T2 Biosystems, Inc.
Form 10-Q
August 04, 2017
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 2017

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: 001-36571

T2 Biosystems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-4827488**
(State or other jurisdiction	**(I.R.S. Employer**
of incorporation or organization)	**Identification No.)**
101 Hartwell Avenue	
Lexington, Massachusetts	**02421**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (781) 761-4646

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, a smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth 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 of 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

As of August 2, 2017, the registrant had 30,764,319 shares of common stock outstanding.

Table of Contents

T2 BIOSYSTEMS, INC.

TABLE OF CONTENTS

Table of Contents

PART I.

FINANCIAL INFORMATION

Item 1. Financial Statements

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(Unaudited)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 46,134	$ 73,488
Accounts receivable	981	327
Prepaid expenses and other current assets	660	820
Inventories, net	1,014	803
Total current assets	48,789	75,438
Property and equipment, net	14,510	13,589
Restricted cash	260	260
Other assets	218	281
Total assets	$ 63,777	$ 89,568
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,660	$ 962
Accrued expenses and other current liabilities	4,701	4,908
Current portion of notes payable	1,365	1,269
Deferred revenue	2,494	2,445
Current portion of lease incentives	248	301
Total current liabilities	10,468	9,885
Notes payable, net of current portion	39,908	39,504
Lease incentives, net of current portion	771	792
Other liabilities	305	49
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2017 and December 31, 2016		

Common stock, $0.001 par value; 200,000,000 shares authorized; 30,763,919 and 30,482,712 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	32	30
Additional paid-in capital	246,141	242,997
Accumulated deficit	(233,848)	(203,689)
Total stockholders equity	12,325	39,338
Total liabilities and stockholders equity	$ 63,777	$ 89,568

See accompanying notes to condensed consolidated financial statements.

Table of Contents

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Product revenue	$ 735	$ 151	$ 1,366	$ 588
Research revenue	221	839	531	1,498
Total revenue	956	990	1,897	2,086
Costs and expenses:				
Cost of product revenue	1,989	1,781	3,617	2,807
Research and development	7,112	6,369	13,697	12,958
Selling, general and administrative	5,759	6,143	11,633	12,347
Total costs and expenses	14,860	14,293	28,947	28,112
Loss from operations	(13,904)	(13,303)	(27,050)	(26,026)
Interest expense, net	(1,654)	(805)	(3,291)	(1,540)
Other income, net	102	62	181	94
Net loss and comprehensive loss	$ (15,456)	$ (14,046)	$ (30,160)	$ (27,472)
Net loss per share basic and diluted	$ (0.50)	$ (0.58)	$ (0.99)	$ (1.13)
Weighted-average number of common shares used in computing net loss per share basic and diluted	30,661,200	24,321,310	30,595,933	24,270,041

See accompanying notes to condensed consolidated financial statements.

Table of Contents

T2 BIOSYSTEMS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities		
Net loss	$ (30,160)	$ (27,472)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,432	1,068
Stock-based compensation expense	2,550	2,527
Loss on sale of T2 owned equipment	107	
Non-cash interest expense	1,291	308
Deferred rent	(74)	(123)
Changes in operating assets and liabilities:		
Accounts receivable	(654)	81
Prepaid expenses and other assets	225	276
Inventories, net	(212)	(752)
Accounts payable	698	(49)
Accrued expenses and other liabilities	(230)	228
Deferred revenue	48	(879)
Net cash used in operating activities	(24,979)	(24,787)
Cash flows from investing activities		
Purchases and manufacture of property and equipment	(2,468)	(3,173)
Net cash used in investing activities	(2,468)	(3,173)
Cash flows from financing activities		
Payment of offering costs for issuance of common stock in public offering		(385)
Proceeds from issuance of common stock and stock options exercises, net	713	700
Proceeds from notes payable, net of issuance costs		4,593
Repayments of note payable	(620)	(392)
Net cash provided by financing activities	93	4,516
Net decrease in cash and cash equivalents	(27,354)	(23,444)
Cash and cash equivalents at beginning of period	73,488	73,662
Cash and cash equivalents at end of period	$ 46,134	$ 50,218
Supplemental disclosures of cash flow information		

Cash paid for interest	$ 1,981	$ 1,146
Supplemental disclosures of noncash investing and financing activities		
Accrued property and equipment	$ 51	$ 184

See accompanying notes to condensed consolidated financial statements.

Table of Contents

T2 BIOSYSTEMS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Nature of Business

T2 Biosystems, Inc. (the Company) was incorporated on April 27, 2006 as a Delaware corporation with operations based in Lexington, Massachusetts. The Company is an *in vitro* diagnostics company that has developed an innovative and proprietary technology platform that offers a rapid, sensitive and simple alternative to existing diagnostic methodologies. The Company is using its T2 Magnetic Resonance technology (T2MR) to develop a broad set of applications aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier. T2MR enables rapid detection of pathogens, biomarkers and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine, and can detect cellular targets at limits of detection as low as one colony forming unit per milliliter (CFU/mL). The Company s initial development efforts target sepsis and lyme disease, which are areas of significant unmet medical need in which existing therapies could be more effective with improved diagnostics. On September 22, 2014, the Company received market clearance from the U.S. Food and Drug Administration (FDA) for its first two products, the T2Dx Instrument (the T2Dx) and T2Candida Panel (T2Candida). On June 30, 2017 the Company received CE Mark for its T2Bacteria Panel (T2Bacteria).

Liquidity

At June 30, 2017, the Company had cash and cash equivalents of $46.1 million and an accumulated deficit of $233.8 million. The future success of the Company is dependent on its ability to successfully commercialize its FDA approved products, obtain regulatory clearance for and successfully launch its future product candidates, including T2Bacteria, obtain additional capital and ultimately attain profitable operations. Historically, the Company has funded its operations primarily through its August 2014 initial public offering, its December 2015 secondary public offering, its September 2016 private investment in public equity (PIPE) financing, private placements of redeemable convertible preferred stock and through debt financing arrangements.

The Company is subject to a number of risks similar to other newly commercial life science companies, including, but not limited to commercially launching the Company s products, development and market acceptance of the Company s product candidates, development by its competitors of new technological innovations, protection of proprietary technology, and raising additional capital.

Having obtained authorization from the FDA to market T2Dx and T2Candida, the Company has incurred significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, the Company expects that costs and expenses may increase as it continues the research and development of other product candidates and maintains, expands and protects its intellectual property portfolio. The Company may seek to fund its operations through public equity or private equity or debt financings, as well as other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. The Company s failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company s business, results of operations and financial condition and the Company s ability to develop and commercialize T2Dx, T2Candida, T2Bacteria and other product candidates.

Management believes that its existing cash and cash equivalents at June 30, 2017, together with the additional remaining liquidity on the Company s Term Loan Agreement of up to an additional $10.0 million, will be sufficient to allow the Company to fund its current operating plan for 12 months from the date the financial statements are issued. The borrowing on the Term Loan Agreement is available at any time through July 27, 2018, and is subject to certain conditions including that the Company receive 510(k) clearance for the marketing of T2Bacteria™ by the U.S. Food and Drug Administration (FDA) by April 30, 2018 (see Note 5). Because certain elements of the Company s plan are outside of the Company s control they cannot be considered probable, as defined by ASU 2014-15, *Presentation of Financial Statements - Going Concern*. Should the Company s current operating plan not materialize as expected, including the Company s ability to draw additional borrowings on the Term Loan Agreement on a timely basis, the Company would delay certain research projects and capital expenditures and reduce or eliminate certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern for a period of 12 months from the date the financial statements are issued.

Table of Contents

For more information, refer to the section titled Liquidity and Capital Resources in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations and the section entitled Risk Factors in the Annual Report on Form 10-K for the year ended December 31, 2016, for additional risks associated with our capital needs.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company s financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP as defined in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB). The Company s condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, T2 Biosystems Securities Corporation. All intercompany balances and transactions have been eliminated.

We have evaluated subsequent events from June 30, 2017 through the date of the issuance of these consolidated financial statements and have determined that no material subsequent events have occurred that would affect the information presented in these consolidated financial statements.

Unaudited Interim Financial Information

Certain information and footnote disclosures normally included in the Company s annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2016.

The accompanying interim condensed consolidated balance sheet as of June 30, 2017, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2017 and 2016, the condensed consolidated statements of cash flows for the three and six months ended June 30, 2017 and 2016 and the related financial data and other information disclosed in these notes are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company s financial position as of June 30, 2017, and the results of its operations and its cash flows for the three and six months ended June 30, 2017 and 2016. The results for the three and six months ended June 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017, any other interim periods, or any future year or period.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company s chief operating decision maker is the Chief Executive Officer. The Company views its operations and manages its business in one operating segment, which is the business of developing and, upon regulatory clearance, launching commercially its diagnostic products aimed at lowering mortality rates, improving patient outcomes and reducing the cost of healthcare by helping medical professionals make targeted treatment decisions earlier.

5

Table of Contents

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options and unvested restricted stock are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

Guarantees

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while each such officer or director is, or was, serving at the Company s request in such capacity. The term of the indemnification is the officer s or director s lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors and officers liability insurance coverage that limits its exposure and enables the Company to recover a portion of any future amounts paid.

The Company leases office, laboratory and manufacturing space under noncancelable operating leases. The Company has standard indemnification arrangements under the leases that require it to indemnify the landlords against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation or nonperformance of any covenant or condition of the Company s leases.

In the ordinary course of business, the Company enters into indemnification agreements with certain suppliers and business partners where the Company has certain indemnification obligations limited to the costs, expenses, fines, suits, claims, demands, liabilities and actions directly resulting from the Company s gross negligence or willful misconduct, and in certain instances, breaches, violations or nonperformance of covenants or conditions under the agreements.

As of June 30, 2017 and December 31, 2016, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Revenue Recognition

The Company generates revenue from product sales, which includes the sale of instruments, consumable diagnostic tests and related services, and research and development agreements with third parties. The Company recognizes revenue in accordance with FASB ASC Topic 605, Revenue Recognition (ASC 605). Accordingly, the Company recognizes revenue when all of the following criteria have been met:

i. Persuasive evidence of an arrangement exists

ii. Delivery has occurred or services have been rendered

iii. The seller s price to the buyer is fixed or determinable

iv. Collectability is reasonably assured

If any of the above criteria have not been met, the Company defers revenue until such time each of the criteria have been satisfied.

Product revenue is generated by the sale of instruments and consumable diagnostic tests predominantly through the Company s direct sales force in the United States and distributors in geographic regions outside the United States. The Company does not offer product return or exchange rights (other than those relating to defective goods under warranty) or price protection allowances to its customers, including its distributors. Payment terms granted to distributors are the same as those granted to end-user customers and payments are not dependent upon the distributors receipt of payment from their end-user

Table of Contents

customers. The Company either sells instruments to customers and international distributors, or retains title and places the instrument at the customer site pursuant to a reagent rental agreement. When the instrument is directly purchased by a customer, the Company recognizes revenue when all applicable revenue recognition criteria are met. When the instrument is placed under a reagent rental agreement, the Company s customers generally agree to fixed term agreements, which can be extended, certain of which may include minimum purchase commitments and/or incremental charges on each consumable diagnostic test purchased, which varies based on the volume of test cartridges purchased. Revenue from the sale of consumable diagnostic tests, which includes the incremental charge, is recognized upon delivery or shipment as a component of product revenue in the Company s consolidated statements of operations and comprehensive loss.

Direct sales of instruments include warranty, maintenance and technical support services for one year following the installation of the purchased instrument (Maintenance Services). After the completion of the initial Maintenance Services period, customers have the option to renew the Maintenance Services for additional one year periods in exchange for additional consideration. In addition, the Company may provide training to customers. The Company defers revenue from the initial sale of the instrument equal to the relative fair value of the one year of Maintenance Services and training and recognizes the amounts ratably over the service delivery period.

The Company warrants that consumable diagnostic tests will be free from defects, when handled according to product specifications, for the stated life of the product. To fulfill valid warranty claims, the Company either provides a credit to its customers on future orders or provides a replacement product. Accordingly, the Company defers revenue associated with the estimated defect rates of the consumable diagnostic tests.

The Company does not offer rights of return for instruments or consumable diagnostic tests.

Shipping and handling costs incurred associated with products sold to customers are recorded as a cost of product revenue in the consolidated statement of operations and comprehensive loss. Shipping and handling costs billed to customers in connection with a product sale are recorded as a component of product revenue in the consolidated statements of operations and comprehensive loss.

For multiple-element arrangements, the Company identifies the deliverables included within each agreement and evaluates which deliverables represent separate units of accounting. The determination that multiple elements in an arrangement meet the criteria for separate units of accounting requires the Company s management to exercise judgment. The Company accounts for those components as separate elements when the following criteria are met: (1) the delivered items have value to the customer on a stand-alone basis; and, (2) if there is a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and within its control.

The consideration received is allocated among the separate units of accounting based on a selling price hierarchy. The selling price hierarchy is based on: (1) vendor specific objective evidence (VSOE), if available; (2) third party evidence of selling price if VSOE is not available; or (3) best estimated selling price (BESP) if neither VSOE nor third party evidence is available. The Company generally expects that it will not be able to establish selling price using third-party evidence due to the nature of our products and the markets in which the Company competes, and, as such, the Company typically will determine selling price using VSOE or BESP.

When the Company establishes selling price using BESP, consideration is given to both market and Company-specific factors, including the cost to produce the deliverable and the anticipated margin on that deliverable, as well as the characteristics of markets in which the deliverable is sold.

Revenue earned from activities performed pursuant to research and development agreements is reported as research revenue in the consolidated statements of operations and comprehensive loss, using the proportional performance method as the work is completed, limited to payments earned, and the related costs are expensed as incurred as research and development expense. The timing of receipt of cash from the Company s research and development agreements generally differs from when revenue is recognized.

Table of Contents

Product Recall

In July 2016, the Company initiated a voluntary recall and replacement of its T2Candida cartridges at certain customer sites because T2Candida was experiencing higher than normal invalid test rates as the T2Candida cartridges aged. As of June 30, 2016, as a result of this voluntary recall, the Company deferred revenue totaling $149,000 and recorded additional costs of product revenue of $41,000 related to returned products, which are no longer usable. As of June 30, 2017, the Company had $20,000 of deferred revenue and $2,000 of warranty reserve remaining, both related to this voluntary recall. The impact of the voluntary recall on T2Candida cartridges in inventory was not material to the condensed consolidated financial statements.

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of consumable diagnostic tests sold to customers and related license and royalty fees. Cost of product revenue also includes depreciation on revenue generating T2Dx systems that have been placed with customers under reagent rental agreements; costs of materials, direct labor and manufacturing overhead costs on the T2Dx systems sold to customers; and other costs such as customer support costs, royalties and license fees, warranty and repair and maintenance expense on the T2Dx systems that have been placed with customers under reagent rental agreements.

Research and Development Costs

Costs incurred in the research and development of the Company s product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under research revenue arrangements, and include salaries and benefits, stock compensation, research-related facility and overhead costs, laboratory supplies, equipment and contract services.

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Accounting Standards Adopted

In August 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern which is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. Substantial doubt about an entity s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its financial obligations as they become due within one year after the date that the financial statements are issued (or are available to be issued). ASU No. 2014-15 provides guidance to an organization s management, with principles and definitions intended to reduce diversity in the timing and content of disclosures commonly provided by organizations in the footnotes of their financial statements. ASU No. 2014-15 was effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. This standard has been adopted and the Company does not believe it is required to make any additional disclosures.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory* (ASU 2015-11). The standard simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value for entities using the first-in-first out method of valuing inventory. ASU 2015-11 eliminates other measures required by current guidance to determine net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years and early adoption is permitted. The Company s adoption of this standard did not have a material effect on its condensed consolidated financial statements.

In March 2016, the FASB released ASU No. 2016-09 *Improvements to Employee Share-Based Payment Accounting* (ASU 2016-09) which is intended to simplify income tax accounting for excess tax benefits, accounting for forfeitures, and employer statutory withholding. Under the current guidance, excess tax benefits that result from an award vesting or settling are recognized in additional paid-in capital in the period that they reduce cash taxes payable. This requires the provision to be computed on a with and without option basis and may result in net operating loss and credit carryforwards on the balance sheet being less than what is available on the tax return. Under the new guidance, the income tax effects of awards will be recognized as a component of income tax expense when the awards vest or are settled (regardless if cash taxes are reduced). For interim reporting purposes, companies will account for excess tax benefits and tax deficiencies as discrete items in the period during

Table of Contents

which they occurred. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted, however all of the guidance included in the update must be applied when adopted. The Company must use a modified retrospective transition method for adopting and record the cumulative effect of all unrecognized benefits and any change in valuation allowances at the end of the prior tax period as an adjustment to retained earnings. The Company s adoption of this standard did not have a material effect on its condensed consolidated financial statements and prior periods have not been adjusted. As a result, the Company established a net operating loss deferred tax asset of $1.2 million to account for prior period excess tax benefits through retained earnings, however an offsetting valuation allowance of $1.2 million will also be established through retained earnings because it is not more likely than not that the deferred tax asset will be realized due to historical and expected future losses, such that there is no impact on the Company s condensed consolidated financial statements. The Company also elected to maintain the use of estimated forfeitures in the calculation of stock based compensation.

In March 2016, the FASB issued ASU No. 2016-06, *Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments* (ASU 2016-06), which applies to all issuers of or investors in debt instruments with embedded call or put options. ASU 2016-06 clarifies the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. Entities performing the assessment under the guidance of ASU 2016-06 are required to assess the embedded call or put options solely in accordance with the four-step deci