of 1933, as amended, Sections 10(b) and 13(a) of the Exchange Act and rules 10b-5, 12b-20, 13a-1, 13a-11 and 13a-13 promulgated thereunder; and (iii) ordered the Company to pay the agreed-to civil penalty. On September 15, 2017 and October 31, 2017, respectively, two of the Company's former officers consented to entry of final judgment to settle the SEC's claims against them. The Company is not a party to the litigation between the SEC and the remaining former officer, and the Company can make no assurance regarding the outcome of that action or the SEC's claims against that individual.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Cautionary Note Regarding Forward-Looking Information

This report contains forward-looking statements regarding, among other things, our future development efforts, our collaborations, our future operating results and financial position, our business strategy, our prospects and other objectives for our operations. You can identify these forward-looking statements by their use of words such as "anticipate," "believe," "estimate," "expect," "forecast," "goals," "intend," "may," "might," "plan," "project," "target," "will," "should" and other words and terms of similar meaning, although not all forward-looking statements contain such identifying words. You also can identify them by the fact that they do not relate strictly to historical or current facts. We caution you that there are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by these forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our clinical development activities, our ability to obtain any necessary financing to conduct our planned activities, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our drug candidates, our ability to obtain, maintain and enforce intellectual property rights for our drug candidates, our dependence on our existing and future strategic partners, and other risk factors. Please refer to the section entitled "Risk Factors" in Item 1A of Part II and elsewhere in this report for a description of these risks and uncertainties. Unless required by law, we do not undertake any obligation to update any forward-looking statements.

Overview

We are a biopharmaceutical company dedicated to advancing a broad portfolio of targeted medicines for oncology and other areas of unmet medical need. Our strategy is to retain North American rights to our oncology portfolio while securing partners in development and commercialization outside of North America. We are working to develop and commercialize our lead candidate tivozanib in North America as a treatment for renal cell carcinoma, or RCC. We have 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 advanced RCC, or aRCC and for adult patients who are vascular endothelial growth factor receptor and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for aRCC. We have entered into partnerships to fund the development and commercialization of AV-203 and ficlatuzumab, both clinical stage assets in oncology. We are currently seeking a partner to develop our preclinical AV-353 platform in pulmonary arterial hypertension. We previously partnered with Novartis International Pharmaceutical Ltd., or Novartis, to develop our AV-380 program in cachexia and other indications. Effective August 28, 2018 we expect to regain the rights to AV-380 and are considering a variety of options to continue the program's development.

Going Concern

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. To continue as a going concern, we must secure additional funding to support our current operating plan. As of June 30, 2018, we had approximately $18.1 million in cash, cash equivalents and marketable securities. Based on these available cash resources, we do 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 our ability to continue as a going concern. We expect that, in order to obtain additional funding, we will need to receive additional milestone payments and royalties from our partners and / or complete public or private financings of debt or equity. We may also seek to procure additional funds through future arrangements with collaborators, licensees or other third parties, and these arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates. Moreover, we may not be able receive milestone payments or complete financings or enter into such arrangements on acceptable terms, if at all. For more information, refer to "—Liquidity and

Capital Resources—Operating Capital Requirements and Going Concern" below and Note 1, "—Liquidity and Going Concern" of the Notes to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Tivozanib

Our pipeline includes our lead candidate tivozanib, an oral, once-daily, vascular endothelial growth factor receptor tyrosine kinase inhibitor, or VEGFR TKI. Tivozanib is a potent, selective and long half-life inhibitor of all three VEGF receptors and is designed to optimize VEGF blockade while minimizing off-target toxicities, potentially resulting in improved efficacy and minimal dose modifications. Tivozanib has been investigated in several tumor types, including renal cell, hepatocellular, colorectal and breast cancers, as well as in age-related macular degeneration. We have exclusive rights to develop and commercialize tivozanib in all countries outside of Asia and the Middle East under a license from Kyowa Hakko Kirin Co., Ltd. (formerly Kirin Brewery Co. Ltd.), or KHK. We have sublicensed to EUSA Pharma (UK) Limited, or EUSA, the right to develop and commercialize tivozanib in our licensed territories outside of North America, including Europe (excluding Russia, Ukraine and the Commonwealth of Independent

States), Latin America (excluding Mexico), Africa and Australasia. The EUSA sublicense excludes non-oncologic ocular conditions, to which we have retained development rights in all of our licensed territories.

Clinical and Regulatory Development in RCC

First-Line Phase 3 Trial (TIVO-1): We conducted a global phase 3 clinical trial, which we refer to as the TIVO-1 trial, comparing the efficacy and safety of tivozanib with sorafenib (Nexavar®), an approved therapy, for the first-line treatment of aRCC. The trial met its primary endpoint for progression-free survival, or PFS, with a median PFS in the tivozanib arm of 11.9 months compared with 9.1 months in the sorafenib arm. The trial also showed significant improvement in overall response rate, or ORR, of 33.1% for tivozanib versus 23.3% for sorafenib. The trial showed a favorable tolerability profile for tivozanib, as evidenced by fewer dose interruptions and dose reductions than sorafenib. However, the trial showed a non-statistically significant trend favoring the sorafenib treatment group in overall survival, or OS, with a final median OS for the tivozanib treatment arm of 28.2 months and a final median OS for the sorafenib arm of 30.8 months. We believe that an imbalance in subsequent therapy combined with the significant activity seen with tivozanib treatment following sorafenib contributed to the discordance in the efficacy results in the TIVO-1 trial between the PFS and ORR benefit, which significantly favored tivozanib, and the OS, which trended in favor of sorafenib.

In 2012, we submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, seeking U.S. marketing approval for tivozanib. In June 2013, the FDA issued a complete response letter informing us that it would not approve tivozanib for the first-line treatment of aRCC based solely on the data from this single pivotal trial (TIVO-1), and recommended that we perform an additional clinical trial adequately sized to assure the FDA that tivozanib does not adversely affect OS.

TIVO-1 Extension Study - One-way crossover from sorafenib to tivozanib (Study 902): We completed a TIVO-1 extension study in which patients with aRCC received tivozanib as second-line treatment subsequent to disease progression on the sorafenib treatment arm in the TIVO-1 first-line RCC trial. We presented the results at the 2015 American Society of Clinical Oncology, or ASCO, Annual Meeting. In March 2018, long-term follow-up results from Study 902 were published in the European Journal of Cancer under the title “Efficacy of Tivozanib Treatment after Sorafenib in Patients with Advanced Renal Cell Carcinoma: Crossover of a Phase 3 Study,” reporting a median PFS of 11.0 month, a median OS of 21.6 months and an 18% ORR, further supporting the rationale for our current phase 3 TIVO-3 trial discussed below.

First-Line Approval in Europe: In February 2016 EUSA submitted an application for the use of tivozanib as a first-line treatment for aRCC to the European Medicines Agency, or EMA, based on the data from our TIVO-1 clinical trial, as supported by data from the TIVO-1 extension trial, one phase 1 trial and two phase 2 trials in RCC. In June 2017, following an oral explanation, the Committee for Medicinal Products for Human Use, or CHMP, which is the scientific committee of the EMA, issued an opinion recommending tivozanib for approval. In August 2017, the European Commission approved tivozanib in all 28 countries of the European Union, Norway and Iceland. Tivozanib is sold under the brand name FOTIVDA, and is approved for the first-line treatment of adult patients with aRCC and for adult patients who are VEGFR and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for aRCC.

EUSA has commercially launched FOTIVDA in the United Kingdom, Germany, Austria and Scotland. In November 2017, EUSA initiated product sales in Germany. In February 2018, EUSA commercially launched FOTIVDA in the United Kingdom upon receiving reimbursement approval from the UK’s National Institute for Health and Care Excellence, or the NICE, for the first-line treatment of adult patients with aRCC. In April 2018, FOTIVDA sales were also initiated in Austria. In July 2018, FOTIVDA received reimbursement approval in Scotland for the first-line treatment of adult patients with aRCC. EUSA is working to secure reimbursement approval and commercially launch

FOTIVDA in additional European countries.

Third-Line Phase 3 Trial (TIVO-3): In May 2016, we initiated enrollment in a phase 3 trial of tivozanib in the third-line treatment of patients with aRCC, which we refer to as the TIVO-3 trial. The TIVO-3 clinical trial was designed to address the FDA's concern about the negative OS trend expressed in the complete response letter from June 2013. Pending the results from the TIVO-3 trial, our intention is to seek regulatory approval in the United States for tivozanib as a third-line treatment for RCC. In addition, we plan to seek approval for tivozanib as a first-line treatment using the TIVO-3 data together with the results from the TIVO-1 trial. Our TIVO-3 trial design, which we reviewed with the FDA, provides for a randomized, controlled, multi-center, open-label phase 3 clinical trial, with subjects randomized 1:1 to receive either tivozanib or sorafenib. Subjects enrolled in the trial must have failed two systemic therapies, including a VEGFR TKI. Patients may have received prior immunotherapy, including immune checkpoint (PD-1) inhibitors, reflecting the evolving treatment landscape. The primary objective of the TIVO-3 trial is to show improved PFS. Secondary endpoints include OS, safety and ORR. The trial's sites are located in North America and Europe. The TIVO-3 trial does not include a crossover design; accordingly, patients who progress in one therapy are not offered the opportunity to cross over to the other therapy.

The TIVO-3 trial enrolled a total of 351 patients. The trial has passed three semi-annual safety data assessments, and in October 2017, TIVO-3 successfully passed a pre-planned interim futility analysis. Based on the results of the futility analysis, which were reviewed by an independent statistician, the trial continued as planned without modification.

We expect to report topline results from the TIVO-3 study (including PFS and preliminary OS data) in the fourth quarter of 2018, approximately 6-8 weeks after the trial records 255 PFS events. We plan to announce when 255 PFS events have occurred and the topline data analysis for the trial has been initiated.

RCC PD-1 Combination Trial with Opdivo® (TiNivo): In recent clinical trials, VEGFR TKI and immune checkpoint (PD-1) inhibitor combinations have shown promising efficacy in treating aRCC. However, several combinations of non-specific VEGFR TKIs with anti-PD-1 antibodies have encountered toxicity levels that we believe have challenged or prohibited such VEGFR TKIs from safely combining with PD-1 inhibitors for RCC treatment, or required them to combine at reduced doses, which can potentially reduce efficacy. In our clinical trials, tivozanib has demonstrated lower rates of key potential overlapping toxicities with PD-1 inhibitors. Based on this data, we believe that tivozanib's tolerability profile may allow tivozanib to combine with PD-1 inhibitors with improved tolerability relative to other TKI plus PD-1 combinations reported to date.

In March 2017, we initiated enrollment in a phase 1b/2 clinical trial of tivozanib in combination with Opdivo (nivolumab), an immune checkpoint (PD-1) inhibitor, for the treatment of aRCC, which we refer to as the TiNivo trial. The TiNivo trial enrolled a total of 28 patients. We are sponsoring the trial, for which Bristol-Myers Squibb, or BMS, has supplied nivolumab. The TiNivo trial is being led by the Institut Gustave Roussy in Paris under the direction of Professor Bernard Escudier, MD, Chairman of the Genitourinary Oncology Committee. The phase 1b portion of the TiNivo trial enrolled six patients. In June 2017, we successfully completed the phase 1 dose escalation portion of the trial, where oral tivozanib was administered in two escalating dose cohorts in combination with intravenous nivolumab at a constant 240 mg every two weeks. The full dose tivozanib regimen of 1.5 mg daily for 21 days, followed by a 7-day rest period, was selected as the recommended phase 2 dose for the expansion portion of the trial. On November 3, 2017, the results from the phase 1b portion of the TiNivo trial were presented at the 16th International Kidney Cancer Symposium of the Kidney Cancer Association. The phase 1b portion of the TiNivo trial demonstrated that the combination of tivozanib and nivolumab was well tolerated to the full dose and schedule of single agent tivozanib, with no dose limiting toxicities.

The phase 2 portion of the trial, which enrolled an additional 22 patients, was designed to assess the safety, tolerability, and anti-tumor activity of the combination of tivozanib and nivolumab. On February 10, 2018, we presented the preliminary results from the phase 2 portion of the TiNivo trial, with available data from 27 of the 28 patients, at the 2018 ASCO Genitourinary Cancers Symposium. The combination was generally well tolerated. Treatment-related Grade 3/4 adverse events occurred in 44% of patients, the most common of which was hypertension. Preliminary efficacy was assessed in 14 patients, who were treated with the full dose and schedule of oral tivozanib in combination with intravenous nivolumab and enrolled at least four months prior to the data cutoff date. Of these patients, 7 had received at least one prior systemic therapy, including 2 that had received prior PD-1 therapy, and 7 were treatment naive. An ORR was observed in 64% of patients (partial responses), and a disease control rate (partial response plus stable disease) was observed in 100% of patients. The 2 patients who received prior PD-1 therapy both achieved a partial response. At the time of data collection, 11 of the 14 evaluable patients remained on study. We expect to present updated phase 2 results at the ESMO 2018 Congress in October 2018. We also intend to explore further development of tivozanib as a combination therapy with immune checkpoint inhibitors.

Clinical Development in HCC

NCCN-AVEO Phase 1b/2 Trial. In January 2018, Dr. Renuka Iyer from the Roswell Park Cancer Institute presented data at the 2018 ASCO Gastrointestinal Cancers Symposium from a multicenter, investigator-sponsored phase 1b/2 trial of tivozanib in previously untreated patients with advanced, unresectable hepatocellular carcinoma, or HCC. The trial was one of several studies funded by a grant we provided to the National Comprehensive Cancer Network.

The trial was designed to evaluate the safety and efficacy of tivozanib in advanced HCC, and enrolled a total of 21 patients at three trial sites. In the phase 1b portion of the trial, which used a modified 3 + 3 dose escalation design, 8 patients were dosed with tivozanib starting at 1.0 mg or 1.5 mg daily for 21 days followed by 7 days off drug. No dose-limiting toxicities were seen in cycle one in patients treated with 1.0 mg, and tivozanib at 1.0 mg daily was selected for the phase 2 expansion portion of the trial.

Of 19 evaluable patients in the trial, at a median follow up of 16.9 months, the trial's primary endpoint of median PFS and PFS at week 24 were 5.5 months and 47%, respectively. A partial response was seen in 4 of 19 patients (21%) and stable disease in 8 of 19 patients (42%), for a disease control rate of 63%. OS at 6 and 12 months was 58% and 25%, respectively, with a median OS of 7.5 months. As of the date of the presentation, four patients had maintained stable disease for over two years. There were no significant changes in hepatitis B or hepatitis C viral load during study treatment. Tivozanib was generally well tolerated at 1.0 mg daily, with adverse events consistent with those observed in previous tivozanib trials.

Following these trial results, we plan to explore potential development opportunities of tivozanib in HCC, both as a monotherapy and as a combination therapy.

Ficlatuzumab

Ficlatuzumab is a potent Hepatocyte Growth Factor, or HGF, inhibitory antibody. HGF is the sole known ligand of the c-Met receptor, which is believed to trigger many activities that are involved in cancer development and metastasis. We have partnered with Biodesix, Inc., or Biodesix, under a worldwide Co-Development and Collaboration Agreement, or the Biodesix Agreement, to develop and commercialize ficlatuzumab. Under the Biodesix Agreement, we and Biodesix each contribute half of the development costs of ficlatuzumab.

Development in HNSCC. We and Biodesix are funding an investigator-sponsored clinical trial of ficlatuzumab in combination with cetuximab in squamous cell carcinoma of the head and neck, or HNSCC. In June 2017, preliminary results from the phase 1 trial were presented at the 2017 ASCO Annual Meeting. The trial of ficlatuzumab in combination with the EGFR inhibitor cetuximab in patients with cetuximab-resistant, metastatic HNSCC demonstrated activity with an overall response rate of 17% (two partial responses out of twelve patients), a disease control rate of 67% and prolonged PFS and OS compared to historical controls, in addition to being well tolerated. A randomized, phase 2, multicenter, investigator-initiated trial to confirm these findings was initiated in the fourth quarter of 2017 under the direction of Julie E. Bauman, MD, MPH, Chief, Division of Hematology/Oncology at the University of Arizona Cancer Center. The phase 2 trial is expected to enroll approximately 60 patients randomized to receive either ficlatuzumab alone or ficlatuzumab and cetuximab.

Development in AML. We and Biodesix are funding an investigator-sponsored clinical trial of ficlatuzumab in combination with cytarabine in acute myeloid leukemia, or AML. In June 2017, preliminary results from the phase 1 trial were presented at the 2017 ASCO Annual Meeting. This trial, exploring ficlatuzumab in combination with high-dose cytarabine in patients with high risk relapsed or refractory AML, demonstrated early signs of tolerability and activity, including a 50% complete response rate in the eight evaluable patients. The phase 2 portion is ongoing and expected to enroll ten additional patients.

Development in pancreatic cancer. We and Biodesix are funding an investigator-sponsored clinical trial of ficlatuzumab in combination with nab-paclitaxel and gemcitabine in pancreatic cancer. The trial was initiated in December 2017 to test the safety and tolerability of ficlatuzumab when combined with nab-paclitaxel and gemcitabine in previously untreated metastatic pancreatic ductal cancer, or PDAC. Preclinical findings demonstrated a beneficial effect of the drug combination of ficlatuzumab and gemcitabine compared to either drug alone in an in-vivo model of PDAC. The goal of the trial is designed to determine maximum tolerated dose of ficlatuzumab when combined with gemcitabine and nab-paclitaxel. Secondary outcome measures include response rate and PFS. The trial, which is being conducted under the direction of Kimberly Perez, M.D. at the Dana-Farber Cancer Institute, is expected to enroll approximately 30 patients.

We continue to evaluate additional opportunities for the further clinical development of ficlatuzumab. The expansion of the ficlatuzumab clinical program, beyond what we are committed to, would require additional manufacturing efforts and costs.

AV-203

AV-203 is a potent anti-ErbB3 (also known as HER3) specific monoclonal antibody with high ErbB3 affinity. We have observed potent anti-tumor activity in mouse models. AV-203 selectively inhibits the activity of the ErbB3

receptor, and our preclinical studies suggest that neuregulin-1 (also known as heregulin), or NRG1, levels predict AV-203 anti-tumor activity. We have completed a phase 1 dose escalation trial of AV-203, which established a recommended phase 2 dose, demonstrated good tolerability and promising early signs of activity, and reached the maximum planned dose of AV-203 monotherapy.

We have partnered with CANbridge Life Sciences Ltd., or CANbridge, to develop, manufacture and commercialize AV-203 in all countries outside of North America. We have retained the North American rights to AV-203. CANbridge's obligations include conducting and funding clinical development of AV-203 through phase 2 proof-of-concept in esophageal squamous cell carcinoma. Following proof-of-concept, we may decide to participate in later-stage worldwide development efforts. In December 2017, CANbridge filed an initial new drug application, or IND, in China seeking regulatory authorization to initiate clinical trials of AV-203. If the IND is approved, CANbridge expects that AV-203 will reenter the clinic in 2018.

AV-380

AV-380 is a potent humanized IgG1 inhibitory monoclonal antibody targeting growth differentiation factor 15, or GDF15, a divergent member of the TGF-ß family, for the potential treatment or prevention of cachexia. Cachexia is defined as a multi-factorial syndrome of involuntary weight loss characterized by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. Cachexia is associated with various cancers as well as chronic kidney disease, congestive heart failure, chronic obstructive pulmonary disease, or COPD, anorexia nervosa and other diseases.f AV-380 focuses on a significant area of unmet patient need. It is estimated that approximately 30% of all cancer patients die due to cachexia and over half of cancer patients who die do so with cachexia present (J Cachexia Sarcopenia Muscle 2010). In the United States alone, the estimated prevalence of cancer cachexia is over 400,000 patients, and the prevalence of cachexia due to cancer, COPD, congestive heart failure, frailty and end stage renal disease combined is estimated to total more than 5 million patients (Am J Clin Nutr 2006).

We believe that AV-380 represents a unique approach to treating cachexia because it addresses key underlying mechanisms of the syndrome. We have established preclinical proof-of-concept for GDF15 as a key driver of cachexia by demonstrating, in animal models, that the administration of GDF15 induces cachexia, and that inhibition of GDF15 reverses cachexia and provides a potential indication of an OS benefit. We have demonstrated preclinical proof-of-concept for AV-380 in multiple cancer cachexia models and have completed cell line development. In connection with the AV-380 program, we have in-licensed certain patents and patent applications from St. Vincent's Hospital Sydney Limited in Sydney, Australia, which we refer to as St. Vincent's.

In August 2015, we granted Novartis International Pharmaceutical Ltd., or Novartis, the exclusive right to develop and commercialize AV-380 and our related antibodies worldwide. On June 29, 2018, Novartis notified us that it is terminating our collaboration without cause. Accordingly, effective August 28, 2018 we expect to regain the rights to AV-380 and are considering a variety of options to continue the program's development.

AV-353 Platform

The AV-353 platform includes a number of potent inhibitory antibody candidates specific to Notch 3. The Notch 3 pathway is important in cell-to-cell communication involving gene regulation mechanisms that control multiple cell differentiation processes during the entire life cycle. Scientific literature has implicated the Notch 3 receptor pathway in multiple diseases, including cancer, cardiovascular diseases and neurodegenerative conditions. Publications, including Nature Medicine (2009), have implicated the Notch 3 pathway in PAH, a rare and life-threatening disorder that affects approximately 250,000 people worldwide (Global Data 2016 PAH Opportunity Analyzer; 2012 Decision Resources PAH Report) and is caused by thickening of the arterial walls in small arteries between the heart and the lungs, resulting in restricted blood flow. Currently, no known cure for PAH exists. Existing treatments for PAH have focused on controlling symptoms by avoiding vasoconstriction and increasing vasodilation of blood vessels but have not reversed the underlying cause of the disease. However, the results of a preclinical research study conducted at the University of California at San Diego and presented in a poster at the November 2016 American Heart Association meeting using one of our anti-Notch3 antibody candidates generated preclinical data that supports the ability of the antibody to potentially reverse the thickening of vascular smooth muscle cells, which would represent a disease-modifying approach to treatment. We are currently seeking a partner to develop the AV-353 platform worldwide for the potential treatment of PAH.

Strategic Partnerships

CANbridge

In March 2016, we entered into a collaboration and license agreement with CANbridge, or the CANbridge Agreement, under which we granted CANbridge the exclusive right to develop, manufacture and commercialize AV-203, our proprietary ErbB3 (HER3) inhibitory antibody, for the diagnosis, treatment and prevention of disease in all countries outside of North America. In addition, CANbridge has a right of first negotiation if we determine to outlicense any North American rights. The parties have both agreed not to develop or commercialize any ErbB3 inhibitory antibody other than AV-203 during the term of the CANbridge Agreement.

In December 2017, CANbridge filed an IND application with the China Food and Drug Administration for a clinical study of AV-203 in esophageal squamous cell carcinoma. CANbridge has responsibility for all activities and costs associated with the development, manufacture and commercialization of AV-203 in its territories. CANbridge is obligated to use commercially reasonable efforts to develop and obtain regulatory approval for AV-203 in each of China, Japan, the United Kingdom, France, Italy, Spain and Germany. Under the CANbridge Agreement, CANbridge is required to conduct and fund the clinical development of AV-203 through phase 2 proof-of-concept in esophageal squamous cell carcinoma, after which we may elect to contribute to certain worldwide development efforts.

Pursuant to the CANbridge Agreement, CANbridge paid us an upfront fee of $1.0 million in April 2016, net of foreign withholding taxes. CANbridge also reimbursed us for $1.0 million in certain AV-203 manufacturing costs that we previously incurred. CANbridge paid this manufacturing reimbursement in two installments of $0.5 million each, one in March 2017 and one in September 2017, net of foreign withholding taxes. We are eligible to receive a $2.0 million development and regulatory milestone payment upon the receipt of the regulatory approval of the above-mentioned IND application. In addition, we are also eligible to receive up to $40.0 million in potential additional development and regulatory milestone payments and up to $90.0 million in potential commercial milestone payments based on annual net sales of licensed products. Upon commercialization, we are eligible to receive a tiered royalty, with a percentage range in the low double-digits, on net sales of approved licensed products. CANbridge's obligation to pay royalties for each licensed product expires on a country-by-country basis on the later of the expiration of patent rights covering such licensed product in such country, the expiration of regulatory data exclusivity in such country or ten years after the first commercial sale of such licensed product in such country. A percentage of any milestone and royalty payments received by us under the CANbridge Agreement, excluding upfront and reimbursement payments, are due to Biogen Idec International GmbH, or Biogen, as a sublicensing fee under our option and license agreement with Biogen dated March 18, 2009, as amended.

The term of the CANbridge Agreement continues until the last to expire royalty term applicable to licensed products. Either party may terminate the CANbridge Agreement in the event of a material breach of the CANbridge Agreement by the other party that remains uncured for a period of 45 days, in the case of a material breach of a payment obligation, and 90 days in the case of any other material breach. CANbridge may terminate the CANbridge Agreement without cause at any time upon 180 days' prior written notice to us. We may terminate the CANbridge Agreement upon thirty days' prior written notice if CANbridge challenges any of the patent rights licensed to CANbridge under the CANbridge Agreement.

EUSA

In December 2015, we entered into a license agreement with EUSA, or the EUSA Agreement, under which we granted to EUSA the exclusive, sublicensable right to develop, manufacture and commercialize tivozanib in the territories of Europe (excluding Russia, Ukraine and the Commonwealth of Independent States), Latin America (excluding Mexico), Africa and Australasia for all diseases and conditions in humans, excluding non-oncologic ocular conditions. EUSA is obligated to use commercially reasonable efforts to seek regulatory approval for and commercialize tivozanib throughout its licensed territories for RCC. EUSA has responsibility for all activities and costs associated with the further development, manufacture, regulatory filings and commercialization of tivozanib in its licensed territories.

EUSA made research and development reimbursement payments to us of $2.5 million upon the execution of the EUSA Agreement in 2015, and $4.0 million in September 2017 upon its receipt of marketing approval from the EMA in August 2017 for tivozanib (FOTIVDA) for the treatment of aRCC. In September 2017, EUSA elected to opt-in to co-develop the TiNivo trial. As a result of EUSA's exercise of its opt-in right, it became an active participant in the ongoing conduct of the TiNivo trial and is able to utilize the resulting data from the TiNivo trial for regulatory and commercial purposes in its territories. EUSA made an additional research and development reimbursement payment to us of $2.0 million upon its exercise of its opt-in right. This payment was received in October 2017, in advance of the completion of the TiNivo trial, and represents EUSA's approximate 50% share of the total estimated costs of the TiNivo trial. We are also eligible to receive an additional research and development reimbursement payment from EUSA of 50% of our total costs for our TIVO-3 trial, up to $20.0 million, if EUSA elects to opt-in to that study.

We are entitled to receive milestone payments of $2.0 million per country upon reimbursement approval, if any, for RCC in each of France, Germany, Italy, Spain and the United Kingdom, and an additional $2.0 million for the grant of marketing approval for RCC, if any, in three of the licensed countries outside of the European Union, as mutually

agreed by the parties. In February 2018, EUSA obtained reimbursement approval from the NICE in the United Kingdom for the first-line treatment of RCC. Accordingly, we earned a $2.0 million milestone payment that was received from EUSA in March 2018. We are also eligible to receive a payment of $2.0 million per indication in connection with a filing by EUSA with the EMA for marketing approval, if any, for tivozanib for the treatment of each of up to three additional indications and $5.0 million per indication in connection with the EMA's grant of marketing approval for each of up to three additional indications, as well as up to $335.0 million upon EUSA's achievement of certain sales thresholds. Upon commercialization, we are eligible to receive tiered double-digit royalties on net sales, if any, of licensed products in its licensed territories ranging from a low double digit up to mid-twenty percent depending on the level of annual net sales. In November 2017, we began earning sales royalties upon EUSA's commencement of the first commercial launch of tivozanib (FOTIVDA) with the initiation of product sales in Germany. We recognized approximately $97,000 and $143,000 in revenue for sales royalties in the three months and six months ended June 30, 2018, respectively.

The research and development reimbursement payments under the EUSA Agreement are not subject to the 30% sublicensing payment payable to KHK, subject to certain limitations. We would, however, owe KHK 30% of other, non-research and development payments we may receive from EUSA pursuant to the EUSA Agreement, including reimbursement approvals for RCC in up to five specified EU countries, marketing approvals for RCC in three specified non-EU licensed territories, EU marketing approval filings and corresponding marketing approvals by the EMA for up to three additional indications beyond RCC, and sales-based milestones and royalties, as set forth above. The $2.0 million milestone we earned in February 2018 upon EUSA's reimbursement approval for FOTIVDA in the United Kingdom was subject to the 30% KHK sub-license fee, or $0.6 million, which was paid in April 2018.

The term of the EUSA Agreement continues on a product-by-product and country-by-country basis until the later to occur of (a) the expiration of the last valid patent claim for such product in such country, (b) the expiration of market or regulatory data exclusivity for such product in such country or (c) the tenth anniversary of the effective date. Either party may terminate the EUSA Agreement in the event of the bankruptcy of the other party or a material breach by the other party that remains uncured, following receipt of written notice of such breach, for a period of (a) thirty (30) days in the case of breach for nonpayment of any amount due under the EUSA Agreement, and (b) ninety (90) days in the case of any other material breach. EUSA may terminate the EUSA Agreement at any time upon one hundred eighty (180) days' prior written notice. In addition, we may terminate the EUSA Agreement upon thirty (30) days' prior written notice if EUSA challenges any of the patent rights licensed under the EUSA Agreement.

Novartis

In August 2015, we entered into a license agreement with Novartis, or the Novartis Agreement, under which we granted Novartis the exclusive right to develop and commercialize AV-380 and our related antibodies worldwide. Novartis was responsible under the Novartis Agreement for the development, manufacture and commercialization of our antibodies and any resulting approved therapeutic products.

On June 29, 2018, Novartis notified us that it is terminating our collaboration without cause. Accordingly, effective August 28, 2018 we expect to regain the rights to AV-380. We had been eligible to receive milestone payments and royalties tied to the commencement of clinical trials, to regulatory approvals and to sales of such products upon commercialization. We have not included any of the potential milestone or other potential payments to us under the Novartis Agreement in our cash forecasts. Accordingly, termination of the Novartis Agreement will not impact our cash guidance.

Pursuant to the terms of the Novartis Agreement, Novartis' termination without cause triggers, among other things, the termination of all licenses and other rights granted by us to Novartis with regard to the AV-380 program, and the grant by Novartis to us of an irrevocable, exclusive, fully paid-up license, with a right to sub-license, to any patent rights or know-how controlled by Novartis as of the termination date related to the AV-380 program. Following termination, Novartis also has an obligation to transfer to us all preclinical, technical, manufacturing and other data developed by Novartis. We also have the right to purchase the inventory of AV-380 biological drug substance from Novartis at a price equal to Novartis' cost.

On June 28, 2018, we had separately provided Novartis with notice under the Novartis Agreement's dispute resolution provisions of a dispute regarding Novartis' compliance with its diligence obligations with respect to the development of the AV-380 program. If the parties are unable to resolve the dispute at the management level, an arbitration could be commenced. These dispute resolution procedures run in parallel to the termination process.

Biodesix

In April 2014, we entered into a worldwide co-development and collaboration agreement with Biodesix, or the Biodesix Agreement, to develop and commercialize ficlatuzumab. Under the Biodesix Agreement, we and Biodesix are each required to contribute 50% of all clinical, regulatory, manufacturing and other costs to develop ficlatuzumab, and would share equally in any future revenue from development or commercialization, subject to certain exceptions. We retain primary responsibility for clinical development of ficlatuzumab, although all trials are conducted pursuant to a joint development plan.

Under the Biodesix Agreement, we granted Biodesix perpetual, non-exclusive rights to certain intellectual property, including all clinical and biomarker data related to ficlatuzumab, to develop and commercialize VeriStrat®, Biodesix's proprietary companion diagnostic test. Biodesix granted us perpetual, non-exclusive rights to certain intellectual property, including diagnostic data related to VeriStrat, with respect to the development and commercialization of ficlatuzumab; each license includes the right to sublicense, subject to certain exceptions. In October 2016, we amended the Biodesix agreement in connection with the termination of the FOCAL trial, a phase 2 proof-of-concept clinical study of ficlatuzumab in which VeriStrat was used to select clinical trial subjects.

Prior to the first commercial sale of ficlatuzumab, each party has the right to elect to discontinue participating in further development or commercialization efforts with respect to ficlatuzumab, which is referred to as an "Opt-Out". If either we or Biodesix elects to Opt-Out, with such party referred to as the "Opting-Out Party," then the Opting-Out Party shall not be responsible for any future costs associated with developing and commercializing ficlatuzumab other than any ongoing clinical trials. If we elect to Opt-Out, we will continue to make the existing supply of ficlatuzumab available to Biodesix for the purposes of enabling Biodesix to complete the development of ficlatuzumab, and Biodesix will have the right to commercialize ficlatuzumab. After election of an Opt-Out, the non-opting out party shall have sole decision-making authority with respect to further development and commercialization of ficlatuzumab. Additionally, the Opting-Out Party shall be entitled to receive, if ficlatuzumab is successfully developed and commercialized, a royalty equal to 10% of net sales of ficlatuzumab throughout the world, if any, subject to offsets under certain circumstances. Prior to any Opt-Out, the parties shall share equally in any payments received from a third-party licensee; provided, however, after any Opt-Out, the Opting-Out Party shall be entitled to receive only a reduced portion of such third-party payments. The Biodesix Agreement remains in effect until the expiration of all payment obligations between the parties related to development and commercialization of ficlatuzumab, unless earlier terminated.

We and Biodesix are currently funding several investigator-sponsored clinical trials, including ficlatuzumab in combination with ERBITUX® (cetuximab) in squamous cell carcinoma of the head and neck, ficlatuzumab in combination with Cytosar (cytarabine) in acute myeloid leukemia and ficlatuzumab in combination with nab-paclitaxel and gemcitabine in pancreatic cancer. We continue to evaluate additional opportunities for the further clinical development of ficlatuzumab. Such clinical development, beyond what we are committed to, would require additional manufacturing efforts and costs.

St. Vincent's Hospital

In July 2012, we entered into a license agreement with St. Vincent's, or the St. Vincent's Agreement, under which we obtained an exclusive, worldwide sublicensable right to develop, manufacture and commercialize products for therapeutic applications that benefit from inhibition or decreased expression or activity of MIC-1, which is also known as GDF15. We believe GDF15 is a novel target for cachexia, and we are exploiting this license in our AV-380 program for cachexia. Under the St. Vincent's Agreement, we have non-exclusive rights to certain related diagnostic products and research tools and also have a right of first negotiation to obtain an exclusive license to certain improvements that St. Vincent's or third parties may make to licensed therapeutic products. We are obligated to use

diligent efforts to conduct research and clinical development and commercially launch at least one licensed therapeutic product.

In 2012, we paid St. Vincent's an upfront license fee of $0.7 million. In August 2015, in connection with the execution of the Novartis Agreement, we amended and restated the St. Vincent's Agreement and paid St. Vincent's an additional upfront fee of $1.5 million. We are required to make milestone payments, up to an aggregate total of $16.7 million, upon the earlier of achievement of specified development and regulatory milestones or a specified date for the first indication, and upon the achievement of specified development and regulatory milestones for the second and third indications, for licensed therapeutic products, some of which payments may be increased by a mid to high double-digit percentage rate for milestones payments made after we grant any sublicense, depending on the sublicensed territory. In March 2017, as further described above under the heading "—Novartis," we paid a $1.8 million time-based milestone obligation that we owed to St. Vincent's. We will owe an additional $2.3 million time-based milestone obligation to St. Vincent's in March 2019. In addition, we will be required to pay St. Vincent's tiered royalty payments equal to a low-single-digit percentage of any net sales we or our sublicensees make from licensed therapeutic products. The royalty rate escalates within the low-single-digit range during each calendar year based on increasing licensed therapeutic product sales during such calendar year. Our royalty payment obligations for a licensed therapeutic product in a particular country end on the later of 10 years after the date of first commercial sale of such licensed therapeutic product in such country or expiration of the last-to-expire

valid claim of the licensed patents covering such licensed therapeutic product in such country and are subject to offsets under certain circumstances.

The St. Vincent's Agreement remains in effect until the later of 10 years after the date of first commercial sale of licensed therapeutic products in the last country in which a commercial sale is made, or expiration of the last-to-expire valid claim of the licensed patents, unless we elect, or St. Vincent's elects, to terminate the St. Vincent's Agreement earlier. We have the right to terminate the St. Vincent's Agreement on six months' notice if we terminate our GDF15 research and development programs as a result of the failure of a licensed therapeutic product in preclinical or clinical development, or if we form the reasonable view that further GDF15 research and development is not commercially viable, and we are not then in breach of any of our obligations under the St. Vincent's Agreement.

Biogen Idec

In March 2009, we entered into an exclusive option and license agreement with Biogen Idec regarding the development and commercialization of our discovery-stage ErbB3-targeted antibodies for the potential treatment and diagnosis of cancer and other diseases in humans outside of North America. In March 2014, we amended our agreement with Biogen Idec, and regained worldwide rights to AV-203. Pursuant to the amendment, we were obligated to in good faith use reasonable efforts to seek a collaboration partner to fund further development and commercialization of ErbB3-targeted antibodies. We satisfied this obligation in March 2016 upon entering into our CANbridge Agreement. We are obligated to pay Biogen Idec a percentage of milestone payments we receive under the CANbridge Agreement and single-digit royalty payments on net sales related to the sale of AV-203, up to cumulative maximum amount of $50.0 million.

Kyowa Hakko Kirin

In December 2006, we entered into a license agreement with KHK, or the KHK Agreement, under which we obtained an exclusive license, with the right to grant sublicenses subject to certain restrictions, to research, develop, manufacture and commercialize tivozanib, pharmaceutical compositions thereof and associated biomarkers in all potential indications. Our exclusive license covers all territories in the world except for Asia and the Middle East, where KHK has retained the rights to tivozanib. Under the KHK Agreement, we obtained exclusive rights in our territory under certain KHK patents, patent applications and know-how related to tivozanib, to research, develop, make, have made, use, import, offer for sale, and sell tivozanib for the diagnosis, prevention and treatment of any and all human diseases and conditions. We and KHK each have access to and can benefit from the other party's clinical data and regulatory filings with respect to tivozanib and biomarkers identified in the conduct of activities under the KHK Agreement.

Under the KHK Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize tivozanib in our territory. Prior to the first anniversary of the first post-marketing approval sale of tivozanib in our territory, neither we nor any of our subsidiaries has the right to conduct certain clinical trials of, seek marketing approval for or commercialize any other cancer product that also works by inhibiting the activity of a VEGF receptor.

We have upfront, milestone and royalty payment obligations payable to KHK under our KHK Agreement. Upon entering into the KHK Agreement, we made an upfront payment in the amount of $5.0 million. In March 2010, we made a milestone payment to KHK in the amount of $10.0 million in connection with the dosing of the first patient in TIVO-1, our first phase 3 clinical trial of tivozanib. In December 2012, we made a $12.0 million milestone payment to KHK in connection with the acceptance by the FDA of our 2012 NDA filing for tivozanib. Each milestone under the KHK Agreement is a one-time only payment obligation. Accordingly, we did not owe KHK another milestone

payment in connection with the dosing of the first patient in our TIVO-3 trial and would not owe a milestone payment to KHK if we file an NDA with the FDA following the completion of our TIVO-3 clinical trial. If we obtain approval for tivozanib in the U.S., we would owe KHK a one-time milestone payment of $18.0 million, provided that we do not sublicense U.S. rights for tivozanib prior to obtaining a U.S. regulatory approval. If we were to sublicense the U.S. rights, the associated U.S. regulatory milestone would be replaced by a specified percentage of sublicensing revenue, as set forth below.

If we sublicense any of our rights to tivozanib to a third party, as we have done with EUSA pursuant to the EUSA Agreement, the sublicense defines the payment obligations of the sublicensee, which may vary from the milestone and royalty payment obligations under our KHK Agreement relating to rights we retain. We are required to pay KHK a fixed 30% of amounts we receive from our sublicensees, including upfront license fees, milestone payments and royalties, but excluding amounts we receive in respect of research and development reimbursement payments or equity investments, subject to certain limitations.

Certain research and development reimbursement payments by EUSA, including the $2.5 million upfront payment in December 2015, the $4.0 million in September 2017 upon the approval from the EMA of tivozanib (FOTIVDA) and the $2.0 million

upon EUSA's election in September 2017 to opt-in to co-develop the TiNivo trial were not subject to sublicense revenue payments to KHK. In addition, if EUSA elects to opt-in to the TIVO-3 trial, the additional research and development reimbursement payment from EUSA of 50% of the total trial costs, up to $20.0 million, would also not be subject to a sublicense revenue payment to KHK, subject to certain limitations. We would, however, owe KHK 30% of other, non-research and development payments we may receive from EUSA pursuant to the EUSA Agreement, including reimbursement approvals for RCC in up to five specified EU countries, marketing approvals for RCC in three specified non-EU licensed territories, EU marketing approval filings and corresponding marketing approvals by the EMA for up to three additional indications beyond RCC, and sales-based milestones and royalties. The $2.0 million milestone we earned in February 2018 upon EUSA's reimbursement approval for FOTIVDA in the United Kingdom as a first-line treatment for aRCC was subject to the 30% KHK sub-license fee, or $0.6 million, which was paid in April 2018.

We are also required to pay tiered royalty payments on net sales we make of tivozanib in our North American territory, which range from the low to mid-teens as a percentage of net sales. The royalty rate escalates within this range based on increasing tivozanib sales. Our royalty payment obligations in a particular country in our territory begin on the date of the first commercial sale of tivozanib in that country, and end on the later of 12 years after the date of first commercial sale of tivozanib in that country or the date of the last to expire of the patents covering tivozanib that have been issued in that country.

The KHK Agreement will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to KHK, determined on a product-by-product and country-by-country basis, unless we elect to terminate the KHK Agreement earlier. If we fail to meet our obligations under the KHK Agreement and are unable to cure such failure within specified time periods, KHK can terminate the KHK Agreement, resulting in a loss of our rights to tivozanib and an obligation to assign or license to KHK any intellectual property or other rights we may have in tivozanib, including our regulatory filings, regulatory approvals, patents and trademarks for tivozanib.

Financial Overview

We do not have a history of being profitable and, as of June 30, 2018, we had an accumulated deficit of $594.7 million. We anticipate that we will continue to incur significant operating costs over the next several years as we continue our planned development activities for our preclinical and clinical products. We will need additional funding to support our operating activities, and the timing and nature of activities contemplated for 2018 and thereafter will be conducted subject to the availability of sufficient financial resources. Refer to the "—Going Concern" and "Liquidity and Capital Resources—Operating Capital Requirements and Going Concern" sections for a further discussion of our funding requirements.

Revenue

On January 1, 2018, we adopted the provisions of Accounting Standards Codification Topic 606, Revenue From Contracts with Customers, or ASC 606. Refer to Note 3, "Significant Accounting Policies - Revenue Recognition" and Note 4, "Collaborations and License Agreements", to our condensed consolidated financial statements included elsewhere in this Quarterly Form 10-Q for further information.

To date, we have not generated any revenue from our product sales. Our revenues have historically been generated primarily through collaborative research, development and commercialization agreements. Payments to us 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. In November 2017, we began earning sales royalties upon EUSA's commencement of the first commercial launch of tivozanib (FOTIVDA) with the initiation of product sales in Germany.

In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and research and development payments in connection with strategic partnerships, and royalties resulting from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestones, royalties and other payments received under our strategic partnerships, and the payments that we receive upon the sale of our products, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales in the near term. If we or our strategic partners fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

Research and development expenses have historically consisted of expenses incurred in connection with the discovery and development of our product candidates. We recognize research and development expenses as they are incurred. These expenses consist primarily of:

- employee-related expenses, including salaries, bonuses, benefits and stock-based compensation expense;
- external development-related expenses, including clinical trials conducted by contract research organizations and investigative sites, preclinical studies and consultants;
- the cost of acquiring and manufacturing drug development related materials and related distribution;
- costs associated with outsourced development activities, including regulatory and medical affairs;
    - sub-licensee fees for, and milestone payments related to, in-licensed products and technology; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets.

Research and development expenses are net of amounts reimbursed under our agreements with EUSA, Biodesix, and Astellas for their respective shares of development costs incurred by us under our joint development plans with each respective partner.

We anticipate that research and development expenses will continue to decrease during the remainder of 2018 as we seek to complete the TIVO-3 trial and TiNivo trials. This estimate excludes possible additional Company-sponsored clinical trials and any related drug manufacturing and drug supply distribution, regulatory costs associated with a possible NDA submission for tivozanib in RCC and pre-commercialization activities that we may undertake if the topline data results from our TIVO-3 trial support an NDA submission to the FDA for tivozanib in RCC. We expect to receive and report topline data from the TIVO-3 trial in the fourth quarter of 2018.

Currently, we track direct external development expenses and direct salary on a program-by-program basis and allocate general-related expenses, such as indirect compensation, benefits and consulting fees, to each program based on the personnel resources allocated to such program. Facilities, IT costs and stock-based compensation are not allocated amongst programs and are considered overhead.

Uncertainties of Estimates Related to Research and Development Expenses

The process of conducting preclinical studies and clinical trials necessary to obtain FDA approval for each of our product candidates is costly and time-consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate’s early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability.

At this time, we cannot reasonably estimate or know the nature, specific timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates, or the period, if any, in which material net cash inflows may commence from sales of any approved products. This uncertainty is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- our ability to establish and maintain strategic partnerships, the terms of those strategic partnerships and the success of those strategic partnerships, if any, including the timing and amount of payments that we might receive from strategic partners;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for any product candidate;
- the progress and results of our clinical trials;

- the costs, timing and outcome of regulatory review of our product candidates;

- the emergence of competing technologies and products and other adverse market developments;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- additional manufacturing requirements.

As a result of the uncertainties associated with developing drugs, including those discussed above, we are unable to determine the exact duration and completion costs of current or future clinical stages of our product candidates, or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success, if any, of each product candidate, as well as ongoing assessment of each product candidate's commercial potential. We will need to raise substantial additional capital in the future in order to fund the development of our preclinical and clinical product candidates.

General and Administrative Expenses

General and administrative expenses consist principally of salaries, bonuses and related costs for personnel in executive, finance, corporate development, information technology, legal and human resource functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, prosecution and defense costs and professional fees for legal, consulting, auditing and tax services. We anticipate that our general and administrative expenses will remain at current levels during the remainder of 2018, excluding pre-commercialization activities that we may undertake if the topline data results from our TIVO-3 trial support an NDA submission for tivozanib in RCC. We expect to receive and report topline data from the TIVO-3 trial in the fourth quarter of 2018.

Warrants Issued in Connection with Private Placement

In May 2016, we issued warrants to purchase an aggregate of 17,642,482 shares of our common stock in connection with a private placement financing, which we refer to herein as the PIPE Warrants. Refer to"—Liquidity and Capital Resources—Private Placement/PIPE Warrants" below and Note 3, "Significant Accounting Policies - Warrants Issued in Connection with Private Placement" to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, for a further discussion.

The PIPE 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 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 warrant liability is recorded as additional paid-in capital in the Balance Sheet as a component of stockholder's equity.

As of June 30, 2018, PIPE Warrants exercisable for 777,201 shares of common stock had been exercised, for cash proceeds of approximately $0.8 million, and PIPE Warrants exercisable for 16,865,281 shares of common stock were outstanding. In July 2017, we issued to Hercules Capital Inc. 259,067 shares of common stock upon its exercise of all of its PIPE Warrants, and we 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 we issued 518,134 shares of our common stock and received approximately $0.5 million in cash proceeds.

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We recorded non-cash gains of approximately $11.1 million and $9.7 million in the three months and six months ended June 30, 2018, respectively, and non-cash losses of approximately $23.9 million and $24.4 million in the three months and six months ended June 30, 2017, respectively, in our Statement of Operations attributable to the increases and decreases in the fair value of the warrant liability that resulted from a lower stock price as of June 30, 2018 and a higher stock price as of June 30, 2017 relative to prior periods. In the six months ended June 30, 2018, we 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 key assumptions used to value the PIPE Warrants were as follows:

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

Class Action Settlement and Settlement Warrants

In December 2017, we entered into a binding memorandum of understanding, or MOU, to settle a securities class action lawsuit, or the Class Action, captioned In re AVEO Pharmaceuticals, Inc. Securities Litigation et al., No. 1:13-cv-11157-DJC, filed in 2013 in the United States District Court for the District of Massachusetts, or the District Court, against us and certain of our former officers. The Class Action was purportedly brought on behalf of stockholders who purchased our common stock between May 16, 2012 and May 1, 2013, or the Class.

Upon entry into the MOU, our liability related to this settlement became estimable and probable. Accordingly, we recorded an estimated $17.1 million contingent liability, including (a) $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 our insurance carriers, and (b) an approximate $2.1 million estimate for the fair value on December 31, 2017 of 2.0 million warrants to purchase shares of our common stock, or the Settlement Warrants, that we agreed to issue to the Class, with a corresponding non-cash charge to the Statement of Operations as a component of operating expenses. The Settlement Warrants are exercisable for a one-year period from their date of issue at an exercise price equal to $3.00 per share, which was the closing price on December 22, 2017, the trading day prior to the execution of the MOU.

In January 2018, we entered into a definitive stipulation of settlement agreement, or 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, or the Final Judgment.

The settlement became effective on June 29, 2018, or the Effective Date, which was the date on which all of the following conditions had been met: (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. Pursuant to the Final Judgment, all claims against us were released upon the Effective Date. In addition, pursuant to the Stipulation, we have 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. We had agreed to use our best efforts to issue and deliver the Settlement Warrants within ten business days following the Effective Date. On July 16, 2018, we issued and delivered the Settlement Warrants.

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. We recorded non-cash gains of approximately $0.7 million in each of the

three months and six months ended June 30, 2018, respectively, in our Statement of Operations attributable to the decrease in the fair value of the Settlement Warrants that principally resulted from a lower volatility rate relative to prior periods.

Refer to Note 9, “Legal Proceedings” to our condensed consolidated financial statements and Part II, Item 1 under the heading “Legal Proceedings” included elsewhere in this Quarterly Report on Form 10-Q, for a further discussion of the Class Action settlement.

The key assumptions used to estimate the fair value of 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	—	—	—

Interest Expense, Net

Interest expense consists of interest, amortization of debt discount, and amortization of deferred financing costs associated with our loans payable, and is shown net of interest income, which consists of interest earned on our cash, cash equivalents and marketable securities. The primary objective of our investment policy is capital preservation.

Income Taxes

We calculate our provision for income taxes on ordinary income based on our projected annual tax rate for the year. As of June 30, 2018, we are forecasting a net loss for the year ended December 31, 2018 and an effective tax-rate of 0%, and since we maintain a full valuation allowance on all of our deferred tax assets, we have recorded no income tax provision or benefit in the current quarter. On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the Act. The Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

On December 22, 2017, the U.S. Securities and Exchange Commission, or SEC, issued guidance under Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act directing taxpayers to consider the impact of the U.S. legislation as “provisional” when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law.

We are still in the process of evaluating the new law and therefore have not determined the full effect it will have on our business, including our financial statements.

Significant Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of asset and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reported periods. On an ongoing basis, we evaluate our estimates and judgments for changes in facts and circumstances, including those related to revenue recognition, contract research accruals, measurement of the PIPE Warrant liability, estimated settlement liabilities and stock-based compensation. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate. Our significant accounting policies are described in the notes to our condensed consolidated financial

statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the three months and six months ended June 30, 2018, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2017, which we filed with the SEC on March 13, 2018, except as set forth below:

On January 1, 2018, we adopted ASC 606 using the modified retrospective method and applied the new guidance to the most current period presented with the cumulative effect of changes reflected in the opening balance of the accumulated deficit. The adoption of ASC 606 resulted in an approximate $2.7 million increase in each of deferred revenue and the accumulated deficit at the transition date. The transition adjustment related solely to our EUSA Agreement. The transition adjustment resulted from a change to our accounting policy with respect to the recognition of milestone payments as a result of adopting ASC 606. Refer to Note 3 – “Significant Accounting Policies - Revenue Recognition” and Note 4 – “Collaborations and License Agreements – EUSA”, to our condensed consolidated financial statements included elsewhere in this Quarterly Form 10-Q for further information.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, refer to Note 3 – “Significant Accounting Policies—Recently Adopted Accounting Pronouncements”, to our condensed consolidated financial statements included elsewhere in this Quarterly Form 10-Q.

Results of Operations

Comparison of Three and Six Months Ended June 30, 2018 and 2017

Revenues (in thousands)

	Three Months Ended June 30,		Comparison		Six Months Ended June 30,		Comparison	
	2018	2017	$	%	2018	2017	$	%
EUSA	$433	$99	$334	337 %	$1,459	$198	$1,261	637 %
Novartis	—	15	(15)	(100)%	—	1,820	(1,820)	(100)%
CANbridge	—	—	—	-%	—	500	(500)	(100)%
Ophthotech	—	87	(87)	(100)%	—	115	(115)	(100)%
Other	—	150	(150)	(100)%	—	250	(250)	(100)%
Total	$433	$351	$82	23 %	$1,459	$2,883	$(1,424)	(49)%

In 2018 as compared to 2017, revenue increased under our partnership with EUSA by $0.3 million and $1.3 million in the three-month and six-month periods, respectively, related to the European market approval of tivozanib. In August 2017, the European Commission approved tivozanib in first-line RCC in all 28 countries of the European Union,

Norway and Iceland. Tivozanib is sold under the brand name FOTIVDA. In November 2017, we began earning sales royalties upon EUSA's commencement of the first commercial launch of tivozanib (FOTIVDA) with the initiation of product sales in Germany. EUSA has commercially launched FOTIVDA in Germany, the United Kingdom and Austria. We earned sales royalties of $97,000 and $143,000 in the three months and six months ended June 30, 2018, respectively.

In February 2018, EUSA obtained reimbursement approval for tivozanib (FOTIVDA) from the NICE in the UK in first-line aRCC and, accordingly, we earned a $2.0 million milestone payment from EUSA. In accordance with our adoption of ASC 606 on January 1, 2018, we recognized approximately $0.7 million of this milestone payment in revenue for the cumulative catch-up for the period from contract execution in December 2015 through the milestone achievement in February 2018, with the approximate $1.3 million balance classified as deferred revenue that is being recognized as revenue over the remainder of our performance period through April 2022.

Refer to Note 4 "Collaborations and License Agreements – EUSA", to our condensed consolidated financial statements included elsewhere in this Quarterly Form 10-Q, regarding the specific application of ASC 606 to our EUSA Agreement. Refer to Note 3 "Significant Accounting Policies – Recently Adopted Accounting Pronouncements", to our condensed consolidated financial statements included elsewhere in this Quarterly Form 10-Q, for a comparison of revenue recognized during the three months and six months ended June 30, 2018 under ASC 606 compared to the revenue that would have been recognized in that period had we continued to apply the provisions of ASC 605.

In 2018 as compared to 2017, revenue decreased by $2.3 million in the six-month period under our partnerships with Novartis and CANbridge related to payments received in the first quarter of 2017. In February 2017, Novartis paid $1.8 million out of

its future payment obligations to us under the license agreement. The funds were used to satisfy a $1.8 million time-based milestone obligation that we owed to St. Vincent's on March 2, 2017. In March 2017, CANbridge paid us $0.5 million for the reimbursement of manufacturing development activities conducted by us prior to the effective date of the collaboration and license agreement.

Research and Development Expenses (in thousands)

	Three Months Ended June 30,		Comparison		Six Months Ended June 30,		Comparison	
	2018	2017	$	%	2018	2017	$	%
Tivozanib	$4,443	$6,397	$(1,954)	(31)%	$9,362	$12,114	$(2,752)	(23)%
AV-380 Program in Cachexia	42	15	27	180%	57	1,820	(1,763)	(97)%
Ficlatuzumab	101	257	(156)	(61)%	236	487	(251)	(52)%
Overhead	301	212	89	42 %	636	416	220	53 %
Total research and development expenses	$4,887	$6,881	$(1,994)	(29)%	$10,291	$14,837	$(4,546)	(31)%

In 2018 as compared to 2017, research and development expenses decreased in the three-month period by $2.0 million, principally due to a $2.0 million decrease in tivozanib expenses that resulted from a $1.7 million decrease related to the year-to-year conduct of the TIVO-3 trial. We initiated the TIVO-3 trial in May 2016 and completed enrollment in August 2017. In 2018 as compared to 2017, the TIVO-3 trial is winding down as the majority of the patients are off treatment in advance of reaching the required number of events needed to conduct the primary analysis as compared to being in active enrollment in the same period in 2017.

In 2018 as compared to 2017, research and development expenses decreased in the six-month period by $4.5 million, principally due to decreases of $2.7 million in net tivozanib expenses and $1.8 million in AV-380 for a time-based milestone obligation due to St. Vincent's in the first quarter of 2017 that was not incurred in the same period in 2018. The $2.7 million net decrease in tivozanib expenses principally included a decrease of $3.1 million related to the year-to-year conduct of the TIVO-3 trial as highlighted above, partially offset by a $0.6 million increase related to the 30% sub-license fee due to KHK in connection with the $2.0 million milestone earned under our EUSA Agreement in February 2018 for reimbursement approval from the NICE in the UK in first-line aRCC.

We anticipate that research and development expenses will continue to decrease during the remainder of 2018 as we seek to complete the TIVO-3 trial and TiNivo trials. This estimate excludes possible additional Company-sponsored clinical trials and any related drug manufacturing and drug supply distribution, regulatory costs associated with a possible NDA submission for tivozanib in RCC and pre-commercialization activities that we may undertake if the topline data results from our TIVO-3 trial support an NDA submission for tivozanib in RCC. We expect to receive and report topline data from the TIVO-3 trial in the fourth quarter of 2018,

General and Administrative Expenses (in thousands)

	Three Months Ended June 30,		Comparison		Six Months Ended June 30,		Comparison	
	2018	2017	$	%	2018	2017	$	%
General and administrative expenses	$2,827	$2,302	$ 525	23 %	5,437	4,633	$ 804	17 %

In 2018 as compared to 2017, general and administrative expenses increased in the three-month period by $0.5 million, principally due to increases of $0.2 million in professional fees and $0.2 million in stock-based compensation expense resulting from a higher stock price in 2018 as compared to 2017 in connection with annual stock option grants.

In 2018 as compared to 2017, general and administrative expenses increased in the six-month period by $0.8 million, principally due to increases of $0.2 million in professional fees and $0.5 million in stock-based compensation expense resulting from a higher stock price in 2018 as compared to 2017 in connection with annual stock option grants.

We anticipate that general and administrative expenses will remain at current levels during the remainder of 2018, excluding pre-commercialization activities that we may undertake if the topline data results from our TIVO-3 trial support an NDA submission for tivozanib in RCC. We expect to receive and report topline data from the TIVO-3 trial in the fourth quarter of 2018.

Settlement Costs (in thousands)

	Three Months Ended June 30,		Comparison		Six Months Ended June 30,		Comparison	
	2018	2017	$	%	2018	2017	$	%
Settlement costs	$(709)	$ —	$(709)	100%	$(667)	$ —	$(667)	100%

In December 2017, we entered into a MOU related to our class action settlement that included the issuance of the 2.0 million Settlement Warrants to purchase shares of our common stock. The Settlement Warrants were revalued at each balance sheet date prior to issuance. On July 16, 2018 the Company issued and delivered the Settlement Warrants. 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.

In 2018, settlement costs decreased in each of the three-month and six-month periods attributable to the decreases in the fair value of the Settlement Warrants that principally resulted from a lower volatility rate of our common stock used in the Black-Scholes valuations relative to prior periods.

Change in Fair Value of PIPE Warrant Liability (in thousands)

	Three Months Ended June 30,		Comparison		Six Months Ended June 30,		Comparison	
	2018	2017	$	%	2018	2017	$	%
Change in fair value of warrant liability	11,125	$(23,925)	$35,050	(146)%	$9,660	$(24,409)	$34,069	(140)%

In May 2016, we issued the PIPE Warrants in connection with a private placement financing and recorded the warrants as a liability. The PIPE Warrants are subject to revaluation at each balance sheet date. In 2018 as compared to 2017, the change in fair value of the PIPE Warrant liability decreased by approximately $35.0 million and $34.1 million in the three-month and six-month periods, respectively, principally due to lower revaluations resulting from lower stock prices.

In 2018, we recorded approximate non-cash gains of $11.1 million and $9.7 million in the three-month and six-month periods, respectively, in our Statement of Operations attributable to the decreases in the fair value of the PIPE Warrant

liability that principally resulted from a lower stock price of $2.26 on June 30, 2018 compared to the stock prices of $2.90 on March 31, 2018 and $2.79 on December 31, 2017.

In 2017, we recorded approximate non-cash losses of $23.9 million and $24.4 million in the three-month and six-month periods, respectively, in our Statement of Operations attributable to the increases in the fair value of the PIPE Warrant liability that principally resulted from a higher stock price of $2.22 on June 30, 2017 compared to the stock prices of $0.59 on March 31, 2017 and $0.54 on December 31, 2016.

Interest Expense, net (in thousands)

	Three Months Ended June 30,		Comparison		Six Months Ended June 30,		Comparison	
	2018	2017	$	%	2018	2017	$	%
Interest expense, net	$(549)	$(530)	$ (19)	4 %	$(1,042)	$(1,081)	$ 39	(4)%

In December 2017, we refinanced our debt facility, the terms of which included a reduction in the then interest rate from 11.9% to 9.45%, an extension in the interest-only period by no less than 12 months, which could be extended up to a maximum of 24 months, assuming the achievement of specified milestones relating to the development of tivozanib, and an extension in the loan maturity from December 2019 to July 2021. In June 2018, the interest rate increased from 9.45% to 9.70% due to a corresponding increase in the prime interest rate, which is a component of the overall interest rate.

We anticipate that interest expense in 2018 will continue to decrease due to the lower interest rates as a result of our debt refinancing in December 2017.

Provision for Income Taxes (in thousands)

	Three Months Ended June 30,		Comparison		Six Months Ended June 30,		Comparison	
	2018	2017	$	%	2018	2017	$	%
Provision for income taxes	$ —	$ —	$ —	-%	$ —	$ (50)	$ 50	(100)%

In 2017, we recorded a $50,000 tax provision for foreign withholding taxes incurred in March 2017 related to the $0.5 million reimbursement payment from CANbridge for manufacturing development activities conducted by us prior to the effective date of the collaboration and license agreement. No foreign withholding taxes were incurred in the three months and six months ended June 30, 2018.

Liquidity and Capital Resources

We have financed our operations to date primarily through the sale of private placements and public offerings of our common stock and preferred stock, license fees, milestone payments and research and development funding from strategic partners, and loan proceeds. As of June 30, 2018, we had cash, cash equivalents and marketable securities of approximately $18.1 million. See "—Operating Capital Requirements and Going Concern" below and Note 1 to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a further discussion of our liquidity and the conditions and events which raise substantial doubt regarding our ability to continue as a going concern. Currently, our funds are invested in a U.S. government money market fund and corporate debt securities, including commercial paper. The following table sets forth the primary sources and uses of cash for each of the periods set forth below (in thousands):

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities	$(15,602)	$(12,447)
Net cash provided by (used in) investing activities	18,579	(1,034)
Net cash provided by financing activities	163	29,245
Net increase in cash and cash equivalents	$3,140	$15,764

Our operating activities used cash of $15.6 million and $12.4 million in 2018 and 2017, respectively. Cash used in operations was principally due to our net loss adjusted for non-cash items and changes in working capital.

Our investing activities provided cash of $18.6 million in 2018 and used cash of $1.0 million in 2017, principally due to net changes in the maturities and purchases of marketable securities.

Our financing activities provided cash of $0.2 million and $29.2 million in 2018 and 2017, respectively. In 2018, we raised approximately $0.7 million from the issuance of our common stock, including approximately $0.5 million from

the exercise of 0.5 million PIPE Warrants in January 2018 and approximately $0.2 million from the exercise of stock options, offset by a $0.5 million end-of-term debt payment in January 2018 in connection with the 2014 Amendment of our loan facility. In 2017, we raised approximately $29.2 million in net cash proceeds, including $15.4 million from an underwritten public offering of 34.5 million shares of our common stock in March 2017, and $8.8 million from sales of 6.5 million shares of our common stock under our FBR Sales Agreement and $5.0 million from additional borrowings under our loan agreement with Hercules in June 2017.

Settlement Warrants

On July 16, 2018, we issued and delivered 2.0 million Settlement Warrants to purchase shares of our common stock for a one-year period after the date of issuance at an exercise price equal to $3.00 per share. Refer to the section above, “Class Action Settlement and Settlement Warrants” for further discussion.

Sales Agreement with Leerink

On November 30, 2017, we filed a shelf registration statement on Form S-3 with the SEC, which we refer to as the 2017 Shelf. The 2017 Shelf (File No. 333-221873) was declared effective by the SEC on December 15, 2017 and covers the offering, issuance and sale from time to time of up to $200 million of our common stock, preferred stock, debt securities, warrants and/or units. The 2017 Shelf was filed to replace our then-existing 2015 shelf registration statement, which was terminated upon the 2017 Shelf being declared effective by the SEC on December 15, 2017.

In February 2018, we entered into a sales agreement, which we refer to as the Leerink Sales Agreement, with Leerink Partners LLC, or Leerink, pursuant to which we may issue and sell shares of our common stock from time to time up to an aggregate amount of $50 million, at our option, through Leerink as our sales agent, with any sales of common stock through Leerink being made by any method that is deemed an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or in other transactions. Any such shares of common stock will be sold pursuant to a prospectus supplement filed under the 2017 Shelf. We agreed to pay Leerink a commission of up to 3% of the gross proceeds of any sales of common stock pursuant to the Leerink Sales Agreement. At the time of filing this Quarterly Report on Form 10-Q, no shares of our common stock have been sold under the Leerink Sales Agreement.

Public Offering

On March 31, 2017, we closed an underwritten public offering of 34.5 million shares of our common stock, including the exercise in full by the underwriter of its option to purchase 4.5 million shares, at the public offering price of $0.50 per share for gross proceeds of approximately $17.3 million. Certain of our executive officers and a director purchased an aggregate of 420,000 shares and an entity affiliated with New Enterprise Associates, a greater than 5% stockholder, purchased 6.0 million shares in this offering at the same public offering price per share as the other investors. The net offering proceeds to us were approximately $15.4 million after deducting underwriting discounts and estimated offering expenses payable by us.

Private Placement / PIPE Warrants

In May 2016, we entered into a securities purchase agreement with a select group of qualified institutional buyers, institutional accredited investors and accredited investors pursuant to which we sold 17,642,482 units, at a price of $0.965 per unit, for gross proceeds of approximately $17.0 million. Each unit consisted of one share of our common stock and a PIPE Warrant to purchase one share of our common stock. The PIPE Warrants have an exercise price of $1.00 per share and are exercisable in any manner at any time for a period of five years from the date of issuance. Certain of our directors and executive officers purchased an aggregate of 544,039 units in this offering at the same price as the other investors. The net offering proceeds to us were approximately $15.4 million after deducting placement agent fees and other offering expenses payable by us. As of June 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, we issued to Hercules Capital Inc. 259,067 shares of common stock upon its exercise of all of its PIPE Warrants, and we 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 we issued 518,134 shares of our common stock and received approximately $0.5 million in cash proceeds.

Credit Facilities

On May 28, 2010, we entered into a loan and security agreement with Hercules Capital Inc. and certain of its affiliates, or the First Loan Agreement. The First Loan Agreement was subsequently amended in March 2012, or the 2012 Amendment; September 2014, or the 2014 Amendment and May 2016, or the 2016 Amendment. In December 2017, we refinanced the First Loan Agreement, as amended, by entering into an amended and restated loan and security agreement, or the 2017 Loan Agreement, with Hercules Funding III, LLC and Hercules Capital, Inc., which we collectively refer to as Hercules.

Pursuant to the 2014 Amendment, we received $10.0 million in additional loan proceeds from Hercules and were required to make an end-of-term payment of approximately $0.5 million on January 1, 2018. This payment was made on the first business day of 2018.

Pursuant to the 2016 Amendment, we received additional loan proceeds from Hercules, in an aggregate amount of $10.0 million, received in installments of $5.0 million in each of May 2016 and June 2017, which increased the aggregate outstanding principal balance under the First Loan Agreement to $20.0 million. We are required to make an end-of-term payment totaling $0.3 million on December 1, 2019. The 2016 Amendment included a financial covenant that required us to maintain an unrestricted cash position greater than or equal to $10.0 million through the date of completion of our TIVO-3 trial with results that were satisfactory to Hercules. Principal payments were scheduled to commence on January 1, 2018 and the loan was scheduled to mature on December 1, 2019.

In December 2017, we entered into the 2017 Loan Agreement to refinance our existing loan facility with Hercules and to retire the $20.0 million in secured debt then-outstanding under the First Loan Agreement. Per the terms of the 2017 Loan Agreement, the new $20.0 million loan facility has a 42-month maturity from closing, no financial covenants, a lower interest rate and an interest-only period of no less than 12 months, which could be extended up to a maximum of 24 months, assuming the achievement of specified milestones relating to the development of tivozanib. Per the 2017 Loan Agreement, Hercules did not receive any additional warrants to purchase shares of our common stock and no longer has the option, subject to our written consent, to participate in our

future equity financings up to $2.0 million through the purchase of our common stock either with cash or through the conversion of outstanding principal under the loan.

Pursuant to the 2017 Loan Agreement, the loan maturity date has been revised from December 2019 to July 2021. We are not required to make principal payments until February 1, 2019, at which time we will be required to make 29 equal monthly payments of principal and interest, in the approximate amount of $0.8 million through July 2021. An additional end-of-term payment of approximately $0.8 million is due on July 1, 2021, which increases the total end-of-term payments under the 2014 Amendment, 2016 Amendment and 2017 Loan Agreement to approximately $1.6 million. The end-of-term payments under the 2014 Amendment, in the approximate amount of $0.5 million, and the 2016 Amendment, in the amount of $0.3 million, continue to be due on their original due dates of January 1, 2018 and December 1, 2019, respectively. The financial covenant per the 2016 Amendment to maintain an unrestricted cash position greater than or equal to $10.0 million through the date of completion of our TIVO-3 trial with results that are satisfactory to Hercules has been removed. Per the 2017 Loan Agreement, the interest rate decreased from 11.9% to 9.45%. In June 2018, the interest rate increased from 9.45% to 9.70% due to the corresponding increase in the prime interest rate

The interest-only period could be extended by two 6-month deferrals upon the achievement of specified milestones relating to the development of tivozanib, including (i) on or prior to September 30, 2018, we have received positive data with respect to our TIVO-3 trial for the treatment of RCC for patients in the third-line setting which positive data supports the filing for a new drug application with the Food and Drug Administration, or FDA, subject to confirmation by Hercules at its reasonable discretion, and (ii) on or prior to June 28, 2019, we have received approval from the FDA for our tivozanib product for the treatment of RCC for patients in the third-line setting, subject to confirmation by Hercules at its reasonable discretion.

We must make interest payments on the principal balance of the loan each month it remains outstanding. Per annum interest is payable on the loan balance at the greater of 9.45% and an amount equal to 9.45% plus the prime rate minus 4.75%, as determined daily, provided however, that the per annum interest rate shall not exceed 15.0%. Our annual interest rate as of June 30, 2018 was 9.70%.

We have determined that the risk of subjective acceleration under the material adverse events clause included in the 2017 Loan Agreement is remote and, therefore, have classified the outstanding principal amount in current and long-term liabilities based on the timing of scheduled principal payments. As of June 30, 2018, we are in compliance with all of the loan covenants and, through the date of this filing, the lenders have not asserted any events of default under the loan. We do not believe that there has been a material adverse change as defined in the 2017 Loan Agreement. The loans are secured by a lien on all of our personal property (other than intellectual property), whether owned as of, or acquired after, the date of the First Loan Agreement.

Operating Capital Requirements and Going Concern

We have devoted substantially all of our resources to our drug development efforts, comprised of research and development, manufacturing, conducting clinical trials for our product candidates, protecting our intellectual property and general and administrative functions relating to these operations. Our future success is dependent on our ability to develop our product candidates and ultimately upon our ability to attain profitable operations. We anticipate that we will continue to incur significant operating losses for the next several years as we incur expenses to continue to execute on our clinical development strategy to advance our preclinical and clinical stage assets. We will require substantial additional funds to continue our development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for substantial working capital to support our development activities for tivozanib. For example, we estimate that the aggregate remaining costs for the TIVO-3 trial, including drug supply and distribution, could be in the range of $6.0 million to $9.0 million through

2019. We estimate that the overall cost for the TIVO-3 trial, including drug supply and distribution, could be in the range of $45.0 million to $48.0 million. Our aggregate remaining costs for the TiNivo trial, including tivozanib drug supply and distribution, could be in the range of $1.0 million to $1.2 million through 2019. We estimate that the overall cost for the TiNivo trial, including drug supply and distribution, could be in the range of $4.0 million to $4.5 million. BMS is providing nivolumab for the study. In addition, in September 2017, EUSA elected to opt-in to co-develop the TiNivo trial and paid the maximum $2.0 million for its approximate 50% share of the total trial costs.

Moreover, we have future payment obligations and cost-sharing arrangements under certain of our collaboration and license agreements. For example, under our agreements with KHK and St. Vincent’s, we are required to make certain clinical and regulatory milestone payments, have royalty obligations with respect to product sales and are required to pay a specified percentage of sublicense revenue in certain instances.

During the six months ended June 30, 2018, we received approximately $2.7 million in funding, including approximately $0.5 million received in January 2018 related to the exercise of 0.5 million PIPE Warrants, the $2.0 million milestone payment by EUSA for the February 2018 reimbursement approval by the NICE for aRCC in the UK that was received in March 2018 and approximately $0.2 million related to the exercise of stock options. The corresponding 30% sub-license fee due to KHK was paid in April 2018.

As of June 30, 2018, we had approximately $18.1 million in cash, cash equivalents and marketable securities, working capital of $2.8 million and an accumulated deficit of $594.7 million. Based on these available cash resources, we believe that we do 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 our ability to continue as a going concern.

Our 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 our control:

- Earn royalty payments pursuant to the EUSA Agreement. In August 2017, EUSA obtained marketing approval from the EMA for tivozanib (FOTIVDA) for the treatment of aRCC.
- Earn milestone payments pursuant to our collaboration and license agreements or restructure / monetize existing potential milestone and/or royalty payments under those collaboration and license agreements.
- Raise funding through the possible additional sales of our common stock, including public or private equity financings.
- Partner our AV-353 platform to secure potential additional non-dilutive funds and advance development of the AV-353 platform for the potential treatment of PAH.

Pursuant to our EUSA Agreement, we are 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 KHK. We are also eligible to receive an additional research and development reimbursement payment from EUSA of 50% of the total costs for our 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.

In addition, CANbridge filed an IND application with the China Food and Drug Administration in December 2017 for a clinical study of AV-203 in esophageal squamous cell carcinoma. Pursuant to our CANbridge Agreement, we are entitled to receive a $2.0 million development and regulatory milestone payment upon the receipt of the regulatory approval of this IND application.

There can be no assurance, however, that we 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 our 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, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our 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 our 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 our collaborators and other resources cannot be considered probable at this time because none of our 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 our control. Accordingly, substantial doubt is deemed to exist about our ability to continue as a going concern within one year after the date these financial statements are issued.

We believe that our approximate $18.1 million in cash, cash equivalents and marketable securities at June 30, 2018 would allow us to fund our planned operations into the first quarter of 2019. This estimate assumes no receipt of additional milestone payments and royalties from our partners, no funding from new partnership agreements, no equity financings, no debt financings, no sales of equity under our Leerink Sales Agreement and no additional sales of equity through the exercise of our outstanding PIPE

Warrants or the Settlement Warrants. Accordingly, the timing and nature of activities contemplated for the remainder of 2018 and thereafter will be conducted subject to the availability of sufficient financial resources.

There are numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products. Accordingly, our future funding requirements may vary from our current expectations and will depend on many factors, including, but not limited to:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and of conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
    - the absence of any breach, acceleration event or event of default under our 2017 Loan Agreement with Hercules or under any other agreements with third parties;
- the outcome of legal actions against us, including the current lawsuits described in Part II, Item 1 of this report under the heading “Legal Proceedings”;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- our ability to continue as a going concern.

We will require additional funding to extend our planned operations. We may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to raise substantial additional capital in the near term, whether on terms that are acceptable to us, or at all then we may be required to:

- delay, limit, reduce or terminate our clinical trials or other development activities for one or more of our product candidates; and/or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, if approved.

Contractual Obligations and Commitments

There have been no additional material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission, or the SEC, on March 13, 2018.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2018, we had cash, cash equivalents and marketable securities of approximately $18.1 million. Currently, our funds are invested in a U.S. government money market fund and corporate debt securities, including commercial paper. We do not hold any of these instruments for trading or speculative purposes. Our funds are invested in accordance with investment guidelines as approved by our Board of Directors.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term cash equivalents. Our cash equivalents and marketable securities are subject to interest rate risk and could fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our cash equivalents until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

Our loans payable are subject to interest rate risk. As of June 30, 2018, our aggregate principal balance outstanding on our Hercules Loan Agreement was $20.0 million. Per annum interest is payable on the principal balance of the loan each month it remains outstanding at the greater of 9.45% or an amount equal to 9.45% plus the prime rate minus 4.75% as determined daily, provided however, that the per annum interest rate shall not exceed 15.0%. As of June 30, 2018, the interest rate was 9.70%. For every 1% increase in the prime rate over 4.75%, given the amount of debt outstanding under the Hercules Loan Agreement as of June 30, 2018, we would have an increase in future annual cash outflows of approximately $0.2 million over the next twelve-month period as a result of such 1% increase.

We are also exposed to market risk related to change in foreign currency exchange rates. We contract with contract research organizations and investigational sites that are located around the world. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign currency exchange rate risk.

Item 4. Controls and Procedures.

Our management, with the participation of our President and Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2018. The term “disclosure controls and procedures” means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our President and

Chief Executive Officer and our Chief Financial Officer concluded that as of June 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, during the quarter ended June 30, 2018 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except as noted below.

During the quarter ended March 31, 2018, we implemented internal controls to ensure we adequately evaluated our contracts and properly assessed the impact of ASC 606, to facilitate our adoption on January 1, 2018. In addition, we implemented certain additional controls in connection with the ongoing accounting for our revenue arrangements under ASC 606, including controls to re-evaluate the constraint on variable consideration at each reporting period.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We recently settled a consolidated class action lawsuit, or the Class Action, In re AVEO Pharmaceuticals, Inc. Securities Litigation et al., No. 1:13-cv-11157-DJC, that had been filed in 2013 against us and certain of our former officers (Tuan Ha-Ngoc, David N. Johnston, William Slichenmyer, and Ronald DePinho) in the United States District Court for the District of Massachusetts, or the District Court. The Class Action had been dismissed without prejudice in March 2015, and the lead plaintiffs then filed a second amended complaint bringing similar allegations, but which no longer named Mr. DePinho as a defendant. We moved to dismiss again, and the District Court ruled in our favor and dismissed the second amended complaint with prejudice in November 2015. The lead plaintiffs appealed the District Court's decision and also filed a motion to vacate and reconsider the District Court's judgment. In January 2017, the District Court granted the plaintiffs' motion to vacate the dismissal and judgment. In February 2017, the plaintiffs filed a third amended complaint, on behalf of stockholders who purchased common stock between May 16, 2012 and May 1, 2013, or the Class, alleging claims similar to those alleged in the prior complaints, namely that we and certain of our former officers and directors violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the phase 3 trial design and results for our TIVO-1 clinical trial in an effort to lead investors to believe that the drug would receive approval from the FDA. In July 2017, the District Court entered an order referring the case to alternative dispute resolution. The parties mediated during the fall of 2017.

On December 26, 2017, the parties entered into a binding memorandum of understanding, or MOU, to settle the Class Action. Under the terms of the MOU, we agreed to cause certain of our and the individual defendants' insurance carriers to provide the Class with a cash payment of $15.0 million, which included the cash amount of any attorneys' fees or litigation expenses that the District Court may award. Additionally, we agreed to issue to the Class warrants, or the Settlement Warrants, for the purchase of 2.0 million shares of our common stock, which are exercisable, subject to certain conditions, from the date of issue until the expiration of a one-year period after the date of issue at an exercise price of $3.00 per share, equal to the closing price on December 22, 2017, the trading day prior to the execution of the MOU. On January 29, 2018, the parties entered into a definitive Stipulation of Settlement, or the Stipulation, which was filed with the District Court on February 2, 2018. On February 8, 2018, the District Court issued an order preliminarily approving the terms of the Stipulation. In February 2018, the insurance carriers funded the settlement escrow account for the $15.0 million cash settlement. On May 30, 2018, the District Court held the final approval hearing and approved the settlement and the plaintiffs' request for attorneys' fees and expenses subject to an order of final approval and final judgment. Upon the conclusion of a 30-day appeal period, and the occurrence of certain specified circumstances, the settlement become effective on June 29, 2018. On July 16, 2018, we issued and delivered the Settlement Warrants.

Also in 2013, the Securities and Exchange Commission, or SEC, served a subpoena on us for documents and information concerning tivozanib, including related communications with the FDA, investors and others. In September 2015, the SEC invited us to discuss the settlement of potential claims asserting that we violated federal securities laws by omitting to disclose to investors the recommendation by the staff of the FDA on May 11, 2012, that we conduct an additional clinical trial with respect to tivozanib. On March 29, 2016, the SEC filed a complaint against us and three of our former officers in the U.S. District Court for the District of Massachusetts alleging that we misled investors about our efforts to obtain FDA approval for tivozanib. Without admitting or denying the allegations in the SEC's complaint, we consented to the entry of a final judgment pursuant to which we paid the SEC a $4.0 million civil penalty to settle the SEC's claims against us. On March 31, 2016, the District Court entered a final judgment which (i) approved the settlement; (ii) permanently enjoined us from violating Section 17(a) of the Securities Act of 1933, as amended, or the Securities Act, Sections 10(b) and 13(a) of the Exchange Act and rules 10b-5, 12b-20, 13a-1, 13a-11 and 13a-13 promulgated thereunder; and (iii) ordered us to pay the agreed-to civil penalty. On September 15, 2017 and October 31, 2017, respectively, two of our former officers consented to entry of final judgment to settle the SEC's

claims against them. We are not a party to the litigation between the SEC and the remaining former officer, and we can make no assurance regarding the outcome of that action or the SEC's claims against that individual.

Refer to Note 9 – "Legal Proceedings", in the Notes to Condensed Consolidated Financial Statements for further discussion.

Item 1A. Risk Factors

Our business is subject to numerous risks. We caution you that the following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in this Quarterly Report on Form 10-Q and other filings with the SEC, press releases, communications with investors and oral statements. Any or all of our forward-looking statements in this Quarterly Report on Form 10-Q and in any other public statements we make may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in the discussion below will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may differ materially from those anticipated in our forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosure we make in our reports filed with the SEC.

Risks Related to Our Financial Position and Need for Additional Capital

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

We may be forced to delay or reduce the scope of our development programs and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. As of June 30, 2018, we had approximately $18.1 million in cash, cash equivalents and marketable securities. Based on these available cash resources, we believe we do 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 our ability to continue as a going concern within one year after the date these financial statements are issued. Management’s plans in this regard are described in Note 1 of the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q However, we cannot guarantee that we will be able to obtain sufficient additional funding when needed or that such funding, if available, will be obtainable on terms satisfactory to us. In the event that these plans cannot be effectively realized, there can be no assurance that we will be able to continue as a going concern.

We have incurred significant losses since inception and anticipate that we will continue to incur significant operating losses for the foreseeable future. It is uncertain if we will ever attain profitability.

We have incurred a net loss of $5.0 million for the six months ended June 30, 2018 and as of June 30, 2018, had an accumulated deficit of $594.7 million. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, we may never attain profitability. Our losses have resulted principally from costs incurred in our discovery and development activities. We anticipate that we will continue to incur significant operating costs over the next several years as we seek to develop our product candidates. As noted above, we and our auditors have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

If we do not successfully develop and obtain and maintain regulatory approval for our existing and future pipeline of product candidates and effectively manufacture, market and sell any product candidates that are approved, we may never generate product sales. Even if we do generate product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We will require substantial additional funding, and a failure to obtain this necessary capital when needed would force us to delay, limit, reduce or terminate our research, product development or commercialization efforts.

We will require substantial additional funds to continue our development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for substantial working capital to support development and commercialization activities for tivozanib beyond our cash runway. For example, we estimate that the aggregate remaining costs for the TIVO-3 trial, including drug supply and distribution, could be in the range of $6.0 million to $9.0 million through 2019. We estimate that the overall cost for the TIVO-3 trial, including drug supply and distribution, could be in the range of $45.0 million to $48.0 million. Our aggregate remaining costs for the TiNivo trial in collaboration with BMS and EUSA, including tivozanib drug supply and distribution, could be in the range of $1.0 million to $1.2 million through 2019. We estimate that the overall cost for the TiNivo trial, including drug supply and distribution, could be in the range of $4.0 million to $4.5 million. BMS is providing nivolumab for the study. In addition, in September 2017, EUSA elected to opt-in to co-develop the TiNivo trial and paid the maximum $2.0 million for its approximate 50% share of the total trial costs.

Moreover, we have future payment obligations and cost-sharing arrangements under certain of our collaboration and license agreements. For example, under our agreements with KHK and St. Vincent’s, we are required to make certain clinical and

regulatory milestone payments, have royalty obligations with respect to product sales and are required to pay a portion of sublicense revenue in certain instances.

We believe that our approximately $18.1 million in cash, cash equivalents and marketable securities at June 30, 2018 would allow us to fund our planned operations into the first quarter of 2019. This estimate assumes no receipt of additional milestone payments and royalties from our partners, no funding from new partnership agreements, no equity financings, no debt financings, no sales of equity under our sales agreement with Leerink, which we refer to as the Leerink Sales Agreement, and no additional sales of equity through the exercise of our outstanding PIPE Warrants or Settlement Warrants. Accordingly, the timing and nature of activities contemplated for the remainder of 2018 and thereafter will be conducted subject to the availability of sufficient financial resources.

Furthermore, there are numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products. Accordingly, our future capital requirements may vary from our current expectations and depend on many factors, including but not limited to:

- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates and of conducting preclinical and clinical trials;
- the timing of, and the costs involved in, completing our clinical trials and obtaining regulatory approvals for our product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the absence of any breach, acceleration event or event of default under our loan agreement with Hercules, which we refer to as the Hercules Loan Agreement, or under any other agreements with third parties;
- the outcome of any legal actions against us;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- our ability to continue as a going concern.

We will require additional funding to extend our planned operations. We may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all.

If we are unable to raise substantial additional capital in the near term, whether on terms that are acceptable to us, or at all, Hercules may accelerate payments if we were to default under the Hercules Loan Agreement and we may be required to:

- delay, limit, reduce or terminate our clinical trials or other development activities for one or more of our product candidates; and/or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, if approved.

We are a development stage company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Other than the European marketing approval for tivozanib (FOTIVDA) received by our partner EUSA in August 2017, all of our product candidates are in the development stage. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop one new medicine from the time it is discovered to when it is available for treating patients. Preclinical studies and clinical trials may involve highly uncertain results and a high risk of failure. Moreover, positive data from preclinical studies and clinical trials of our product candidates may not be predictive of results in ongoing or subsequent preclinical studies and clinical trials. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a development stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To be profitable, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to our Litigation

We have concluded a settlement with the SEC, but the SEC is still pursuing an action against our former officer.

We paid $4.0 million to settle a lawsuit filed by the SEC in federal court alleging that we violated federal securities laws by omitting to disclose the recommendation of the staff of the FDA, on May 11, 2012, that we conduct an additional clinical trial with respect to tivozanib. See Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading “Legal Proceedings” for a further discussion of these claims. The SEC also named three of our former officers as defendants in the same lawsuit. The SEC and two of our former officers have settled. The lawsuit against the remaining officer is still pending. We are not a party to the continuing litigation between the SEC and the former officer. However, that individual has and may continue to seek advancement of legal expenses or indemnification for any losses, either of which could be material to the extent not covered by our director and officer liability insurance.

Risks Related to Development and Commercialization of Our Drug Candidates

In the near term, we are substantially dependent on the success of tivozanib. If we are unable to complete the clinical development of, obtain and maintain marketing approval for or successfully commercialize tivozanib, either alone or

with our collaborators, or if we experience significant delays in doing so, our business could be substantially harmed.

Other than the European marketing approval for tivozanib received by our partner EUSA in August 2017, we currently have no products approved for sale and are investing a significant portion of our efforts and financial resources in the development of tivozanib for marketing approval in North America. Our prospects are substantially dependent on our ability to develop, obtain marketing approval for and successfully commercialize tivozanib in North America in one or more disease indications.

The success of tivozanib will depend on a number of factors, including the following:

- our ability to secure the substantial additional capital required to complete our clinical trials of tivozanib, including the TIVO-3 trial and the TiNivo trial;
- successful design, enrollment and completion of clinical trials;
    - a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval;

- timely receipt of marketing approvals from applicable regulatory authorities;
- the performance of the contract research organizations, or CROs, we have hired to manage our clinical studies, as well as that of our collaborators and other third-party contractors;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- maintenance of existing or establishment of new supply arrangements with third-party raw materials suppliers and manufacturers including with respect to the supply of active pharmaceutical ingredient for tivozanib and finished drug product that is appropriately packaged for sale;
- adequate ongoing availability of raw materials and drug product for clinical development and any commercial sales;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally, including our ability to maintain our license agreement with KHK;
- protection of our rights in our intellectual property portfolio, including our ability to maintain our license agreement with KHK;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors;
- successful identification of biomarkers for patient selection; and
- our ability to compete with other therapies.

Many of these factors are beyond our control, including clinical trial results, the regulatory approval process, potential threats to our intellectual property rights and the development, manufacturing, marketing and sales efforts of our collaborators. If we are unable to develop, receive marketing approval for and successfully commercialize tivozanib on our own or with our collaborators, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

If we fail to develop and commercialize other product candidates, we may be unable to grow our business.

Although the development and commercialization of tivozanib is our primary focus, as part of our growth strategy, we are developing a pipeline of product candidates. These other product candidates will require additional, time-consuming and costly development efforts, by us or by our collaborators, prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically. Successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

If preclinical or clinical trials of any product candidates that we or our collaborators may develop fail to demonstrate satisfactory safety and efficacy to the FDA and other regulators, we or our collaborators may incur additional costs or delays, or may be unable to complete, the development and commercialization of these product candidates.

We, and any collaborators, including our partners and sublicensees, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. We and our collaborators must complete extensive preclinical development and clinical trials that demonstrate the safety and efficacy of our product candidates in humans before we can obtain these approvals.

Preclinical and clinical testing is expensive, is difficult to design and implement, and can take many years to complete. It is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The preclinical and clinical development of our product candidates is susceptible to the risk of failure inherent at

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any stage of product development, as well as failure to demonstrate efficacy at all in a clinical trial or across a broad population of patients, the occurrence of adverse events that are medically severe or commercially unacceptable, failure to comply with protocols or regulatory requirements and determination by the applicable regulatory authority that a product candidate may not continue development or is not approvable. Even if a product candidate has a beneficial effect, that effect may not be detected during preclinical or clinical evaluation due to a variety of factors, including the size, duration, design, measurements, conduct or analysis of our preclinical and clinical trials. Conversely, as a result of the same factors, our preclinical or clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our preclinical or clinical trials we may fail to detect toxicity or intolerability of our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

Any inability to timely or successfully complete preclinical and clinical development could result in additional unplanned costs and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if we, or any collaborators, are required to conduct additional clinical trials or other testing of our product candidates beyond those planned, or if the results of these trials or tests are unfavorable, uncertain, only modestly favorable or indicate safety concerns, we or our collaborators, may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

Our failure to successfully complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval would significantly harm our business.

Adverse events or undesirable side effects caused by, or other unexpected properties of, tivozanib or our other product candidates may be identified during development and could delay or prevent their marketing approval or limit their use.

Adverse events or undesirable side effects caused by, or other unexpected properties of, tivozanib or our other product candidates could cause us, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt preclinical or clinical trials of one or more of our product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If any of our product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any collaborators, may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development of the compound.

If we or our collaborators experience any of a number of possible complications in connection with preclinical or clinical trials of our product candidates, potential clinical development, marketing approval or commercialization of our product candidates could be delayed or prevented.

We or our collaborators may experience numerous complications in connection with preclinical or clinical trials that could delay or prevent clinical development, marketing approval or commercialization of our product candidates including:

- regulators or institutional review boards may not authorize us, any collaborators or our or their investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delay or failure to reach agreement on clinical trial contracts or clinical trial protocols with prospective trial sites;
- unfavorable or inconclusive clinical trial results;

- our decision or a regulatory order to conduct additional clinical trials or abandon product development programs;
- the number of patients required for our clinical trials may be larger than anticipated, patient enrollment may be slower than anticipated or participants may drop out of these clinical trials at a higher rate than anticipated;
- the costs of our clinical trials may be greater than we anticipate;
- our third-party contractors, including those manufacturing our product candidates, or conducting clinical trials on our behalf, may fail to successfully comply with regulatory requirements or meet their contractual obligations in a timely manner or at all;
- patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to increase the needed enrollment size for the clinical trial, extend the clinical trial's duration, or drop the patients from the final efficacy analysis for the clinical trial, which can negatively affect the statistical power of the results;
- We may decide, or regulators or institutional review boards may require that we suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' clinical trial designs or interpretation of data from preclinical studies and clinical trials;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or any collaborators, enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us and our collaborators will increase if we experience delays in testing or pursuing marketing approvals, and we may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization. We do not know whether any trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any of our product candidates.

If we or our collaborators experience delays or difficulties in the enrollment of patients in clinical trials, receipt of necessary regulatory approvals could be delayed or prevented.

We or our collaborators may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the availability of approved therapeutics for the relevant disease;

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