

OSIRIS THERAPEUTICS, INC.

Form 10-Q

November 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018

or

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

For the transition period from to

Commission File Number: 001-32966

OSIRIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Maryland
(State or other jurisdiction of incorporation or organization)

71-0881115
(I.R.S. Employer Identification No.)

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7015 Albert Einstein Drive, Columbia, Maryland
(Address of principal executive offices)

21046
(Zip Code)

443-545-1800

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

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Class	Outstanding at November 3, 2018
Common Stock, par value \$0.001 per share	34,525,886

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PART I -- FINANCIAL INFORMATION

Item 1. Financial Statements

OSIRIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(amounts in thousands, except per share data)

(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	\$ 31,658	\$ 3,081
Short-term investments	8,701	24,807
Trade receivables, net	20,592	26,053
Inventory, net	10,576	11,278
Insurance receivable	4,788	4,788
Prepaid expenses and other current assets	3,421	2,920
Total current assets	79,736	72,927
Property and equipment, net	3,116	3,587
Other assets	1,849	1,608
Total assets	\$ 84,701	\$ 78,122
Liabilities and Equity		
Current liabilities		
Accounts payable	\$ 4,291	\$ 5,269
Accrued liabilities	10,704	9,399
Accrued shareholder litigation	19,400	18,500
Other current liabilities	1,994	1,934
Total current liabilities	36,389	35,102
Other long-term liabilities	2,450	1,626
Total liabilities	38,839	36,728
Equity		
Common stock, \$0.001 par value, 72,000 shares authorized, 34,526 shares issued and outstanding at September 30, 2018, and 90,000 shares authorized, 34,526 shares issued and outstanding at December 31, 2017	35	35
Additional paid-in-capital	284,124	283,905
Accumulated other comprehensive loss	(330)	(208)
Accumulated deficit	(237,967)	(242,338)

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Total equity	45,862	41,394
Total liabilities and equity	\$ 84,701	\$ 78,122

See accompanying notes to the condensed consolidated financial statements.

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OSIRIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(amounts in thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ 36,491	\$ 29,806	\$ 102,001	\$ 85,938
Cost of revenue	9,808	7,926	28,333	23,405
Gross profit	26,683	21,880	73,668	62,533
Operating expenses:				
Research and development	1,590	909	4,886	3,052
Sales and marketing	15,931	14,825	49,107	44,256
General and administrative	4,302	6,634	15,150	16,920
Shareholder litigation expense	900	—	900	—
Total operating expenses	22,723	22,368	70,043	64,228
Income (loss) from continuing operations	3,960	(488)	3,625	(1,695)
Other (expense) income, net	(21)	(1,763)	548	(1,371)
Income (loss) before income taxes from continuing operations	3,939	(2,251)	4,173	(3,066)
Income tax (expense) benefit	(100)	198	(170)	134
Income (loss) from continuing operations	3,839	(2,053)	4,003	(2,932)
Discontinued operations, net of tax	368	9,811	368	9,811
Net income	4,207	7,758	4,371	6,879
Other comprehensive income (loss):				
Unrealized (loss) gain on investments	(100)	(21)	(122)	33
Comprehensive income	\$ 4,107	\$ 7,737	\$ 4,249	\$ 6,912
Net income (loss) per share from continuing operations:				
Basic	\$ 0.11	\$ (0.06)	\$ 0.12	\$ (0.08)
Diluted	\$ 0.11	\$ (0.06)	\$ 0.12	\$ (0.08)
Net income per share from discontinued operations:				
Basic	\$ 0.01	\$ 0.28	\$ 0.01	\$ 0.28
Diluted	\$ 0.01	\$ 0.28	\$ 0.01	\$ 0.28
Net income per share:				
Basic	\$ 0.12	\$ 0.22	\$ 0.13	\$ 0.20
Diluted	\$ 0.12	\$ 0.22	\$ 0.13	\$ 0.20
Weighted average common shares outstanding:				
Basic	34,526	34,526	34,526	34,524
Diluted	34,594	34,526	34,565	34,525

See accompanying notes to the condensed consolidated financial statements.

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OSIRIS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 4,371	\$ 6,879
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Receipt of Mesoblast common stock	—	(10,000)
Shareholder litigation expense	900	—
Provision for excess and obsolete inventory	1,238	180
Loss on disposal of fixed assets	—	123
Realized loss on investments	240	2,102
Depreciation	658	518
Stock-based compensation expense	219	49
Changes in operating assets and liabilities:		
Accounts receivables, net	5,461	1,220
Inventory, net	(536)	(1,228)
Prepaid expenses and other assets	(742)	(651)
Accounts payable, accrued liabilities, and other liabilities	1,211	(1,791)
Net cash provided by (used in) operating activities	13,020	(2,599)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(187)	(718)
Proceeds from sale of investments	16,248	23,250
Purchases of investments	(504)	(19,660)
Net cash provided by investing activities	15,557	2,872
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from the exercise of options to purchase common stock	—	128
Net cash provided by financing activities	—	128
NET INCREASE IN CASH AND CASH EQUIVALENTS	28,577	401
Cash and cash equivalents at beginning of period	3,081	2,833
Cash and cash equivalents at end of period	\$ 31,658	\$ 3,234

See accompanying notes to the condensed consolidated financial statements.

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OSIRIS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

THREE AND NINE-MONTH PERIODS ENDED SEPTEMBER 30, 2018 AND 2017

1. Description of Business

Osiris Therapeutics, Inc. (“we”, “us”, “our”, “Osiris”, or the “Company”) researches, develops, manufactures and commercializes regenerative medicine products intended to improve the health and lives of patients and lower overall healthcare costs. We are headquartered in Columbia, Maryland and operate in one segment. We continue to advance our research and development (“R&D”) by focusing on innovation in regenerative medicine, including the development of bioengineered stem cell and tissue-based products. We have achieved commercial success with products in orthopedics, sports medicine and wound care, including the Grafix product line, Stravix, BIO4 and Cartiform.

We are a fully integrated company, having developed capabilities in R&D, manufacturing, marketing and sales of our products. We are focused on the long-term commercial growth of the Company through the delivery of differentiated products for use across multiple fields of medicine with clear value propositions for patients, providers and third-party payors.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Osiris Therapeutics International GmbH. All intercompany transactions have been eliminated in consolidation. Osiris Therapeutics International GmbH does not have any operations.

The condensed financial statements included in this quarterly report have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and accounting principles generally accepted in the United States of America (“GAAP”).

The condensed consolidated balance sheet as of December 31, 2017 is derived from the Company's audited financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been omitted in accordance with the SEC's rules and regulations for interim financial statements. This Quarterly Report on Form 10-Q should be read in conjunction with our financial statements and footnotes included in our Annual Report on Form 10-K for the years ended December 31, 2017, 2016, and 2015 (the "Annual Report"). In the opinion of management, these condensed consolidated financial statements include all adjustments (consisting solely of normal recurring adjustments) considered necessary to fairly present the results of operations, financial position and cash flows for the periods indicated.

Operating results for any interim period are not necessarily indicative of the results that may be achieved for the full year.

Use of Estimates

We make certain estimates and assumptions in preparing our condensed consolidated financial statements in accordance with GAAP. These estimates and assumptions affect the reported amount of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses for the period presented. Actual results may differ from these estimates.

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Income per Common Share

Basic income per common share is calculated by dividing net income by the weighted average number of common shares outstanding during the period. Diluted income per common share adjusts basic income per share for the potentially dilutive effects of common share equivalents, using the treasury stock method, and includes the incremental effect of shares that would be issued upon the assumed exercise of stock options.

	Three months ended September 30, 2018		2017		Nine months ended September 30, 2018		2017	

We maintain cash and cash equivalents as well as short-term investment balances in accounts that exceed federally insured limits. Our investments consist primarily of marketable securities with a total portfolio duration of approximately two years. We have historically provided credit in the normal course of business to contract counterparties and to the end user customers and distributors of our products. Trade accounts receivable in the accompanying condensed consolidated balance sheets consist primarily of amounts due from end user customers and distributors of our products within the United States.

The Company's revenue concentrations through distributors of 10% or greater are as follows:

Distributor	Three-months Ended September 30,				Nine-months Ended September 30,			
	2018		2017		2018		2017	
A	19	%	20	%	19	%	20	%

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The Company's accounts receivable concentrations of 10% or greater are as follows:

Distributor	September 30,		December 31,	
A	2018	%	2017	%
	25	%	24	%

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers (“Topic 606”).” This ASU outlines a single set of comprehensive principles for recognizing revenue under GAAP and supersedes existing revenue recognition guidance. The main principle of this ASU is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted the new standard on a modified retrospective basis as of January 1, 2018. The Company completed a comprehensive assessment of customer contracts and concluded that the adoption of this ASU did not have a material impact on our condensed consolidated financial statements; therefore, no adjustment was recorded upon adoption. See Note 8, “Revenue,” for additional information.

In August 2016, the FASB issued ASU No. 2016-15, “Statement of Cash Flows (Topic 203).” This ASU addresses eight specific cash flow issues and clarifies their presentation and classification in the statement of cash flows. The Company adopted this ASU on January 1, 2018 and concluded that the adoption of this ASU did not have a material impact on our condensed consolidated financial statements. As such, no retrospective adjustment was recorded.

On December 22, 2017, the SEC issued Staff Accounting Bulletin No. 118 (“SAB 118”) to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the newly-enacted U.S. Tax Cuts and Jobs Act (the “Act”). SAB 118 allows registrants to include a provisional amount to account for the implications of the Act where a reasonable estimate can be made and requires the completion of the accounting no later than one year from the date of enactment of the Act or December 22, 2018.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)." This ASU requires, among other things, a lessee to recognize assets and liabilities associated with the rights and obligations attributable to most leases but also recognize expenses similar to current lease accounting. This ASU also requires certain qualitative and quantitative disclosures designed to assess the amount, timing and uncertainty of cash flows arising from leases, along with additional key information about leasing arrangements. Originally, entities were required to adopt Leases (Topic 842) using a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application. However, in July 2018, the FASB issued ASU 2018-11, "Leases (Topic 842): Targeted Improvements," which now allows entities the option of recognizing the cumulative effect of applying the new standard as an adjustment to the opening balance of retained earnings in the year of adoption while continuing to present all prior periods under previous lease accounting guidance. In July 2018, the FASB also issued ASU 2018-10, "Codification Improvements to Topic 842, Leases," which clarifies how to apply certain aspects of ASU 2016-02. ASU 2016-02, ASU 2018-10 and ASU 2018-11 (now commonly referred to as ASC Topic 842 (ASC 842)) is effective for the Company's fiscal year beginning January 1, 2019. The Company plans to elect the transition option provided under the ASU, which will not require adjustments to comparative periods nor require modified disclosures in those comparative periods. Upon adoption, the Company expects to elect the transition package of practical expedients permitted within the new standard, which among other things, allows the carryforward of the historical lease classification. Based on its anticipated election of practical expedients, the Company anticipates the recognition of right of use assets and related lease liabilities on its consolidated balance sheets related to its leases. The Company is finalizing its analysis of data gathered to evaluate the impact of adopting this ASU on its consolidated financial statements. The Company will apply this ASU and its related updates on a modified retrospective basis as of January 1, 2019. The adoption of the guidance will likely have a material effect on the consolidated balance sheets, resulting in the recording of an operating lease asset and liability. The impact

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on the consolidated statement of comprehensive income and the consolidated statement of cash flows are expected to be immaterial.

In June 2016, the FASB issued ASU 2016-13, “Financial Instruments—Credit Losses (Topic 326).” The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity’s current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In February 2018, the FASB issued ASU 2018-02, “Income Statement - Reporting Comprehensive Income (Topic 220), Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income.” This ASU gives entities the option to reclassify the disproportionate income tax effects caused by the Act from accumulated other comprehensive income to retained earnings. The update also requires new disclosures, some of which are applicable for all entities. The guidance in ASU 2018-02 is effective for annual reporting periods beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of this ASU on its consolidated financial statements and the timing of adoption although we do not believe the impact of adoption will be material.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820), Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement.” This ASU eliminates, adds, and modifies certain disclosure requirements for fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public companies will be required to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance in ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact of this ASU on its consolidated financial statements and the timing of adoption although we do not believe the impact of adoption will be material.

In August 2018, the FASB issued ASU 2018-15, “Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.” This ASU requires implementation costs incurred by customers in cloud computing arrangements to be deferred over the non-cancellable term of the cloud computing arrangements plus any optional renewal periods (1) that are reasonably certain to be exercised by the customer or (2) for which exercise of the renewal option is controlled by the cloud service provider. The guidance in ASU 2018-15 is effective for annual reporting periods beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact of this ASU on its consolidated financial statements and the timing of adoption.

3. Investments

Our investments consisted of the following as of September 30, 2018 and December 31, 2017:

	September 30, 2018			
(in \$000's)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. government agencies	\$ 2,116	\$ —	\$ (79)	\$ 2,037
Obligations of government sponsored enterprises (1)	894	—	(35)	859
Corporate debt securities	4,804	2	(150)	4,656
Foreign government bonds	1,183	—	(34)	1,149
Total (2)	\$ 8,997	\$ 2	\$ (298)	\$ 8,701

(1) Includes investments in notes issued by the Federal Home Loan Bank and the Federal Farm Credit Bank.

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- (2) During the nine-month period ended September 30, 2018, investments were sold or matured which resulted in net proceeds of \$16.2 million and realized losses of \$0.2 million. Investments were sold in order to provide the funds necessary in cash and cash equivalents for the payment of the settlement of the securities class action lawsuit.

(in \$000's)	December 31, 2017			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. government agencies	\$ 6,077	\$ —	\$ (73)	\$ 6,004
Obligations of government sponsored enterprises (1)	3,737	—	(31)	3,706
Corporate debt securities	12,479	21	(66)	12,434
Foreign government bonds	2,689	—	(26)	2,663
Total	\$ 24,982	\$ 21	\$ (196)	\$ 24,807

- (1) Includes investments in notes issued by the Federal Home Loan Bank and the Federal Farm Credit Bank.

Unrealized losses on all fixed maturity investments in a continuous loss position for more than twelve consecutive months were \$0.3 million and \$0.2 million as of September 30, 2018 and December 31, 2017, respectively. Unrealized losses on all fixed maturity investments in a continuous loss position for less than twelve consecutive months were not material as of September 30, 2018 and December 31, 2017. As of September 30, 2018 and December 31, 2017, there were no material unrealized losses that the Company believed to be other-than-temporary.

The following table summarizes maturities of our investments available-for-sale as of September 30, 2018:

(in \$000's)	September 30, 2018	
	Cost	Fair Value
Maturities:		
Within 1 year	\$ 1,613	\$ 1,571
After 1 year through 5 years	7,384	7,130
Total investments available for sale	\$ 8,997	\$ 8,701

Realized losses net of investment income were not material for three-month period ended September 30, 2018 and 2017, respectively. Realized losses net of investment income were \$0.2 million for both the nine-month periods ended September 30, 2018 and 2017. The realized losses net of investment income have been included as a component of "Other income, net" in the accompanying unaudited condensed consolidated statements of comprehensive income.

4. Inventory, net

Inventory, net consisted of the following:

	September 30, 2018	December 31, 2017
(in \$000's)		
Raw materials and supplies	\$ 849	\$ 1,330
Work-in-process	6,608	5,605
Finished goods	6,364	6,350
	13,821	13,285
Reserve for excess and obsolete inventory	(3,245)	(2,007)
Inventory, net	\$ 10,576	\$ 11,278

Work-in-process inventory is largely product that is in quarantine pending completion of our quality assurance procedures. Finished goods inventory included gross consigned inventory of \$1.9 million and \$1.5 million as of September 30, 2018 and December 31, 2017, respectively. This consigned finished goods inventory was reduced by reserves of \$0.8 million and \$0.6 million as of September 30, 2018 and December 31, 2017, respectively.

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5. Property and Equipment, net

Property and equipment, net, consisted of the following:

(in \$000's)	Depreciable Life (in years)	September 30, 2018	December 31, 2017
Laboratory and manufacturing equipment	3-7	\$ 3,197	\$ 3,083
Computer hardware, furniture and fixtures	3-7	986	1,134
Leasehold improvements	(A)	6,359	6,344
		10,542	10,561
Accumulated depreciation		(7,426)	(6,974)
Property and equipment, net		\$ 3,116	\$ 3,587

(A) Shorter of economic life or lease term.

Depreciation expense was \$0.2 million and \$0.7 million for the three and nine-month periods ended September 30, 2018, respectively, and \$0.2 million and \$0.5 million for the three and nine-month periods ended September 30, 2017, respectively.

6. Accrued Liabilities

Accrued liabilities consisted of the following:

(in \$000's)	September 30, 2018	December 31, 2017
Payroll and related	\$ 1,943	\$ 1,980
Commissions	5,178	5,651
Legal and accounting	1,564	905
Lease liabilities	321	120
Other	1,698	743
Total	\$ 10,704	\$ 9,399

7. Financial Instruments and Fair Value

Fair value is defined as the price at which an asset could be exchanged or a liability transferred (an exit price) in an orderly transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied.

Financial assets recorded at fair value in the accompanying financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The levels are directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities and are as follows:

Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets at the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 Inputs are other than quoted prices included in Level 1, which are either directly or indirectly observable for the asset or liability through correlation with market data at the reporting date and for the duration of the instrument's anticipated life.

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Unobservable inputs that are supported by little or no market activity and that are significant to the fair value Level 3 of the assets or liabilities and which reflect management's best estimate of what market participants would use in pricing the asset or liability at the reporting date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

When quoted prices in active markets for identical assets are available, we use these quoted market prices to determine the fair value of financial assets and classify these assets as Level 1. In other cases where a quoted market price for identical assets in an active market is either not available or not observable, we obtain the fair value from a third party vendor that uses pricing models, such as matrix pricing, to determine fair value. These financial assets would then be classified as Level 2. In the event quoted market prices were not available, we would determine fair value using broker quotes or an internal analysis of each investment's financial statements and cash flow projections. In these instances, financial assets would be classified based upon the lowest level of input that is significant to the valuation. Thus, financial assets might be classified in Level 3 even though there could be some significant inputs that may be readily available.

Assets and liabilities measured at fair value on a recurring basis are summarized below as of September 30, 2018 and December 31, 2017:

(in \$000's)	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Assets				
Investments: Available for Sale Securities				
U.S. government agencies	\$ —	\$ 2,037	\$ —	\$ 2,037
Obligations of government sponsored enterprises	—	859	—	859
Corporate debt securities	—	4,656	—	4,656
Foreign government bonds	—	1,149	—	1,149
Total investments available for sale	\$ —	\$ 8,701	\$ —	\$ 8,701

(in \$000's)	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets				
Investments: Available for Sale Securities				
U.S. government agencies	\$ —	\$ 6,004	\$ —	\$ 6,004
Obligations of government sponsored enterprises	—	3,706	—	3,706
Corporate debt securities	—	12,434	—	12,434
Foreign government bonds	—	2,663	—	2,663
Total investments available for sale	\$ —	\$ 24,807	\$ —	\$ 24,807

There were no transfers in or out of Level 1, 2, or 3 during the nine-months ended September 30, 2018.

8. Revenue

The Company began accounting for revenue in accordance with Topic 606 on January 1, 2018, using the modified retrospective method. Under the new revenue standard for arrangements that are determined to be within the scope of Topic 606, the Company recognizes revenue following the five-step model: (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 obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines the performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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Accordingly, the Company recognizes revenue when title to the product, ownership and risk of loss transfer to the customer, which is either the date of receipt by the customer or when we receive appropriate notification that the product has been used or implanted in a patient. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to in exchange for transferring the goods. The nature of the Company's contracts gives rise to certain types of variable consideration, including rebates and other discounts. The Company includes estimated amounts of variable consideration in the transaction price to the extent that it is probable there will not be a significant reversal of revenue. Estimates are based on historical or anticipated performance and represent our best judgment at the time. Any estimates are evaluated on a quarterly basis until the uncertainty is resolved.

The Company provides a variety of products and services to its customers. Most of the Company's contracts consist of a single, distinct performance obligation or promise to transfer goods to a customer. For contracts that include multiple performance obligations, the Company allocates the total transaction price to each performance obligation using our best estimate of the standalone selling price of each identified performance obligation.

The Company's incremental costs of obtaining a contract would generally have less than a one-year duration; therefore, the Company applies the practical expedient available and expenses costs to obtain a contract when incurred.

The following table presents our revenues disaggregated by product line:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
(in \$000's)				
Grafix/Stravix	\$ 27,307	\$ 21,739	\$ 75,278	\$ 62,484
BIO4	6,879	5,827	19,827	16,970
Cartiform	2,299	2,240	6,889	6,451
Other	6	—	7	33
Total	\$ 36,491	\$ 29,806	\$ 102,001	\$ 85,938

9. Income Taxes

We calculate our interim tax provision in accordance with the guidance for accounting for income taxes in interim periods. At the end of each interim period, we estimate the annual effective tax rate and apply that tax rate to our ordinary quarterly pre-tax income from continuing operations. The tax expense or benefit related to significant, unusual or extraordinary discrete events during the interim period is recognized in the interim period in which those events occurred. In addition, the effect of changes in enacted tax laws or rates or tax status is recognized in the interim period in which the change occurs. On December 22, 2017, the U.S. enacted the Act, which significantly changed U.S. tax law. The Act lowered the Company's U.S. statutory federal income tax rate from 35% to 21% effective January 1, 2018. The Company's effective income tax rate for the three and nine-month periods ended September 30, 2018 is lower than the federal statutory income tax rate primarily due to the estimated reduction of the valuation allowance resulting from the projected reversal of deferred tax assets during 2018. For the three and nine-month periods ended September 30, 2018, our tax expense was (\$100) thousand and (\$170) thousand, respectively, primarily due to minimum state taxes, and interest and penalties related to uncertain tax positions. Our tax benefit for the three and nine-month periods ended September 30, 2017 was \$198 thousand and \$134 thousand, respectively, due to the intraperiod tax allocation. A full valuation allowance has been recorded on the net deferred tax assets as of September 30, 2018 and December 31, 2017.

During the third quarter of 2018, we filed amended U.S. Federal and state income tax returns for 2015 and 2016 as well as the original 2017 U.S. Federal and state income tax returns which resulted in the reexamination of the provisional amount recorded in the 2017 financial statements. This reexamination updated the gross tax basis of the deferred tax assets and liabilities, however, due to the full valuation allowance, there is no income tax effect or impact on our condensed consolidated financial statements.

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10. Commitments and Contingencies

Operating Leases

We lease facilities and equipment under various non-cancellable operating lease agreements expiring through 2023. As of September 30, 2018, the Company's total future minimum lease payments under non-cancelable operating leases were \$6.6 million.

Legal

The Company is party to outstanding legal proceedings and claims as described below. The Company cannot predict with any certainty the final outcome of any legal proceedings or claims made against it as described in the paragraphs below, and there can be no assurance that the ultimate resolution of any such matter will not have a material adverse impact on the Company's consolidated financial position, results of operations, or cash flows.

The Company records accruals for certain outstanding legal proceedings, investigations or claims when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, the Company does not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then the Company discloses a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If the Company cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed.

The assessments of whether a loss is probable or a reasonable possibility, and whether the loss or range of loss is reasonably estimable, often involve a series of complex judgments about future events. Among the factors that the Company considers in this assessment are the nature of existing legal proceedings, investigations and claims, the asserted or possible damages or loss contingency (if reasonably estimable), the progress of the matter, existing law and precedent, the opinions or views of legal counsel and other advisers, the involvement of the U.S. Government and its agencies in such proceedings, the Company's experience in similar matters and the experience of other companies, the facts available to the Company at the time of assessment, and how the Company intends to respond, or has responded, to the proceeding, investigation or claim. The Company's assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where the Company is not currently able to reasonably estimate the range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate or uncertain, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the matters are in the early stages, (iii) the matters involve novel or

unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement have not reached the point where the Company believes a reasonable estimate of loss, or range of loss, can be made. In such instances, the Company believes that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

The Company does not accrue for estimated legal fees and other directly related costs as they are expensed as incurred.

In addition to the matters described in the paragraphs below, in the normal course of its business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies, none of which we believe to be material.

Based on our analysis and assessment as described above, including consultation with our legal counsel, management believes there are no matters that are probable or reasonably possible that require accrual or disclosure, except for the matters described below.

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Securities Class Action

On November 23, 2015, a putative class action lawsuit was filed in the United States District Court for the District of Maryland by a single plaintiff, individually and on behalf of other persons similarly situated, against the Company and three current or former executive officers of the Company. An amended complaint clarifying plaintiff's claims was filed on April 6, 2018. The action, captioned Kiran Kumar Nallagonda v. Osiris Therapeutics, Inc. et al., Case 1:15-cv-03562 (the "Nallagonda Action"), alleges, among other things, that the defendants made materially false or misleading statements and material omissions in the Company's filings with the SEC in violation of the federal securities laws. The complaint seeks certification as a class action, unspecified damages and reimbursement of attorneys' fees. On March 21, 2016, the court entered an order appointing Dr. Raffy Mirzayan as lead plaintiff and the firm of Hagens Berman Sobol Shapiro LLP as lead counsel. On March 11, 2018, we entered into a memorandum of understanding to settle the Nallagonda Action. Subsequently, on June 5, 2018, the parties executed a Stipulation and Settlement Agreement in which the Company agreed in principle to pay \$18.5 million in cash to create a settlement fund for the benefit of class members. On June 12, 2018, the lead plaintiff filed an Unopposed Motion for Preliminary Approval of the parties' settlement. On September 4, 2018, the Court entered an order preliminarily approving the settlement and scheduling a hearing for February 4, 2019 to determine whether the proposed settlement is fair, reasonable and adequate and whether the case should therefore be dismissed with prejudice. The Company also expects that lead plaintiff will seek an award of attorneys' fees and expenses from the settlement fund. Both the settlement itself and any award to lead plaintiff of attorneys' fees and expenses remain subject to Court approval. The Company can provide no assurance that the Court will approve the settlement. On October 3, 2018, the Company deposited the \$18.5 million settlement payment into an escrow account, pending final Court approval of the settlement.

The Company had a \$5.0 million executive and corporate securities liability insurance policy in place at the time of the allegations. The Company received the remaining \$4.8 million of unused policy coverage for the shareholder settlement of the Nallagonda Action on October 9, 2018 which is recorded as Insurance receivable in the condensed consolidated balance sheets at both September 30, 2018 and December 31, 2017.

Shareholder Derivative Actions

On March 2, 2016, a shareholder derivative complaint was filed in the Circuit Court for Howard County in the State of Maryland (Case No. 13C16106811) by a single plaintiff, derivatively and on behalf of the Company, against certain current and former directors and certain former executive officers (the "Connelley Action"). This action, captioned Kevin Connelley v. Lode Debrabandere et al., alleges that each of the individual directors and officers named as defendants (i) violated their fiduciary duties to the Company's shareholders; (ii) abused their ability to control and influence the Company; (iii) engaged in gross mismanagement of the assets and business of the Company; and (iv) was unjustly enriched at the expense of, and to the detriment of, the Company. The alleged claims generally relate to the matters that are the subject of the Nallagonda Action. The plaintiff seeks, among other things, unspecified monetary damages, reimbursement of attorneys' fees and shareholder votes on amendments to the Company's Articles of Incorporation and Bylaws with respect to various corporate governance policies. On June 2, 2016, the Court entered an order that, subject to certain qualifications, stayed the action until 30 days after the entry of an order either:

(1) denying all motions to dismiss in the Nallagonda Action, or (2) finally dismissing the Nallagonda Action with prejudice. On March 12, 2018, the plaintiff filed an amended complaint clarifying his claims. On or about July 31, 2018, the parties advised the Court that the Company and the plaintiffs in various derivative actions, including the plaintiff in the Connelley Action, had entered into a Memorandum of Understanding to resolve those derivative actions (see below).

On February 9, 2017, a shareholder derivative complaint was filed in the United States District Court for the District of Maryland (Case No. 1:17-cv-00381-JKB) by a single plaintiff, derivatively and on behalf of the Company, against certain current and former directors (the “Recupero Action”). This action, captioned Recupero v. Friedli et al., alleges, among other things, that each of the individual directors named as defendants (i) violated their fiduciary duties to the Company’s shareholders, including that such violations constituted constructive fraud; (ii) engaged in gross mismanagement of the assets and business of the Company; and (iii) was unjustly enriched at the expense of, and to the detriment of, the Company. The plaintiff seeks, among other things, unspecified monetary damages, reimbursement of attorneys’, accountants’ and experts’ fees, and that the Company take all necessary actions to improve and comply with corporate governance, internal procedures and existing laws. On March 28, 2017, the Court entered an order that stays

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the action until: (1) the Nallagonda Action is dismissed with prejudice and all appeals relating thereto have been exhausted; (2) all motions to dismiss the Nallagonda Action are denied; or (3) either party provides 30 days' notice that they no longer consent to a stay. On April 5, 2018, the plaintiff filed an amended complaint clarifying her claims. On July 31, 2018, the parties notified the Court that the Company and the plaintiffs in certain derivative actions, including the plaintiff in the Recupero Action, had entered into a Memorandum of Understanding to resolve those derivative actions (see below). On August 1, 2018, the Court stayed all further proceedings in the Recupero Action pending consideration of the proposed settlement by the Court in the Salley Action.

On May 11, 2017, a shareholder derivative complaint was filed in the Circuit Court for Howard County in the State of Maryland, (Case No. 13C17111441) by a single plaintiff, derivatively on behalf of the Company, against certain former executive officers and certain current and former directors (the "Lee Action"). This action, captioned Brian Lee v. Peter Friedli, et. al., alleges that each of the individual defendants violated their fiduciary duties by allegedly failing to adopt and implement adequate accounting and financial reporting systems and for allegedly causing the Company to make false and misleading statements regarding its financial condition. The alleged claims generally relate to the matters that are the subject of the Nallagonda Action and seek substantially similar relief. On September 5, 2017, the defendants moved to either stay or dismiss the plaintiffs' complaint. That motion was subsequently withdrawn. On February 14, 2018, the plaintiff filed an amended derivative complaint. No defendant has responded to that pleading. On July 31, 2018, the parties advised the Court that the Company and the plaintiffs in various derivative actions, including the plaintiff in the Lee Action, had entered into a Memorandum of Understanding to resolve those derivative actions (see below). The Court subsequently denied the parties' joint request for a stay of proceedings. Thereafter, on August 15, 2018, the parties filed a Joint Stipulation of Dismissal Without Prejudice and the Lee Action was closed.

On December 21, 2017, a shareholder derivative action was filed in the United States District Court for the District of Maryland (Case No. 1:17-cv-03777) by a single plaintiff, derivatively and on behalf of the Company, against certain former executive officers and certain current and former directors (the "Salley Action"). This action, captioned Todd Salley v. Lode Debrabandere, et. al., alleges that each of the individual defendants violated their fiduciary duties by failing to maintain adequate internal controls and by causing the Company to make false and misleading statements regarding the Company's financial condition. The alleged claims generally relate to the matters that are the subject of the Nallagonda Action and seek substantially similar relief. No defendant has responded to the complaint. On July 31, 2018, the parties notified the Court that the Company and the plaintiffs in certain derivative actions, including the plaintiff in the Salley Action, had entered into a Memorandum of Understanding to resolve those derivative actions (see below). On August 1, 2018, the Court stayed all further proceedings in the Salley Action except for those related to the proposed settlement. On October 1, 2018, the parties advised the Court that they anticipate filing a motion for preliminary approval of the proposed settlement by October 31, 2018.

On October 24, 2018, the parties to the derivative actions entered into a settlement agreement to resolve those cases. The parties' agreement calls for the Company to adopt certain governance changes. We expect that the plaintiffs will seek recovery of attorney's fees during the fourth quarter of 2018. We accrued \$0.9 million as our estimated settlement cost. On November 1, 2018, the United States District Court for the District of Maryland entered an order preliminarily approving the settlement agreement. A final settlement hearing is currently scheduled for February 1, 2019. We can provide no assurance that the Courts will approve the settlement.

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11. Discontinued Operations

In October 2013, we sold our therapeutics business, including Prochymal, a stem cell drug for treatment of graft versus host disease, and related assets, to Mesoblast International SARL (“Mesoblast”), a wholly owned subsidiary of Mesoblast Limited. The agreement with Mesoblast provided for the receipt of \$50 million in initial consideration and up to an additional \$50 million in contingent consideration upon Mesoblast achieving certain clinical and regulatory milestones. In addition, we are entitled to earn royalties on future sales by Mesoblast of Prochymal and other products utilizing the acquired technology. In July 2017, we recognized \$10.0 million in Mesoblast Limited common stock (classified as a trading security) and \$350 thousand for reimbursement of expenses as a milestone payment, net of approximately \$0.5 million in income tax expense, in discontinued operations in 2017. Mesoblast Limited common stock was sold during the three and nine-month periods ended September 30, 2017 that resulted in a loss of approximately \$1.7 million, which was reported in other income (expense), net in our condensed consolidated statement of comprehensive income. In 2018, we received a cash payment of approximately \$0.4 million in royalty income from Mesoblast for sales during calendar year 2017.

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

CAUTIONARY STATEMENTS ABOUT FORWARD-LOOKING INFORMATION

This Quarterly Report on Form 10-Q includes “forward-looking statements” within the meaning of Section 21E of the Exchange Act. Statements included or incorporated herein which are not historical facts are forward looking statements. When used in this Form 10-Q, the words “estimates,” “expects,” “anticipates,” “projects,” “plans,” “intends,” “believes,” “forecasts,” “will” and variations of such words or similar expressions are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying forward looking statements.

Forward-looking statements reflect management’s current views with respect to future events and performance and are based on currently available information and management’s assumptions regarding future events. While management believes that its assumptions are reasonable, forward-looking statements are subject to various known and unknown risks and uncertainties and actual results may differ materially from those expressed or implied herein. In connection with the “safe harbor provisions” of the Private Securities Litigation Reform Act of 1995, we note that certain factors, among others, which could cause future results to differ materially from the forward-looking statements, expectations and assumptions expressed or implied herein are discussed in greater detail under Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Part I, Item 1A, “Risk Factors” of our Annual Report on Form 10-K for the years ended December 31, 2017, 2016, and 2015 (our “Annual Report”) and may be discussed elsewhere herein or in other documents we file with the SEC. Examples of forward-looking statements may include, without limitation, statements regarding any of the following: risks relating to the restatement of certain of our 2014 and 2015 financial information (the “restatement”) and related legal proceedings; our delisting from the NASDAQ Stock Market (“NASDAQ”) between March 14, 2017 and July 31, 2018; the outcome of pending legal proceedings and government investigations; our ability to improve our internal control over financial reporting, including our ability to remediate material weaknesses; our product development efforts; our ability to successfully navigate regulatory requirements applicable to our products and product candidates; the success of our product candidates in development; implementation of our corporate strategy; our financial performance; our research and development activities and projected expenditures; our anticipated timeline and commercialization strategy for our products under development; our cash needs; patents, trademarks and other proprietary rights; the safety and ability of our products to perform as intended or expected; our ability to supply a sufficient amount of our marketed products or product candidates and, if or insofar as approved or otherwise commercially available, future products to meet demand; our ability to commercialize and distribute our current and any future marketed products; our relationships with third parties with whom we contract; our ability to maintain and benefit from our arrangements with third parties; our costs to comply with governmental regulations; our plans for or success of sales and marketing; our plans regarding manufacturing; our ability to establish and maintain, and the ability of our customers and end users to obtain, reimbursement for our commercially available products from Medicare and other third-party payors; types of regulatory frameworks we expect will be applicable to our products and potential products; and results of our scientific research.

Except as otherwise required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances and do not intend to do so.

You should read the following management’s discussion and analysis of our financial condition and results of operations in conjunction with our audited financial statements and related notes thereto and other disclosures included as part of our Annual Report, and our unaudited condensed consolidated financial statements for the three- and nine-month periods ended September 30, 2018 and other disclosures included in this Quarterly Report on Form 10-Q.

Our unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, and are presented in U.S. dollars.

When we use the terms “Osiris,” “we,” “us,” and “our” we mean Osiris Therapeutics, Inc., a Maryland corporation.

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Overview of Osiris

Osiris Therapeutics, Inc. researches, develops, manufactures, markets and sells regenerative medicine products intended to improve the health and lives of patients and lower overall healthcare costs. We continue to advance our R&D by focusing on innovation in regenerative medicine, including the development of bioengineered stem cell and tissue-based products. We have achieved commercial success with products in orthopedics, sports medicine and wound care, including the Grafix product line, Stravix, BIO4 and Cartiform.

We are a fully integrated company, having developed capabilities in research and development, manufacturing, marketing and sales of our products. We are focused on the long-term commercial growth of the Company through the delivery of differentiated products for use across multiple fields of medicine with clear value propositions to patients, healthcare providers and third-party payors.

We began operations in 1992 and were a Delaware corporation until, with the approval of our stockholders, we reincorporated as a Maryland corporation in May 2010.

Osiris®, Grafix®, GrafixPL®, Grafix CORE®, Grafix PRIME®, GrafixPL PRIMETM, Grafix XC®, Stravix®, Cartiform®, Prestige LyotechnologySM, OvationOS®, Ovation™, TruSkin® and Menvivo™ are trademarks of the Company. BIO4® is a trademark of Howmedica Osteonics Corp., a subsidiary of Stryker Corporation ("Stryker"). Any other trademarks referred to in this Quarterly Report on Form 10-Q are the property of their owners.

Our business focuses on using unique tissue preservation technologies to develop viable human tissue products designed to improve wound closure and surgical outcomes for patients and physicians over standard of care alone. We have built a substantial direct sales force dedicated exclusively to sell our Grafix and Stravix products and entered into exclusive agreements to market and distribute BIO4 and Cartiform.

Products

All of our current commercialized products are marketed as human cells, tissues and cellular and tissue-based products ("HCT/Ps"), as defined by the United States Food and Drug Administration ("FDA"), that are regulated solely under Section 361 of the Public Health Service Act ("361 HCT/Ps"), and consequently, do not require pre-market approval or licensure from the FDA.

Current Products

Grafix is a product line of several products, Grafix PRIME, Grafix XC and Grafix CORE, and was initially launched in 2010. They are cryopreserved amniotic (amnion) or chorionic (chorion) placental membranes that retain the extracellular matrix, growth factors, endogenous cells, including neonatal epithelial cells (in amnion only) mesenchymal stem cells, and fibroblasts of the native tissue, all of which are beneficial in supporting natural wound repair. Grafix PRIME and Grafix XC (a larger size for surgical applications) are derived from the amnion and Grafix CORE is derived from the chorion. The amnion is the innermost membrane and the chorion is the outermost membrane of the placenta. Our Grafix products are flexible and conforming wound covers designed for direct application to hard-to-treat acute and chronic wounds, including but not limited to diabetic foot ulcers (“DFUs”), venous leg ulcers (“VLUs”), and burns.

GrafixPL PRIME: In 2017, we announced the development of Prestige Lyotechnology, a preservation technique for ambient storage of living tissues. In June 2018, we reported the validation, testing, and upscaling of Prestige Lyotechnology for manufacturing of our products and eliminating the need to preserve and transport our products at constant ultra-low temperatures. We launched our GrafixPL PRIME for sale on October 1, 2018. Our GrafixPL PRIME product is our first commercially available product in the lyopreserved formulation. The two Grafix and GrafixPL product lines are comparably priced, depending on size of the graft, with list prices ranging from \$495-\$3,000.

Stravix is a viable cryopreserved human placental tissue, comprised of amniotic and connective layers of umbilical tissue that has been developed as a wound cover or surgical wrap to support soft tissue repair. It retains native components of the umbilical tissue including the extracellular matrix, growth factors and endogenous viable cells

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including epithelial cells, fibroblasts and mesenchymal stem cells (“MSCs”). Stravix conforms to the site of injury and requires minimal preparation prior to use. It is thicker and has a stronger tensile strength than our Grafix products. Stravix was launched in late 2015.

BIO4 is a viable bone matrix containing endogenous bone forming cells including MSCs, osteoprogenitor cells, osteoblasts, osteoinductive and angiogenic growth factors. It possesses all four characteristics involved in bone repair and regeneration: osteoconductive, osteoinductive, osteogenic, and angiogenic. BIO4 is an alternative to autograft (or a graft of tissue from one’s own body) which requires a procedure of harvesting a patient’s own bone and is associated with donor site morbidity. Originally branded as OvationOS and launched in 2014, BIO4 is marketed and distributed exclusively by a subsidiary of Stryker Corporation (“Stryker”) under the brand name BIO4 since 2015.

Cartiform is a viable osteochondral allograft that contains extracellular matrix, chondrogenic factors and endogenous viable chondrocytes native to the cartilage tissue. The intact architecture of native cartilage is preserved in Cartiform. Cartiform is intended to treat osteochondral defects. Cartiform can fit to any surface contour. Cartiform was launched in 2012 and is exclusively available through Arthrex, Inc. (“Arthrex”).

Menvivo was developed for repair of the meniscus following partial meniscectomy. Menvivo is processed from donated human meniscus tissue and maintains the structural and mechanical properties of the tissue. Extracellular matrix, biological factors and endogenous viable cells of fresh meniscal tissue are retained in Menvivo. Although Menvivo is available to the market as a 361 HCT/P, we have no current plans to actively distribute this product because the proper use of this product requires the development of new implantation techniques and instruments.

Sales, Marketing and Distribution

Grafix, GrafixPL PRIME and Stravix: We currently sell Grafix, GrafixPL PRIME and Stravix through the efforts of our internal direct sales and marketing departments, as well as through a small number of specialty distributors for certain target markets. We focus our marketing efforts for these products in four specific channels: hospital outpatient departments, inpatient surgical procedures, private physician offices, and Department of Veteran Affairs (“VA”) and Department of Defense (“DOD”) hospitals. For our VA and DOD customers, our products are distributed exclusively through resellers designated as Service-Disabled, Veteran-Owned Small Businesses (“SDVOSBs”). SDVOSBs are eligible for set-asides and other preferences in the federal contracting process. For the VA, SDVOSBs enter into Federal Supply Schedule or Strategic Acquisition Center contracts and for the DOD, SDVOSBs enter into Distribution and Pricing contracts.

BIO4: In December 2014, we entered into an exclusive agreement with Howmedica Osteonics Corp., also referred to as Stryker Orthopaedics, a subsidiary of Stryker, for the marketing and distribution of BIO4. We are responsible for supply, manufacturing, inventory management, shipments to customers, continued research and product improvement

activities. Stryker is responsible for the sales and marketing of BIO4 for use in all surgical applications, including spine, trauma, extremity, cranial, and foot and ankle surgery. We collaborate with Stryker on the design and conduct of clinical development programs.

The agreement with Stryker provides for an initial four-year exclusive term, which commenced on the date of Stryker's initial commercial sale of BIO4 in February 2015. The term may be extended by Stryker for an additional exclusive period of four years or an additional non-exclusive period of two years. If Stryker extends the term on an exclusive basis, it has the option to further extend the term on an exclusive basis for two more years. We received an initial exclusivity fee of \$5.0 million in 2015 and are entitled to receive additional fees upon any exercise by Stryker of its right to extend the initial term, whether on an exclusive or non-exclusive basis. These additional fees are reduced on a sliding scale if Stryker meets certain revenue thresholds during the initial term or if revenue goals are not met as a result of us not fulfilling our supply obligations. Stryker is entitled to a certain percentage of sales of allograft services for BIO4 and has limited early termination rights.

Cartiform: In October 2014, we entered into an exclusive agreement for our cartilage product, Cartiform, with Arthrex. The agreement with Arthrex provides Arthrex with exclusive commercial distribution rights to Cartiform. We are responsible for manufacturing, continued research and product improvement activities. We collaborate with Arthrex

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on the design and conduct of clinical development programs. The agreement provides for an initial eight-year exclusive term with automatic renewals of additional two-year periods. Pursuant to the agreement, Arthrex is entitled to a certain commission on Cartiform sales.

Comparison of the Three and Nine-Month Periods Ended September 30, 2018 and 2017

Results of Operations

Revenues

The following tables show net sales by product line for the three and nine-month periods ended September 30, 2018 and 2017, respectively:

	Three Months Ended September 30,				
	2018	2017		Change (\$)	Change (%)
(in \$000's)					
Grafix/Stravix	\$ 27,307	\$ 21,739	\$ 5,568	25.6	%
BIO4	6,879	5,827	1,052	18.1	%
Cartiform	2,299	2,240	59	2.6	%
Other	6	—	6	—	%
Total	\$ 36,491	\$ 29,806	\$ 6,685	22.4	%

	Nine Months Ended September 30,				
	2018	2017		Change (\$)	Change (%)
(in \$000's)					
Grafix/Stravix	\$ 75,278	\$ 62,484	\$ 12,794	20.5	%
BIO4	19,827	16,970	2,857	16.8	%
Cartiform	6,889	6,451	438	6.8	%
Other	7	33	(26)	(78.8)	%
Total	\$ 102,001	\$ 85,938	\$ 16,063	18.7	%

For the Three-Month Period Ended September 30, 2018 Compared to the Three-Month Period Ended September 30, 2017

Revenue was \$36.5 million for the three-month period ended September 30, 2018, which increased \$6.7 million or 22.4%, compared to revenue of \$29.8 million for the three-month period ended September 30, 2017. The increase in revenue was due to the following:

Grafix/Stravix revenue increased \$5.6 million, or 25.6%, primarily due to increased demand from market awareness and acceptance as we increased selling efforts in the operating room and surgical settings as well as hospital outpatient wound care centers. In addition, we received a one-time settlement payment of \$1.3 million from a former distributor that was accounted for on a cash basis, as collection was not reasonably assured, to settle amounts owed to us from previous years, primarily 2015 and 2016. While we are experiencing some pressure to reduce prices, pricing of our Grafix/Stravix products did not significantly impact sales growth on a year-over-year basis during the three-month period ended September 30, 2018.

BIO4 revenue increased \$1.1 million, or 18.1%, due to increased demand from our distribution arrangement with Stryker. Pricing of our BIO4 products did not significantly impact sales growth on a year-over-year basis during the three-month period ended September 30, 2018.

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Cartiform revenue increased \$0.1 million, or 2.6%, primarily due to an increase in sales of larger units to Arthrex. Pricing of our Cartiform products did not significantly impact sales growth on a year-over-year basis during the three-month period ended September 30, 2018.

For the Nine-Month Period Ended September 30, 2018 Compared to the Nine-Month Period Ended September 30, 2017

Revenue was \$102.0 million for the nine-months ended September 30, 2018, which increased \$16.1 million or 18.7%, compared to revenue of \$85.9 million for the nine-months ended September 30, 2017. The increase in revenue was due to the following:

Grafix/Stravix revenue increased \$12.8 million, or 20.5%, primarily due to increased demand from market awareness and acceptance as we increased selling efforts in the operating room and surgical settings as well as hospital outpatient wound care centers. In addition, we received a one-time settlement payment of \$1.3 million from a former distributor that was accounted for on a cash basis, as collection was not reasonably assured, to settle amounts owed to us from previous years, primarily 2015 and 2016. While we are experiencing some pressure to reduce prices, the pricing of our Grafix/Stravix products did not significantly impact sales growth on a year-over-year basis during the nine-month period ended September 30, 2018.

BIO4 revenue increased \$2.9 million, or 16.8%, primarily due to increased demand through our distribution arrangement with Stryker. Pricing of our BIO4 products did not significantly impact sales growth on a year-over-year basis during the nine-month period ended September 30, 2018.

Cartiform revenue increased \$0.4 million, or 6.8%, primarily due to increased sales of larger units through our distribution arrangement with Arthrex. Pricing of our Cartiform products did not significantly impact sales growth on a year-over-year basis during the nine-month period ended September 30, 2018.

Gross Profit

For the Three-Month Period Ended September 30, 2018 Compared to the Three-Month Period Ended September 30, 2017

Gross profit was \$26.7 million for the three-month period ended September 30, 2018, which increased \$4.8 million or 22.0%, compared with gross profit of \$21.9 million for the three-month period ended September 30, 2017. This increase was primarily due to higher revenues, and the collection of the \$1.3 million settlement from a former distributor that was accounted for on a cash basis, which did not have any cost of revenue, as the cost of revenue was recognized in the periods the product was shipped. Our gross profit margin of 73.1% for the three-month period ended September 30, 2018 was comparable to the gross profit margin of 73.4% for the three-month period ended September 30, 2017.

For the Nine-Month Period Ended September 30, 2018 Compared to the Nine-Month Period Ended September 30, 2017

Gross profit was \$73.7 million for the nine-months ended September 30, 2018, which increased \$11.2 million or 17.9%, compared with gross profit of \$62.5 million for the nine-months ended September 30, 2017. This increase was primarily due to higher revenues, and the collection of the \$1.3 million settlement from a former distributor that was accounted for on a cash basis which did not have any cost of revenue, as the cost of revenue was recognized in the periods the product was shipped. Our gross profit margin of 72.2% for the nine-month period ended September 30, 2018 was comparable to the gross profit margin of 72.8% for the nine-month period ended September 30, 2017.

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Research and Development Expense

Research and development expense totaled \$1.6 million, or 4.4% of revenue, for the three-months ended September 30, 2018 compared with \$0.9 million, or 3.0% of revenue, for the three-month period ended September 30, 2017. This increase of \$0.7 million was primarily due to higher costs associated with the development, testing and clinical trials of our lyopreservation technology that allows for ambient storage of viable tissues.

Research and development expenses totaled \$4.9 million, or 4.8% of revenue, for the nine-month period ended September 30, 2018 compared with \$3.1 million, or 3.6% of revenue, for the nine-month period ended September 30, 2017. This increase of \$1.8 million was due to higher costs associated with the development, testing and clinical trials of our lyopreservation technology that will allow for ambient storage of viable tissues.

Sales and Marketing Expense

Sales and marketing expense totaled \$15.9 million, or 43.7% of revenue, for the three-month period ended September 30, 2018 compared with \$14.8 million, or 49.7% of revenue, for the three-month period ended September 30, 2017. This increase of \$1.1 million was primarily due to higher labor and labor related costs, including commissions due to higher sales and a larger sales force. The reduction in sales and marketing expense as a percentage of revenue was due, in part, to lower labor and labor related costs as a percentage of revenue of 2.0% and the effect of the additional \$1.3 million revenue from the one-time settlement with a former distributor which reduced the ratio by 1.6%. Other costs remained relatively constant in dollars, but decreased as a percentage of revenue.

Sales and marketing expense totaled \$49.1 million, or 48.1% of revenue, for the nine-month period ended September 30, 2018 compared with \$44.3 million, or 51.5% of revenue, for the nine-month period ended September 30, 2017. This increase of \$4.8 million was primarily due to higher labor and labor related costs, including commissions due to higher sales and a larger sales force, and higher travel related costs of \$0.6 million resulting from more customer meetings. The reduction in sales and marketing expense as a percentage of revenue was due, in part, to lower labor and labor related costs as a percentage of revenue of 1.8% and the effect of the additional \$1.3 million revenue from the one-time settlement with a former distributor which reduced the ratio by 0.7%. Other costs remained relatively constant in dollars, but decreased as a percentage of revenue.

General and Administrative Expense

General and administrative expense totaled \$4.3 million, or 11.8% of revenue, for the three-month period ended September 30, 2018 compared with \$6.6 million, or 22.3% of revenue, for the three-month period ended September

30, 2017. This decrease of \$2.3 million, as well as the decrease as a percentage of revenue, was primarily due to lower accounting and legal fees as a result of completing the filing of our restated prior year financial statements.

General and administrative expenses totaled \$15.2 million, or 14.9% of revenue, for the nine-month period ended September 30, 2018 compared with \$16.9 million, or 19.7% of revenue, for the nine-month period ended September 30, 2017. This decrease of \$1.7 million, as well as the decrease as a percentage of revenue, was primarily due to lower accounting and legal fees as a result of completing the filing of our restated prior year financial statements.

Shareholder Litigation Expense

We are a party to a securities class action and multiple shareholder derivative actions. During the third quarter of 2018, we recorded a liability of \$0.9 million related to estimated settlement of shareholder derivative actions.

On March 11, 2018, we entered into a memorandum of understanding to settle the securities class action lawsuit. By the terms of the memorandum, we agreed in principle to a total payment of \$18.5 million in cash. We made this payment to settle the class action lawsuit in October 2018. In addition, in October 2018, we received approximately \$4.8 in insurance proceeds related to this settlement.

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Other (Expense) Income, Net

Other (expense) income, net for the three-month period ended September 30, 2018 was \$(21) thousand, and increased \$1.8 million from other (expense) income, net of \$(1.8) million for the three-month period ended September 30, 2017. The increase was primarily due to losses recognized in 2017 on the sale of Mesoblast Limited common stock.

Other (expense) income, net, for the nine-month period ended September 30, 2018, was \$0.5 million, and increased \$1.9 million from other (expense) income, net \$(1.4) million for the nine-month period ended September 30, 2017. The increase was primarily due to losses recognized in 2017 on the sale of Mesoblast Limited common stock.

Income Taxes

Income tax expense for the three and nine-month periods ended September 30, 2018, was \$100 thousand and \$170 thousand, respectively, primarily due to state taxes, and interest and penalties related to uncertain tax positions.

Income tax benefit for the three and nine-month periods ended September 30, 2017, was \$198 thousand and \$134 thousand, respectively, due to the intraperiod tax allocation.

Since realization of deferred tax assets is dependent upon future earnings, a full valuation allowance has been recorded on the net deferred tax assets as of September 30, 2018 and December 31, 2017, which relate primarily to accounts receivable reserves, various accrued expenses and business tax credit carryforwards. In the event that we become profitable, we have general business credits (before a 100% valuation allowance) that may be utilized to reduce our federal tax liability.

Discontinued Operations

In connection with the sale of our therapeutics business to Mesoblast in October 2013, we are entitled to receive contingent consideration as a result of Mesoblast achieving certain milestones and royalty income of future sales by Mesoblast of Prochymal and other products utilizing the acquired technology.

In 2018, we received a cash payment of approximately \$0.4 million in royalty income from Mesoblast for sales during calendar year 2017. In July 2017, we received contingent consideration of \$10.0 million in Mesoblast Limited

common stock and \$350 thousand in cash as a milestone payment, net of approximately \$0.5 million in income tax expense. Mesoblast Limited common stock sold during the three and nine-month periods ended September 30, 2017, resulted in a loss of approximately \$1.7 million, which was reported in other income (expense), net in our condensed consolidated statement of comprehensive income (loss) for the three and nine-month periods ended September 30, 2017.

Liquidity and Capital Resources

Liquidity

At September 30, 2018, we had \$31.7 million in cash and cash equivalents and \$8.7 million in investments. In connection with the securities class action lawsuit, in October 2018, we deposited an \$18.5 million settlement payment into an escrow account, pending final court approval of the settlement. In addition, in October 2018, we received \$4.8 million in insurance proceeds related to the securities class action lawsuit.

Cash Flow

Net cash provided by operating activities during the nine-months ended September 30, 2018 was \$13.0 million and was primarily due to our net income of \$4.4 million, collections on our accounts receivable of \$5.5 million and an increase of \$1.2 million in accounts payable, accrued expenses and other liabilities.

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Net cash provided by investing activities during the nine-month period ended September 30, 2018 was \$15.6 million and primarily reflects net proceeds from sale of our investments. We sold investments in order to have cash and cash equivalents available to pay the settlement of the securities class action lawsuit.

There were no financing activities for the nine-month period ended September 30, 2018.

Capital Resources

We expect our operating capital needs to continue to increase for the remainder of 2018 as we incur costs to advance the commercialization of our products and fund our product development activities. We are subject to the risks associated with the development of new products and may encounter unforeseen expenses, difficulties, complications, delays or other unknown factors that may adversely affect our business and require additional capital.

Our future capital requirements will depend on many factors, including:

revenues generated by sales of our products;

the costs associated with expanding our sales and marketing efforts;

the costs associated with the resolution of legal proceedings related to the restatement;

the expenses we incur in manufacturing and managing the supply chain for our products;

the costs of developing and commercializing new products or technologies;

the cost of maintaining current products as 361 HCT/Ps or obtaining regulatory approval through the BLA regulatory pathway if any of our products lose their 361 HCT/P status;

the number and timing of any acquisitions and other strategic transactions;

the costs associated with capital expenditures; and

unanticipated general and administrative expenses.

We have not had any outstanding debt at any time since 2008. We believe that our cash on hand, investments, and cash flows from operations will be sufficient to finance our operations for at least the next twelve months.

Off-Balance Sheet Arrangements

We have no off-balance sheet financing arrangements and we have not entered into any transactions involving unconsolidated subsidiaries or special purpose entities.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to market risks from changes in interest rates through our investments, which consist primarily of corporate and government bonds. Due to the short duration of our investment portfolio and the high quality of our investments, an immediate 10% change in interest rates would not have a material effect on the value of our portfolio. Therefore, we would not expect our operating results or cash flows to be affected to any material degree by the effect of a sudden change in market interest rates on our securities portfolio.

We do not currently have any material foreign currency exposure.

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Item 4. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended (“the Exchange Act”), is recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our Interim Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our Interim Chief Executive Officer and Chief Financial Officer, has carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this report. As described in Management’s Annual Report on Internal Control over Financial Reporting in Part II, Item 9A, “Controls and Procedures” of our Annual Report, we previously reported material weaknesses in internal control over financial reporting that existed as of December 31, 2017. These material weaknesses in our internal control over financial reporting were not remediated as of September 30, 2018. As a result, our Interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of September 30, 2018.

Notwithstanding the material weaknesses, our management has concluded that the financial statements included in this Quarterly Report on Form 10-Q present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with GAAP.

Changes in Internal Control over Financial Reporting

With the exception of the remediation efforts described in Part II, Item 9A of our Annual Report, there have not been any changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we are subject to claims, asserted or unasserted, or named as a party to lawsuits, arbitrations or investigations. Litigation, in general, and intellectual property and securities litigation in particular, can be expensive and disruptive to normal business operations. Moreover, the results of legal proceedings cannot be predicted any certainty and in the case of the complex legal proceedings, such as intellectual property and securities litigation, the results are difficult to predict. Except as described in Note 10, “Commitments and Contingencies,” to the unaudited condensed consolidated financial statement included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we are not aware of any legal proceedings or claims that we believe would have a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors.

There have not been any material changes in the risk factors previously disclosed under the heading “Risk Factors” in Part I – Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 as filed with the SEC on March 28, 2018.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

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Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

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Item 6. Exhibits.

Exhibit Number	Description of Exhibit
3.1	<u>Articles of Restatement of the Registrant as filed with the State Department of Assessments and Taxation of Maryland on June 4, 2010 (Incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 6, 2010).</u>
3.2	<u>Articles of Amendment of the Registrant as filed with the State Department of Assessments and Taxation of Maryland on June 10, 2015 (Incorporated herein by reference to Exhibit 3.2 to the Annual Report on Form 10-K filed by the Registrant with the SEC on March 28, 2018).</u>
3.3	<u>Articles of Merger between Osiris Therapeutics, Inc., a Delaware corporation, and Osiris Maryland, Inc., a Maryland corporation, as survivor, changing the Form 8-K filed by the Registrant with the SEC on June 2, 2010).</u>
3.4	<u>Articles of Amendment of the Registrant as filed with the State Department of Assessments and Taxation of Maryland on June 28, 2018 (Incorporated herein by reference to Exhibit 3.4 to the Registration Statement on Form 8-A filed by the Registrant with the SEC on July 27, 2018).</u>
3.5	<u>Amended and Restated Bylaws of the Registrant (Incorporated herein by reference to Exhibit 3.5 to the Registration Statement on Form 8-A filed by the Registrant with the SEC on July 27, 2018).</u>
10.1	<u>Form of Indemnification and Advancement of Expenses Letter Agreement (Incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant with the SEC on July 2, 2018).</u>
31.1	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).</u>
31.2	<u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended (Section 302 of the Sarbanes-Oxley Act of 2002).</u>
32.1	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Comprehensive Income, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) related notes.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Osiris Therapeutics, Inc.

Date: November 7, 2018 /s/ JASON KEEFER
Jason Keefer
Interim Chief Executive Officer and President

Date: November 7, 2018 /s/ JOEL ROGERS
Joel Rogers
Chief Financial Officer