Opko Health, Inc.
Form 10-Q
November 09, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)
ý 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 001-33528

OPKO Health, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	75-2402409
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

4400 Biscayne Blvd.
Miami, FL 33137
(Address of Principal Executive Offices) (Zip Code)

(305) 575-4100
(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. ý 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ý 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) (Check one):

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨
	Emerging growth company ¨

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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 ý NO

As of November 1, 2018, the registrant had 559,827,515 shares of Common Stock outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in "Item 1A-Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2017, and described from time to time in our other reports filed with the Securities and Exchange Commission ("SEC"). We do not undertake an obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Risks and uncertainties, the occurrence of which could adversely affect our business, include the following:

- we have a history of losses and may not generate sustained positive cash flow sufficient to fund our operations and research and development programs;
- our need for, and ability to obtain, additional financing when needed on favorable terms, or at all;
- adverse results in material litigation matters or governmental inquiries, including, without limitation, recent lawsuits against the Company and its Chairman and Chief Executive Officer by the SEC, as well as related class action and derivative lawsuits;
- the risks inherent in developing, obtaining regulatory approvals for and commercializing new, commercially viable and competitive products and treatments;
- our research and development activities may not result in commercially viable products;
- that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results;
- the success of our relationship with Pfizer;
- that we may fail to obtain regulatory approval for hGH-CTP or successfully commercialize Rayaldee and hGH-CTP;
- that we may not generate profits or cash flow from our laboratory operations or substantial revenue from Rayaldee and our pharmaceutical and diagnostic products;
- that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied;
- our ability to build a successful pharmaceutical sales and marketing infrastructure;
- our ability and our distribution and marketing partners' ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates and the operation of our laboratories;
- the performance of our third-party distribution partners, licensees and manufacturers over which we have limited control;
- our success is dependent on the involvement and continued efforts of our Chairman and Chief Executive Officer;
- integration challenges for Transition Therapeutics, BioReference, EirGen and other acquired businesses;
- availability of insurance coverage with respect to material litigation matters;
- changes in regulation and policies in the United States ("U.S.") and other countries, including increasing downward pressure on healthcare reimbursement;
- our ability to manage our growth and our expanded operations;
- increased competition, including price competition;
-

changing relationships with payers, including the various state and multi-state Blues programs, suppliers and strategic partners;

- efforts by third-party payors to reduce utilization and reimbursement for clinical testing services;
- our ability to maintain reimbursement coverage for our products and services, including the 4Kscore test;
- failure to timely or accurately bill and collect for our services;
- failure in our information technology systems, including cybersecurity attacks or other data security or privacy incidents;
- failure to obtain and retain new clients and business partners, or a reduction in tests ordered or specimens submitted by existing clients;
- failure to establish, and perform to, appropriate quality standards to assure that the highest level of quality is observed in the performance of our testing services;

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- failure to maintain the security of patient-related information;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to defend our intellectual property rights with respect to our products;
- our ability to operate our business without infringing the intellectual property rights of others;
- our ability to attract and retain key scientific and management personnel;
- failure to obtain and maintain regulatory approval outside the U.S.;
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations; and
- our ability to finance and successfully complete construction of a research, development and manufacturing center in Waterford, Ireland.

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PART I. FINANCIAL INFORMATION

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to the "Company", "OPKO", "we", "our", "ours", and "us" refer to OPKO Health, Inc., a Delaware corporation, including our wholly-owned subsidiaries.

Item 1. Financial Statements

OPKO Health, Inc. and Subsidiaries

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share and per share data)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$43,718	$ 91,499
Accounts receivable, net	157,374	165,516
Inventory, net	43,379	49,333
Other current assets and prepaid expenses	45,346	42,513
Total current assets	289,817	348,861
Property, plant and equipment, net	147,386	146,557
Intangible assets, net	631,434	683,835
In-process research and development	646,339	647,347
Goodwill	713,629	717,099
Investments	42,737	40,642
Other assets	9,652	5,615
Total assets	$2,480,994	$ 2,589,956
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$65,613	$ 74,307
Accrued expenses	214,907	230,301
Current portion of 2033 Senior Notes	30,957	—
Current portion of lines of credit and notes payable	6,353	11,926
Total current liabilities	317,830	316,534
2023 Convertible Notes and 2033 Senior Notes	56,597	29,160
Deferred tax liabilities, net	134,112	148,729
Other long-term liabilities, principally contract liabilities, contingent consideration and line of credit	183,812	239,955
Total long-term liabilities	374,521	417,844
Total liabilities	692,351	734,378
Equity:		
Common Stock - $0.01 par value, 750,000,000 shares authorized; 560,377,422 and 560,023,745 shares issued at September 30, 2018 and December 31, 2017, respectively	5,604	5,600
Treasury Stock - 549,907 and 549,907 shares at September 30, 2018 and December 31, 2017, respectively	(1,791)	(1,791)
Additional paid-in capital	2,907,017	2,889,256
Accumulated other comprehensive loss	(13,138)	(528)
Accumulated deficit	(1,109,049)	(1,036,959)
Total shareholders' equity	1,788,643	1,855,578
Total liabilities and equity	$2,480,994	$ 2,589,956

The accompanying unaudited Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2018	2017	2018	2017
Revenues:				
Revenue from services	$202,811	$200,876	$630,180	$663,333
Revenue from products	25,395	22,795	81,769	73,992
Revenue from transfer of intellectual property and other	21,609	22,369	56,463	67,697
Total revenues	249,815	246,040	768,412	805,022
Costs and expenses:				
Cost of service revenue	137,347	135,203	411,196	419,070
Cost of product revenue	13,609	16,107	43,909	44,441
Selling, general and administrative	84,071	103,177	263,242	318,700
Research and development	30,160	32,508	92,258	92,193
Contingent consideration	1,193	(11,213)	(12,406)	(4,475)
Amortization of intangible assets	16,899	18,023	51,397	53,904
Total costs and expenses	283,279	293,805	849,596	923,833
Operating loss	(33,464)	(47,765)	(81,184)	(118,811)
Other income and (expense), net:				
Interest income	43	249	111	634
Interest expense	(2,944)	(1,840)	(7,933)	(4,771)
Fair value changes of derivative instruments, net	(155)	(7,550)	3,489	1,969
Other income (expense), net	(824)	597	9,653	3,105
Other income and (expense), net	(3,880)	(8,544)	5,320	937
Loss before income taxes and investment losses	(37,344)	(56,309)	(75,864)	(117,874)
Income tax benefit	11,563	24,405	10,437	42,309
Net loss before investment losses	(25,781)	(31,904)	(65,427)	(75,565)
Loss from investments in investees	(1,874)	(4,013)	(11,542)	(11,771)
Net loss	$(27,655)	$(35,917)	$(76,969)	$(87,336)
Loss per share, basic and diluted:				
Loss per share	$(0.05)	$(0.06)	$(0.14)	$(0.16)
Weighted average common shares outstanding, basic and diluted	559,786,382	559,405,309	559,601,097	559,065,232

The accompanying unaudited Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands)

	For the three months ended September 30,		For the nine months ended September 30,	
	2018	2017	2018	2017
Net loss	$(27,655)	$(35,917)	$(76,969)	$(87,336)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss)	(134)	8,557	(7,734)	21,646
Investments:				
Change in unrealized loss, net of tax	—	(6)	—	(749)
Reclassification adjustment due to adoption of ASU 2016-01	—	—	(4,876)	—
Reclassification adjustments for losses included in net loss, net of tax	—	96	—	690
Comprehensive loss	$(27,789)	$(27,270)	$(89,579)	$(65,749)

The accompanying unaudited Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	For the nine months ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(76,969)	$(87,336)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	73,440	76,677
Non-cash interest	3,559	1,944
Amortization of deferred financing costs	155	168
Losses from investments in investees	11,542	11,771
Equity-based compensation – employees and non-employees	16,591	22,292
Gain (loss) on disposal of fixed assets	34	(2,683)
Change in fair value of equity securities and derivative instruments	(14,346)	(1,969)
Change in fair value of contingent consideration	(12,406)	(4,475)
Deferred income tax benefit	(14,541)	(46,366)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	7,701	(13,594)
Inventory, net	4,057	1,729
Other current assets and prepaid expenses	(4,304)	(2,857)
Other assets	(4,633)	(449)
Accounts payable	(9,329)	12,013
Foreign currency measurement	57	608
Contract liabilities	(50,531)	(49,771)
Accrued expenses and other liabilities	(4,559)	(11,892)
Net cash used in operating activities	(74,482)	(94,190)
Cash flows from investing activities:		
Investments in investees	(1,000)	(4,625)
Proceeds from sale of equity securities	1,516	—
Purchase of marketable securities	—	(6)
Proceeds from the sale of property, plant and equipment	1,070	3,979
Capital expenditures	(24,823)	(32,061)
Net cash used in investing activities	(23,237)	(32,713)
Cash flows from financing activities:		
Issuance of 2033 Senior Notes, including to related parties	55,000	—
Proceeds from the exercise of Common Stock options and warrants	1,173	1,916
Borrowings on lines of credit	22,468	75,544
Repayments of lines of credit	(28,435)	(20,643)
Net cash provided by financing activities	50,206	56,817
Effect of exchange rate changes on cash and cash equivalents	(268)	1,715
Net decrease in cash and cash equivalents	(47,781)	(68,371)
Cash and cash equivalents at beginning of period	91,499	168,733
Cash and cash equivalents at end of period	$43,718	$100,362
SUPPLEMENTAL INFORMATION:		
Interest paid	$1,631	$1,409

Income taxes paid, net of refunds	$3,883	$5,899
Non-cash financing:		
Shares issued upon the conversion of:		
Common Stock options and warrants, surrendered in net exercise	$806	$1,546
Issuance of capital stock for contingent consideration settlement:		
OPKO Health Europe	$—	$303

The accompanying unaudited Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)
NOTE 1 BUSINESS AND ORGANIZATION

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories, Inc. ("BioReference"), the nation's third-largest clinical laboratory with a core genetic testing business and an almost 400-person sales and marketing team to drive growth and leverage new products, including the 4Kscore prostate cancer test and the Claros 1 in-office immunoassay platform (in development). Our pharmaceutical business features Rayaldee, an FDA-approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency (launched in November 2016), OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia, and OPK88003, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists (Phase 2b). Our pharmaceutical business also features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer). We are incorporated in Delaware and our principal executive offices are located in leased offices in Miami, Florida.

Through BioReference, we provide laboratory testing services, primarily to customers in the larger metropolitan areas across New York, New Jersey, Maryland, Pennsylvania, Delaware, Washington, DC, Florida, California, Texas, Illinois and Massachusetts as well as to customers in a number of other states. We offer a comprehensive test menu of clinical diagnostics for blood, urine, and tissue analysis. This includes hematology, clinical chemistry, immunoassay, infectious diseases, serology, hormones, and toxicology assays, as well as Pap smear, anatomic pathology (biopsies) and other types of tissue analysis. We market our laboratory testing services directly to physicians, geneticists, hospitals, clinics, correctional and other health facilities.

We operate established pharmaceutical platforms in Ireland, Chile, Spain, and Mexico, which are generating revenue and which we expect to facilitate future market entry for our products currently in development. In addition, we have a development and commercial supply pharmaceutical company and a global supply chain operation and holding company in Ireland. We own a specialty active pharmaceutical ingredients ("APIs") manufacturer in Israel, which we expect will facilitate the development of our pipeline of molecules and compounds for our molecular diagnostic and therapeutic products.

Our research and development activities are primarily performed at facilities in Miramar, FL, Woburn, MA, Waterford, Ireland, Kiryat Gat, Israel, and Barcelona, Spain.

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NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation. The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments or otherwise disclosed herein) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three and nine months ended September 30, 2018, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2018 or any future periods. The unaudited Condensed Consolidated Financial Statements should be read in conjunction with the Consolidated Financial Statements and the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Principles of consolidation. The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of OPKO Health, Inc. and of our wholly-owned subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

Use of estimates. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from these estimates.

Cash and cash equivalents. Cash and cash equivalents include short-term, interest-bearing instruments with original maturities of 90 days or less at the date of purchase. We also consider all highly liquid investments with original maturities at the date of purchase of 90 days or less as cash equivalents. These investments include money markets, bank deposits, certificates of deposit and U.S. treasury securities.

Inventories. Inventories are valued at the lower of cost and net realizable value. Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost and net realizable value. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories. Inventory obsolescence expense for the nine months ended September 30, 2018 and 2017 was $1.5 million and $5.0 million, respectively.

Pre-launch inventories. We may accumulate commercial quantities of certain product candidates prior to the date we anticipate that such products will receive final U.S. FDA approval. The accumulation of such pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever. This risk notwithstanding, we may accumulate pre-launch inventories of certain products when such action is appropriate in relation to the commercial value of the product launch opportunity. In accordance with our policy, this pre-launch inventory is expensed.

Goodwill and intangible assets. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired accounted for by the acquisition method of accounting . Refer to Note 4. Goodwill, in-process research and development ("IPR&D") and other intangible assets acquired in business combinations, licensing and other transactions at both September 30, 2018 and December 31, 2017 was $2.0 billion.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. We determined the fair value of intangible assets, including IPR&D, using the "income method."

Goodwill is tested at least annually for impairment, or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value.

Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the project is completed or abandoned. Upon obtaining regulatory approval, the IPR&D asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is

abandoned, the IPR&D asset is charged to expense.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic

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benefits of our intangible assets are consumed or otherwise used up. Amortization expense was $51.4 million and $53.9 million for the nine months ended September 30, 2018 and 2017, respectively.

Fair value measurements. The carrying amounts of our cash and cash equivalents, accounts receivable, accounts payable and short-term debt approximate their fair value due to the short-term maturities of these instruments. Investments that are considered equity securities as of September 30, 2018 and December 31, 2017 are carried at fair value. Our debt under the credit agreement with JPMorgan Chase Bank, N.A. approximates fair value due to the variable rate of interest.

In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts. Accordingly, the estimates of fair value presented herein may not be indicative of the amounts that could be realized in a current market exchange. Refer to Note 8.

Contingent consideration. Each period we revalue the contingent consideration obligations associated with certain prior acquisitions to their fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as a reduction in contingent consideration expense. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as our development programs progress, revenue estimates evolve and additional data is obtained, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value which may have a material impact on our results from operations and financial position.

Derivative financial instruments. We record derivative financial instruments on our Condensed Consolidated Balance Sheet at their fair value and recognize the changes in the fair value in our Condensed Consolidated Statement of Operations when they occur, the only exception being derivatives that qualify as hedges. For the derivative instrument to qualify as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2018 and December 31, 2017, our foreign currency forward contracts held to economically hedge inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in the fair values of our derivatives instruments, net, in our Condensed Consolidated Statement of Operations. Refer to Note 9.

Property, plant and equipment. Property, plant and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets and includes amortization expense for assets capitalized under capital leases. The estimated useful lives by asset class are as follows: software - 3 years, machinery, medical and other equipment - 5-8 years, furniture and fixtures - 5-12 years, leasehold improvements - the lesser of their useful life or the lease term, buildings and improvements - 10-40 years, and automobiles - 3-5 years. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation expense was $22.0 million and $22.7 million for the nine months ended September 30, 2018 and 2017, respectively. Assets held under capital leases are included within Property, plant and equipment, net in our Condensed Consolidated Balance Sheet and are amortized over the shorter of their useful lives or the expected term of their related leases.

Impairment of long-lived assets. Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Income taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on

deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment. Valuation allowances on certain U.S. deferred tax assets and non-U.S. deferred tax assets are established, because realization of these tax benefits through future taxable income does not meet the more-likely-than-not threshold.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the “Tax Act”) was enacted into law and the new legislation contains several key tax provisions, including a reduction of the corporate income tax rate from 35% to 21% effective

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January 1, 2018, and a one-time mandatory transition tax on accumulated foreign earnings, among others. We are required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring our U.S. deferred tax assets and liabilities, as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Act ("SAB 118"), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date.

Through September 30, 2018, we did not have any significant adjustments to our provisional amounts. As we continue to perform our analysis of the Tax Act, and interpret any additional accounting guidance issued by the FASB, the U.S. Department of the Treasury and the IRS, we may make adjustments to these provisional amounts.

Effective January 1, 2018, the Tax Act provides for a new global intangible low-taxed income (GILTI) provision. Under the GILTI provision, certain foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets are included in U.S. taxable income. We are now subject to GILTI but have not triggered an income inclusion as of September 30, 2018. Any future inclusion is expected to be offset by net operating loss carry forwards in the U.S. We are still evaluating, pending further interpretive guidance, whether to make a policy election to treat the GILTI tax as a period expense or to provide U.S. deferred taxes on foreign temporary differences that are expected to generate GILTI income when they reverse in future years.

We anticipate future impacts at a U.S. state and local tax level related to the Tax Act; however, the limited amount of statutory and interpretive guidance available from applicable state and local tax authorities is not sufficient to reasonably estimate the impact. Consequently, for those jurisdictions, we have not recorded provisional amounts and have continued to apply ASC 740 based on the provisions of the tax laws that were in effect immediately prior to Tax Act enactment.

We operate in various countries and tax jurisdictions globally. For interim reporting purposes, we record income taxes based on the expected effective income tax rate taking into consideration year to date and global forecasted tax results. For the three and nine months ended September 30, 2018, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the valuation allowance against certain U.S. and non-U.S. deferred tax assets, the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Revenue recognition. Effective January 1, 2018, we adopted Accounting Standards Codification Topic 606, Revenue from Contracts with Customers ("Topic 606"). We recognize revenue when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that we expect to receive in exchange for those goods or services. We apply the following five-step model in order to determine this amount: (i) identify the contract(s) with a customer; (ii) identify the performance obligations 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) we satisfy a performance obligation.

We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. For a complete discussion of accounting for Revenues from services, Revenues from products and Revenue from transfer of intellectual property and other, refer to Note 12.

Concentration of credit risk and allowance for doubtful accounts. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of accounts receivable. Substantially all of our accounts receivable are with either companies in the healthcare industry or patients. However, credit risk is limited due to the number of our clients as well as their dispersion across many different geographic regions.

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk since the related healthcare programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. At September 30, 2018 and December 31, 2017, receivable balances (net of contractual adjustments) from Medicare and Medicaid were 15.2% and 15.8%,

respectively, of our consolidated Accounts receivable, net.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At September 30, 2018 and December 31, 2017, receivables due from patients represent approximately 3.2% and 3.2%, respectively, of our consolidated Accounts receivable, net.

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We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer's ability to pay. Actual results could differ from those estimates. Our reported net loss is directly affected by our estimate of the collectability of accounts receivable. The allowance for doubtful accounts was $1.7 million and $1.4 million at September 30, 2018 and December 31, 2017, respectively. The provision for bad debts for the nine months ended September 30, 2018 and 2017 was $0.6 million and $0.7 million, respectively.

Equity-based compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options, as cash flows from operations. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. During the nine months ended September 30, 2018 and 2017, we recorded $16.6 million and $22.3 million, respectively, of equity-based compensation expense.

Research and development expenses. Research and development expenses include external and internal expenses. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. Research and development employee-related expenses include salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities. We expense these costs in the period in which they are incurred. We estimate our liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon our estimate of services received and degree of completion of the services in accordance with the specific third party contract.

Research and development expense includes costs for in-process research and development projects acquired in asset acquisitions which have not reached technological feasibility and which have no alternative future use. For in-process research and development projects acquired in business combinations, the in-process research and development project is capitalized and evaluated for impairment until the development process has been completed. Once the development process has been completed the asset will be amortized over its remaining useful life.

Segment reporting. Our chief operating decision-maker ("CODM") is Phillip Frost, M.D., our Chairman and Chief Executive Officer. Our CODM reviews our operating results and operating plans and makes resource allocation decisions on a Company-wide or aggregate basis. We manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of our pharmaceutical operations we acquired in Chile, Mexico, Ireland, Israel and Spain, Rayaldee product sales and our pharmaceutical research and development. The diagnostics segment primarily consists of clinical laboratory operations we acquired through the acquisition of BioReference and point-of-care operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes. Refer to Note 14.

Shipping and handling costs. We do not charge customers for shipping and handling costs. Shipping and handling costs are classified as Cost of revenues in the Condensed Consolidated Statement of Operations.

Foreign currency translation. The financial statements of certain of our foreign operations are measured using the local currency as the functional currency. The local currency assets and liabilities are generally translated at the rate of exchange to the U.S. dollar on the balance sheet date and the local currency revenues and expenses are translated at average rates of exchange to the U.S. dollar during the reporting periods. Foreign currency transaction gains (losses) have been reflected as a component of Other income (expense), net within the Condensed Consolidated Statement of Operations and foreign currency translation gains (losses) have been included as a component of the Condensed Consolidated Statement of Comprehensive Loss.

Variable interest entities. The consolidation of a variable interest entity ("VIE") is required when an enterprise has a controlling financial interest. A controlling financial interest in a VIE will have both of the following characteristics: (a) the power to direct the activities of a VIE that most significantly impact the VIE's economic performance and (b) the obligation to absorb losses of the VIE that could potentially be significant to the VIE. Refer to Note 5.
Investments. We have made strategic investments in development stage and emerging companies. We record these investments as equity method investments or as equity securities based on our percentage of ownership and whether we have significant influence over the operations of the investees. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Losses from investments in investees in our Condensed Consolidated Statement

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of Operations. Refer to Note 5. For investments classified as equity securities, we record changes in their fair value as Other income (expense) in our Condensed Consolidated Statement of Operations based on their closing price per share at the end of each reporting period, unless the equity security does not have a readily determinable fair value. Refer to Note 5.

Recently adopted accounting pronouncements.

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers." ASU 2014-09, as amended and codified into Topic 606, clarifies the principles for recognizing revenue and develops a common revenue standard for GAAP that removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. As required, we adopted ASU 2014-09 on January 1, 2018 using the full retrospective approach, and have elected to use the following practical expedients that are permitted under the rules of the adoption, which have been applied consistently to all contracts within all reporting periods presented:

- For all reporting periods presented before January 1, 2018, we have not restated revenue from contracts that begin and are completed within the same annual reporting period.
- For all reporting periods presented before January 1, 2018, we have not disclosed the amount of the transaction price allocated to the remaining performance obligations or an explanation of when we expect to recognize that amount as revenue.
- We have applied the practical expedient provided for by Topic 606 by not adjusting the transaction price for significant financing components for periods less than one year.

As a result of adopting ASU 2014-09 on January 1, 2018 using the full retrospective approach, we revised our comparative financial statements for the prior years as if Topic 606 had been effective for those periods. As a result, the following financial statement line items for 2017 were affected:

Condensed Consolidated Statement of Operations

	For the three months ended September 30, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Revenue from services	$200,876	$229,035	$(28,159)
Revenue from transfer of intellectual property and other	22,369	11,665	10,704
Selling, general and administrative	103,177	131,336	(28,159)
Research and development	32,508	32,329	179

	For the nine months ended September 30, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Revenue from services	$663,333	$740,992	$(77,659)
Revenue from transfer of intellectual property and other	67,697	58,819	8,878
Selling, general and administrative	318,700	396,359	(77,659)

Research and development	92,193	90,944	1,249

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Condensed Consolidated Balance Sheet

	December 31, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Other current assets and prepaid expenses	$42,513	$37,113	$5,400
Accrued expenses	230,301	215,102	15,199
Other long-term liabilities, principally contract liabilities, contingent consideration and line of credit	239,955	219,954	20,001
Accumulated deficit	(1,036,959)	(1,007,159)	(29,800)

Condensed Consolidated Statement of Cash Flows

	For the nine months ended September 30, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Net loss	$(87,336)	$(94,965)	$7,629
Contract liabilities	(49,771)	(42,142)	(7,629)

The most significant change above relates to amounts in our clinical laboratory operations that were historically classified as provision for bad debts, primarily related to patient responsibility, which are considered an element of variable consideration as an implicit price concession in determining revenues under Topic 606. Accordingly, we report uncollectible balances associated with individual patients as a reduction of the transaction price and therefore as a reduction in Revenue from services when historically these amounts were classified as provision for bad debts within Selling, general and administrative expenses.

In addition, under Topic 606, the upfront consideration received for a license and contract services combined performance obligation is recognized as revenue to the extent of costs incurred based on the length of the expected performance period and the subjectivity in estimating progress towards satisfaction of the performance obligation. Under previous accounting, we recognized revenue over the expected performance period. The adoption of Topic 606 resulted in a cumulative revenue reduction of $29.8 million and an increase of our accumulated deficit balance as of December 31, 2017; with a corresponding increase in our contract liabilities. For the nine months ended September 30, 2017, Revenue from the transfer of intellectual property and other was increased by $7.6 million for the change in accounting. For a further discussion of the adoption of Topic 606, refer to Note 12.

In January 2016, the FASB issued ASU No. 2016-01, “Financial Instruments - Overall (Subtopic 825-10),” which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The ASU requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. As a result of the required adoption of ASU 2016-01 on January 1, 2018, we recorded a cumulative-effect adjustment to reclassify our net unrealized gains on our equity securities of $4.9 million as of January 1, 2018 from Accumulated other comprehensive loss to Accumulated deficit in our Condensed Consolidated Balance Sheet. Changes in the fair value of our equity securities subsequent to the adoption of ASU 2016-01 on January 1, 2018 will be recognized in net income.

In August 2016, the FASB issued ASU No. 2016-15, “Statement of Cash Flows (Topic 230),” which addresses the classification of eight specific cash flow issues with the objective of reducing the existing diversity in practice. The required adoption of ASU 2016-15 in the first quarter of 2018 did not have a significant impact on our Condensed

Consolidated Financial Statements.

In January 2017, the FASB issued ASU No. 2017-01, “Business Combinations (Topic 805),” which clarifies the definition of a business to assist entities in evaluating whether transactions should be accounted for acquisitions (or disposals) of assets or businesses. The required adoption of ASU 2017-01 in the first quarter of 2018 did not have a significant impact on our Condensed Consolidated Financial Statements.

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Pending accounting pronouncements.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” which will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. ASU 2016-02, as amended, requires new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We have begun a process to identify a complete population of our leases. Such process includes reviewing various contracts to identify whether such arrangements convey the right to control the use of an identified asset. The determination of the impact of this new guidance is ongoing and, as such, we are not able to reasonably estimate the effect the adoption of this new standard will have on our financial statements. Based on our preliminary assessment of this ASU, we believe the new standard will have a significant impact on our Condensed Consolidated Balance Sheet, which has not yet been quantified. In July 2018, the FASB issued an ASU to provide an additional transition method to adopt the guidance by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative effect to the opening balance of retained earnings. We are currently evaluating the choice of transition options.

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles - Goodwill and Other (Topic 350),” which simplifies how an entity is required to test for goodwill impairment. ASU 2017-04 will be effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019, with early adoption permitted after January 1, 2017. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In June 2018, the FASB issued ASU No. 2018-07, “Compensation - Stock Compensation (Topic 718),” which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 will be effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

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NOTE 3 EARNINGS (LOSS) PER SHARE

Basic loss per share is computed by dividing our net loss by the weighted average number of shares outstanding during the period. For diluted earnings per share, the dilutive impact of stock options and warrants is determined by applying the “treasury stock” method. The dilutive impact of the 2033 Senior Notes and 2023 Convertible Notes (each, as defined herein) has been considered using the “if converted” method. In the periods in which their effect would be antidilutive, no effect has been given to outstanding options, warrants or the potentially dilutive shares issuable pursuant to the 2033 Senior Notes and 2023 Convertible Notes (discussed in Note 6) in the dilutive computation.

A total of 292,123 and 179,613 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for three and nine months ended September 30, 2018, respectively, because their inclusion would be antidilutive. A full presentation of diluted earnings per share has not been provided because the required adjustments to the numerator and denominator resulted in diluted earnings per share equivalent to basic earnings per share.

During the three months ended September 30, 2018, 208,000 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 208,000 shares of Common Stock. Of the 208,000 Common Stock options and Common Stock warrants exercised, 0 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the nine months ended September 30, 2018, 540,000 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 353,677 shares of Common Stock. Of the 540,000 Common Stock options and Common Stock warrants exercised, 186,323 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the three months ended September 30, 2017, no Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised.

During the nine months ended September 30, 2017, 1,646,372 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 1,373,515 shares of Common Stock. Of the 1,646,372 Common Stock options and Common Stock warrants exercised, 272,857 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

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NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	September 30, 2018	December 31, 2017
Accounts receivable, net:		
Accounts receivable	$ 159,119	$ 166,962
Less: allowance for doubtful accounts	(1,745)	(1,446)
	$ 157,374	$ 165,516
Inventories, net:		
Consumable supplies	$ 22,728	$ 21,546
Finished products	14,925	21,012
Work in-process	3,018	5,873
Raw materials	5,106	7,467
Less: inventory reserve	(2,398)	(6,565)
	$ 43,379	$ 49,333
Other current assets and prepaid expenses:		
Taxes recoverable	20,259	18,138
Other receivables	4,014	8,798
Prepaid supplies	12,135	8,207
Prepaid insurance	4,695	3,532
Other	4,243	3,838
	$ 45,346	$ 42,513
Intangible assets, net:		
Customer relationships	$ 446,962	$ 448,345
Technologies	340,786	340,921
Trade names	50,490	50,553
Licenses	10,231	10,305
Covenants not to compete	16,369	16,372
Product registrations	9,569	10,475
Other	5,668	5,799
Less: accumulated amortization	(248,641)	(198,935)
	$ 631,434	$ 683,835
Accrued expenses:		
Contract liabilities	$ 61,734	$ 61,388
Employee benefits	39,953	50,377
Clinical trials	12,582	12,191
Taxes payable	4,520	4,609
Contingent consideration	2,092	11,750
Capital leases short-term	3,488	3,399
Milestone payment	9,822	4,868
Professional fees	3,705	2,355
Other	77,011	79,364
	$ 214,907	$ 230,301

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(In thousands)	September 30, 2018	December 31, 2017
Other long-term liabilities:		
Contract liabilities	$ 28,113	$ 78,990
Line of credit	104,025	104,152
Contingent consideration	26,856	29,603
Mortgages and other debts payable	1,142	1,567
Capital leases long-term	6,188	7,786
Other	17,488	17,857
	$ 183,812	$ 239,955

All of the intangible assets and goodwill acquired relate to our acquisitions of principally OPKO Renal, OPKO Biologics, EirGen Pharma Limited ("EirGen") and BioReference. We do not anticipate capitalizing the cost of product registration renewals, rather we expect to expense these costs, as incurred. Our goodwill is not tax deductible for income tax purposes in any jurisdiction we operate in.

The changes in value of the intangible assets and goodwill during the nine months ended September 30, 2018 are primarily due to foreign currency fluctuations between the Chilean Peso, the Euro and the Shekel against the U.S. dollar.

The following table summarizes the changes in Goodwill during the nine months ended September 30, 2018.

(In thousands)	2018 Balance at January 1	Foreign exchange and other	Balance at September 30th
Pharmaceuticals			
CURNA	$4,827	$—	$4,827
EirGen	89,226	(2,789)	86,437
FineTech	11,698	—	11,698
OPKO Chile	5,203	(336)	4,867
OPKO Biologics	139,784	—	139,784
OPKO Health Europe	7,898	(247)	7,651
OPKO Renal	2,069	—	2,069
Transition Therapeutics	3,608	(98)	3,510
Diagnostics			
BioReference	401,821	—	401,821
OPKO Diagnostics	17,977	—	17,977
OPKO Lab	32,988	—	32,988
	$717,099	$(3,470)	$713,629

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NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of September 30, 2018:

(in thousands)

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	$ 17,648	$ 20,046
Variable interest entity, equity method	956	—
Equity securities	22,183	
Equity securities with no readily determinable fair value	439	
Warrants and options	1,511	
Total carrying value of investments	$ 42,737	

Equity method investments

Our equity method investments consist of investments in Pharmsynthez (ownership 9%), Cocrystal Pharma, Inc. (“COCP”) (9%), Non-Invasive Monitoring Systems, Inc. (“NIMS”) (1%), Neovasc, Inc. (“Neovasc”) (6%), VBI Vaccines Inc. (“VBI”) (10%), InCellDx, Inc. (29%), BioCardia, Inc. (“BioCardia”) (5%), and Xenetic Biosciences, Inc. (“Xenetic”) (4%). The total assets, liabilities, and net losses of our equity method investees as of and for the nine months ended September 30, 2018 were $348.6 million, $117.2 million, and $178.0 million, respectively. We have determined that we and/or our related parties can significantly influence the success of our equity method investments through our board representation and/or voting power. Accordingly, we account for our investment in these entities under the equity method and record our proportionate share of their losses in Loss from investments in investees in our Condensed Consolidated Statement of Operations. The aggregate value of our equity method investments based on the quoted market price of their common stock and the number of shares held by us as of September 30, 2018 is $35.2 million.

Equity Securities

Our equity securities consist of investments in RXi Pharmaceuticals Corporation (“RXi”) (ownership 1%), ChromaDex Corporation (0.1%), MabVax Therapeutics Holdings, Inc. (“MabVax”) (2%), and Eloxx Pharmaceuticals, Inc. (“Eloxx”) (4%). We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of these investments. Accordingly, we account for our investment in these entities as equity securities, and we record changes in the fair value of these investments in Other income (expense) each reporting period when they have readily determinable fair value. Equity securities without a readily determinable fair value are adjusted to fair value when an observable price change can be identified. Net gains and losses on our equity securities for the nine months ended September 30, 2018 are as follows:

(in thousands)

Equity Securities	For the nine months ended September 30, 2018
Net gains recognized during the period on equity securities	$ 10,509
Less: Net losses realized during the period on equity securities	(728)
Unrealized net gains recognized during the period on equity securities still held at the reporting date	$ 11,237

Sales of investments

Gains (losses) included in earnings from sales of our investments are recorded in Other income (expense), net in our Condensed Consolidated Statement of Operations. We did not have significant sales activity during the nine months ended September 30, 2018 and 2017. The cost of securities sold is based on the specific identification method.

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Warrants and options

In addition to our equity method investments and equity securities, we hold options to purchase 0.4 million additional shares of BioCardia, 0.1 million of which are vested as of September 30, 2018, and 33 thousand, 0.7 million, 0.5 million, 22 thousand and 29 thousand of warrants to purchase additional shares of COCP, InCellDx, Inc., Xenetic, RXi and NeoVasc, respectively. We recorded the changes in the fair value of the options and warrants in Fair value changes of derivative instruments, net in our Condensed Consolidated Statement of Operations. We also recorded the fair value of the options and warrants in Investments, net in our Condensed Consolidated Balance Sheet. See further discussion of the Company's options and warrants in Note 8 and Note 9.

Investments in variable interest entities

We have determined that we hold variable interests in Zebra Biologics, Inc. ("Zebra"). We made this determination as a result of our assessment that Zebra does not have sufficient resources to carry out its principal activities without additional financial support.

We own 1,260,000 shares of Zebra Series A-2 Preferred Stock and 900,000 shares of Zebra restricted common stock (ownership 29% at September 30, 2018). Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Dr. Richard Lerner, M.D., a member of our Board of Directors, is a founder of Zebra and, along with Dr. Frost, serves as a member of Zebra's Board of Directors. In order to determine the primary beneficiary of Zebra, we evaluated our investment and our related parties' investment, as well as our investment combined with the related party group's investment to identify if we had the power to direct the activities that most significantly impact the economic performance of Zebra. Based on the capital structure, governing documents and overall business operations of Zebra, we determined that, while a VIE, we do not have the power to direct the activities that most significantly impact Zebra's economic performance and have no obligation to fund expected losses. We did determine, however, that we can significantly influence the success of Zebra through our board representation and voting power. Therefore, we have the ability to exercise significant influence over Zebra's operations and account for our investment in Zebra under the equity method.

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NOTE 6 DEBT

In February 2018, we issued a series of 5% Convertible Promissory Notes (the "2023 Convertible Notes") in the aggregate principal amount of $55.0 million. The 2023 Convertible Notes mature 5 years from the date of issuance. Each holder of a 2023 Convertible Note has the option, from time to time, to convert all or any portion of the outstanding principal balance of such 2023 Convertible Note, together with accrued and unpaid interest thereon, into shares of our Common Stock, par value $0.01 per share, at a conversion price of $5.00 per share of Common Stock (the "Shares"). We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon, pro ratably among the holders, upon no fewer than 30 days, and no more than 60 days, notice to the holders. The 2023 Convertible Notes contain customary events of default and representations and warranties of OPKO.

The issuance of the 2023 Convertible Notes and the issuance of the Shares, if any, upon conversion thereof was not, and will not be, respectively, registered under the Securities Act, pursuant to the exemption provided by Section 4(a)(2) thereof, and we have not agreed to register the Shares if or when such Shares are issued.

Purchasers of the 2023 Convertible Notes include an affiliate of Dr. Phillip Frost, M.D., our Chairman and Chief Executive Officer, and Dr. Jane H. Hsiao, Ph.D., MBA, our Vice-Chairman and Chief Technical Officer.

In January 2013, we entered into note purchase agreements (the "2033 Senior Notes") with qualified institutional buyers and accredited investors (collectively, the "Purchasers") in a private placement in reliance on exemptions from registration under the Securities Act. The 2033 Senior Notes were issued on January 30, 2013. The 2033 Senior Notes, which totaled $175.0 million in original principal amount, bear interest at the rate of 3.00% per year, payable semiannually on February 1 and August 1 of each year. The 2033 Senior Notes will mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change as defined in the Indenture, dated as of January 30, 2013, by and between the Company and Wells Fargo Bank N.A., as trustee, governing the 2033 Senior Notes (the "Indenture"), subject to certain exceptions, the holders may require us to repurchase all or any portion of their 2033 Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the 2033 Senior Notes being repurchased, plus any accrued and unpaid interest to but not including the related fundamental change repurchase date.

The following table sets forth information related to the 2033 Senior Notes which is included in our Condensed Consolidated Balance Sheets as of December 31, 2017 and September 30, 2018:

(In thousands)	2033 Senior Notes	Discount	Debt Issuance Cost	Total
Balance at December 31, 2017	$31,850	$(2,565)	$ (125)	$29,160
Amortization of debt discount and debt issuance costs	—	1,686	111	1,797
Balance at September 30, 2018	$31,850	$(879)	$ (14)	$30,957

The 2033 Senior Notes will be convertible at any time on or after November 1, 2032, through the second scheduled trading day immediately preceding the maturity date, at the option of the holders. Additionally, holders may convert their 2033 Senior Notes prior to the close of business on the scheduled trading day immediately preceding November 1, 2032, under the following circumstances: (1) conversion based upon satisfaction of the trading price condition relating to the 2033 Senior Notes; (2) conversion based on the Common Stock price; (3) conversion based upon the occurrence of specified corporate events; or (4) if we call the 2033 Senior Notes for redemption. The 2033 Senior Notes will be convertible into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our election unless we have made an irrevocable election of net share settlement. The initial conversion rate for the 2033 Senior Notes will be 141.48 shares of Common Stock per $1,000 principal amount of 2033 Senior Notes (equivalent to an initial conversion price of approximately $7.07 per share of Common Stock), and will be subject to adjustment upon the occurrence of certain events. In addition, we will, in certain circumstances, increase the conversion rate for holders who convert their 2033 Senior Notes in connection with a make-whole fundamental change (as defined in the Indenture). Holders of the 2033 Senior Notes may require us to repurchase the 2033 Senior Notes for 100% of their principal amount, plus accrued and unpaid interest, on February 1, 2019, February 1, 2023 and February 1, 2028, or following the occurrence of a fundamental change as defined in the

indenture governing the 2033 Senior Notes.

Before February 1, 2019, we may redeem for cash any or all of the 2033 Senior Notes but only if the last reported sale price of our Common Stock exceeds 130% of the applicable conversion price for at least 20 trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date on which we deliver the redemption notice. The redemption price will equal 100% of the principal amount of the 2033 Senior Notes to be redeemed, plus any accrued and unpaid interest to but not including the redemption date. On or after February 1, 2019, we may redeem for cash

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any or all of the 2033 Senior Notes at a redemption price of 100% of the principal amount of the 2033 Senior Notes to be redeemed, plus any accrued and unpaid interest up to but not including the redemption date.

The terms of the 2033 Senior Notes, include, among others: (i) rights to convert into shares of our Common Stock, including upon a fundamental change; and (ii) a coupon make-whole payment in the event of a conversion by the holders of the 2033 Senior Notes on or after February 1, 2017 but prior to February 1, 2019. We determined that these specific terms were considered to be embedded derivatives. Embedded derivatives are required to be separated from the host contract, the 2033 Senior Notes, and carried at fair value when: (a) the embedded derivative possesses economic characteristics that are not clearly and closely related to the economic characteristics of the host contract; and (b) a separate, stand-alone instrument with the same terms would qualify as a derivative instrument. We concluded that the embedded derivatives within the 2033 Senior Notes meet these criteria and, as such, were valued separate and apart from the 2033 Senior Notes and recorded at fair value each reporting period.

For accounting and financial reporting purposes, we combined these embedded derivatives and valued them together as one unit of accounting. In 2017, certain terms of the embedded derivatives expired pursuant to the original agreement and the embedded derivatives no longer met the criteria to be separated from the host contract and, as a result, the embedded derivatives were no longer required to be valued separate and apart from the 2033 Senior Notes and were reclassified to additional paid in capital. Accordingly, there was no derivative income (loss) for the nine months ended September 30, 2018.

From 2013 to 2016, holders of the 2033 Senior Notes converted $143.2 million in aggregate principal amount into an aggregate of 21,539,873 shares of the Company’s Common Stock.

In April 2015, we initially announced that our 2033 Senior Notes were convertible through June 2015 by holders of such notes. This conversion right was triggered because the closing price per share of our Common Stock exceeded $9.19, or 130% of the initial conversion price of $7.07, for at least 20 of 30 consecutive trading days during the applicable measurement period. We have elected to satisfy our conversion obligation under the 2033 Senior Notes in shares of our Common Stock. Our 2033 Senior Notes continued to be convertible by holders of such notes for the remainder of 2015, 2016 and the first quarter of 2017. They may become convertible again if one or more of the conversion conditions specified in the Indenture is satisfied during future measurement periods. Pursuant to the Indenture, a holder who elects to convert the 2033 Senior Notes will receive 141.4827 shares of our Common Stock plus such number of additional shares as is applicable on the conversion date per $1,000 principal amount of 2033 Senior Notes based on the early conversion provisions in the Indenture.

In November 2015, BioReference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. (“CB”), as lender and administrative agent, as amended (the “Credit Agreement”). The Credit Agreement provides for a $175.0 million secured revolving credit facility and includes a $20.0 million sub-facility for swingline loans and a $20.0 million sub-facility for the issuance of letters of credit. BioReference may increase the credit facility to up to $275.0 million on a secured basis, subject to the satisfaction of specified conditions. The Credit Agreement matures on November 5, 2020 and is guaranteed by all of BioReference’s domestic subsidiaries. The Credit Agreement is also secured by substantially all assets of BioReference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in BioReference. Availability under the Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein. As of September 30, 2018, $10.7 million additional funds were available to be borrowed under the Credit Agreement. Principal under the Credit Agreement is due upon maturity on November 5, 2020.

At BioReference’s option, borrowings under the Credit Agreement (other than swingline loans) will bear interest at (i) the CB floating rate (defined as the higher of (a) the prime rate and (b) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) for an interest period of one month plus 2.50%) plus an applicable margin of 0.35% for the first 12 months and 0.50% thereafter or (ii) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) plus an applicable margin of 1.35% for the first 12 months and 1.50% thereafter. Swingline loans will bear interest at the CB floating rate plus the applicable margin. The Credit Agreement also calls for other customary fees and charges, including an unused commitment fee of 0.50% of the lending

commitments.

In February 2018, BioReference and certain of its subsidiaries entered into Amendment No. 7 to the Credit Agreement, which amended the Credit Agreement to permit BioReference and its subsidiaries to use cash on hand, up to a maximum amount set forth in the amendment, to meet the availability requirements that otherwise would trigger (i) covenants that would require BioReference to maintain a minimum fixed charge coverage ratio and provide certain increased reporting under the Credit Agreement and (ii) CB's right, as agent for the lenders under the Credit Agreement, to exercise sole dominion over funds held in certain accounts of BioReference. The other terms of the Credit Agreement remain unchanged.

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The Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require BioReference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws and restrictions on the ability of BioReference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the Credit Agreement, notwithstanding the ability of BioReference to meet its debt service obligations. The Credit Agreement also includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Credit Agreement and execution upon the collateral securing obligations under the Credit Agreement. Substantially all the assets of BioReference and its subsidiaries are restricted from sale, transfer, lease, disposal or distributions to the Company, subject to certain exceptions. BioReference and its subsidiaries net assets as of September 30, 2018 were approximately $0.9 billion, which includes goodwill of $401.8 million and intangible assets of $415.2 million.

In addition to the Credit Agreement with CB, we have line of credit agreements with twelve other financial institutions as of September 30, 2018 and December 31, 2017 in the U.S., Chile and Spain. These lines of credit are used primarily as a source of working capital for inventory purchases.

The following table summarizes the amounts outstanding under the BioReference, Chilean and Spanish lines of credit:

(Dollars in thousands)			Balance Outstanding	
Lender	Interest rate on borrowings at September 30, 2018	Credit line capacity	September 30, 2018	December 31, 2017
JPMorgan Chase	4.01%	$175,000	$105,028	$ 104,152
Itau Bank	5.50%	1,810	1,202	446
Bank of Chile	6.60%	3,800	489	1,598
BICE Bank	5.50%	2,500	543	1,819
BBVA Bank	5.50%	3,250	554	1,665
Security Bank	5.50%	27	27	501
Estado Bank	5.50%	3,500	1,020	2,111
Santander Bank	5.50%	4,500	708	1,988
Scotiabank	5.00%	1,800	—	384
Banco De Sabadell	1.45%	348	—	—
Banco Bilbao Vizcaya	2.45%	348	—	—
Banco Santander	2.20%	348	123	—
Total		$197,231	$109,694	$ 114,664

At September 30, 2018 and December 31, 2017, the weighted average interest rate on our lines of credit was approximately 4.7% and 4.2%, respectively.

At September 30, 2018 and December 31, 2017, we had notes payable and other debt (excluding the 2033 Senior Notes, the 2023 Convertible Notes, the Credit Agreement and amounts outstanding under lines of credit) as follows:

(In thousands)	September 30, 2018	December 31, 2017
Current portion of notes payable	$ 2,210	$ 1,632
Other long-term liabilities	6,127	2,011
Total	$ 8,337	$ 3,643

The notes and other debt mature at various dates ranging from 2018 through 2024 bearing variable interest rates from 1.8% up to 6.3%. The weighted average interest rate on the notes and other debt at September 30, 2018 and December 31, 2017, was 2.8% and 3.0%, respectively. The notes are secured by our office space in Barcelona.

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NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

For the nine months ended September 30, 2018, changes in Accumulated other comprehensive income (loss), net of tax, were as follows:

(In thousands)	Foreign currency	Unrealized gain (loss) in Accumulated OCI	Total
Balance at December 31, 2017	$(5,404)	$ 4,876	$(528)
Other comprehensive loss before reclassifications	(7,734)	—	(7,734)
Reclassification adjustment due to adoption of ASU 2016-01	—	(4,876)	(4,876)
Net other comprehensive loss	(7,734)	(4,876)	(12,610)
Balance at September 30, 2018	$(13,138)	$ —	$(13,138)

NOTE 8 FAIR VALUE MEASUREMENTS

We record fair values at an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability. We utilize a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

As of September 30, 2018, we have equity securities (refer to Note 5), forward foreign currency exchange contracts for inventory purchases (refer to Note 9) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics and OPKO Renal that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with BioCardia, we record the related BioCardia options at fair value as well as the warrants from COCP, InCellDx, Inc., Xenetic, RXi and Neovasc.

Our financial assets and liabilities measured at fair value on a recurring basis are as follows:

(In thousands)	Fair value measurements as of September 30, 2018 Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Equity securities	22,183	—	—	22,183
Common stock options/warrants	—	1,511	—	1,511
Forward contracts	—	23	—	23
Total assets	$22,183	$ 1,534	$ —	$23,717
Liabilities:				
Contingent consideration	—	—	28,948	28,948
Total liabilities	$—	$ —	$ 28,948	$28,948

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(In thousands)	Fair value measurements as of December 31, 2017 Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$107	$ —	$ —	$107
Equity securities	12,461	—	—	12,461
Common stock options/warrants	—	3,333	—	3,333
Total assets	$12,568	$ 3,333	$ —	$15,901
Liabilities:				
Forward contracts	—	317	—	317
Contingent consideration	—	—	41,353	41,353
Total liabilities	$—	$ 317	$ 41,353	$41,670

There have been no transfers between Level 1 and Level 2 and no transfers to or from Level 3 of the fair value hierarchy.

As of September 30, 2018 and December 31, 2017, the carrying value of our other financial instrument assets approximates their fair value due to their short-term nature or variable rate of interest.

The following table reconciles the beginning and ending balances of our Level 3 assets and liabilities as of September 30, 2018:

(In thousands)	September 30, 2018 Contingent consideration
Balance at December 31, 2017	$ 41,353
Change in fair value:	
Included in results of operations	(12,406)
Balance at September 30, 2018	$ 28,947

The estimated fair values of our financial instruments have been determined by using available market information and what we believe to be appropriate valuation methodologies. We use the following methods and assumptions in estimating fair value:

Contingent consideration – We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to OPKO Diagnostics, CURNA and OPKO Renal transactions. If estimated future sales were to decrease by 10%, the contingent consideration related to OPKO Renal, which represents the majority of our contingent consideration liability, would decrease by $1.7 million. As of September 30, 2018, of the $28.9 million of contingent consideration, $2.1 million is recorded in Accrued expenses and $26.9 million is recorded in Other long-term liabilities. As of December 31, 2017, of the $41.4 million of contingent consideration, $11.8 million is recorded in Accrued expenses and $29.6 million is recorded in Other long-term liabilities.

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NOTE 9 DERIVATIVE CONTRACTS

The following table summarizes the fair values and the presentation of our derivative assets (liabilities) in the Condensed Consolidated Balance Sheets:

(In thousands)	Balance Sheet Component	September 30, 2018	December 31, 2017
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 1,511	$ 3,333
Forward contracts	Unrealized gains on forward contracts are recorded in Other current assets and prepaid expenses. Unrealized (losses) on forward contracts are recorded in Accrued expenses.	$ 23	$ (317)

We enter into foreign currency forward exchange contracts to cover the risk of exposure to exchange rate differences arising from inventory purchases on letters of credit. Under these forward contracts, for any rate above or below the fixed rate, we receive or pay the difference between the spot rate and the fixed rate for the given amount at the settlement date.

To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2018 and December 31, 2017, our derivative financial instruments do not meet the documentation requirements to be designated as hedges. Accordingly, we recognize the changes in Fair value of derivative instruments, net in our Condensed Consolidated Statement of Operations. The following table summarizes the losses and gains recorded for the three and nine months ended September 30, 2018 and 2017:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	2018	2017	2018	2017
Derivative gain (loss):				
Common Stock options/warrants	$(288)	$(342)	$3,299	$(854)
2033 Senior Notes	—	(6,829)	—	3,185
Forward contracts	133	(379)	190	(362)
Total	$(155)	$(7,550)	$3,489	$1,969

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NOTE 10 RELATED PARTY TRANSACTIONS

In February 2018, we issued the 2023 Convertible Notes in the aggregate principal amount of $55.0 million. Refer to Note 6. Purchasers of the 2023 Convertible Notes include an affiliate of Dr. Phillip Frost, M.D., our Chairman and Chief Executive Officer, and Dr. Jane H. Hsiao, Ph.D., MBA, our Vice-Chairman and Chief Technical Officer.

We hold investments in Zebra (ownership 29%), Neovasc (6%), ChromaDex Corporation (0.1%), MabVax (2%), COCP (9%), NIMS (1%) and BioCardia (5%). These investments were considered related party transactions as a result of our executive management's ownership interests and/or board representation in these entities. See further discussion of our investments in Note 5.

In February 2018, we invested an additional $1.0 million in COCP for a convertible note, which was converted into 538,544 shares of its common stock in May 2018. In April 2017, we invested an additional $1.0 million in COCP for 138,889 shares of its common stock, and in August 2016, we invested an additional $2.0 million in COCP for 162,602 shares of its common stock.

In November 2017, we invested an additional $3.0 million in Neovasc for 2,054,794 shares of its common stock, 2,054,794 Series A warrants, 2,054,794 Series B warrants and 822,192 Series C warrants. In April 2018, we exercised our Series B warrants in a cashless exercise and received 106,909,044 shares of Neovasc common stock.

In July 2017, we invested an additional $0.1 million in MabVax for 50,714 shares of common stock and in May 2017, we invested an additional $0.5 million in MabVax for 1,667 shares of Series L Preferred Stock and 107,607 shares of Series I Preferred Stock.

In November 2016, we entered into a Pledge Agreement with the Museum of Science, Inc. and the Museum of Science Endowment Fund, Inc. pursuant to which we will contribute an aggregate of $1.0 million over a four-year period for constructing, equipping and the general operation of the Frost Science Museum. Dr. Frost and Mr. Pfenniger serve on the Board of Trustees of the Frost Science Museum and Mr. Pfenniger is the Vice Chairman of the Board of Trustees.

We lease office space from Frost Real Estate Holdings, LLC ("Frost Holdings") in Miami, Florida, where our principal executive offices are located. Effective January 1, 2017, we entered into an amendment to our lease agreement with Frost Holdings. The lease, as amended, is for approximately 29,500 square feet of space. The lease provides for payments of approximately $81 thousand per month in the first year increasing annually to $86 thousand per month in the third year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking.

Our wholly-owned subsidiary, BioReference, purchases and uses certain products acquired from InCellDx, Inc., a company in which we hold a 29% minority interest.

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost for out-of-pocket operating costs for the use of the airplane by Dr. Frost or Company executives for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive. For the three and nine months ended September 30, 2018, we recognized approximately $34 thousand and $174 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2017, we recognized $168 thousand and $309 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

For a discussion of related-party transactions that took place subsequent to the quarter ended September 30, 2018, refer to Note 15.

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NOTE 11 COMMITMENTS AND CONTINGENCIES

In connection with our acquisitions of CURNA, OPKO Diagnostics and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of September 30, 2018, we have recorded $28.9 million as contingent consideration, with $2.1 million recorded within Accrued expenses and $26.9 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

On September 7, 2018, the Securities and Exchange Commission ("SEC") filed a lawsuit in the Southern District of New York (the "SEC Complaint") against a number of individuals and entities (the "Defendants"), including the Company and its CEO and Chairman, Phillip Frost. The SEC alleges that the Company (i) aided and abetted an illegal "pump and dump" scheme perpetrated by a number of the Defendants, and (ii) failed to file required Schedules 13D or 13G with the SEC. The Complaint also alleges that Dr. Frost participated in the alleged "pump and dump" scheme with respect to two companies, failed to file required Schedules 13D or 13G with the SEC, and unlawfully sold securities without registering the sales with the SEC. The SEC seeks final judgments permanently enjoining the Company and Dr. Frost from future violations of the charged provisions of the federal securities laws with respect to both OPKO and Dr. Frost, Sections 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 13d-1(a) thereunder relating to the alleged failure to make the appropriate filings on Schedules 13D or 13G and Section 20(e) of the Exchange Act and Section 15(b) of the Securities Act of 1933 (the "Securities Act") relating to allegations that OPKO and Dr. Frost aided and abetted the alleged "pump and dump" schemes, and, with respect to Dr. Frost alone, Sections 5(a) and (c) of the Securities Act alleging that Dr. Frost failed to register certain securities transactions and Section 10(b) of the Exchange Act and Rule 10b-5 thereunder as well as Section 17(a)(2) of the Securities Act relating to the alleged commission of fraud. The complaint makes no allegations about OPKO's financial statements or business practices.

Following the SEC's announcement of the SEC Complaint, we have been named in seven class action lawsuits and five derivative suits relating to the allegations in the SEC Complaint among other matters. The Company intends to vigorously defend itself against the claims. Based on the early stages of these legal proceedings, at this time, the Company is not able to reasonably estimate a possible range of loss, if any, that may result from these allegations. For a more detailed discussion of pending matters, please see Part II, Item 1, "Legal Proceedings."

In August 2017, we entered into a Commitment Letter (the "Commitment Letter") with Veterans Accountable Care Group, LLC ("VACG") in connection with submission of a bid by its affiliate, the Veterans Accountable Care Organization, LLC ("VACO") in response to a request for proposal ("RFP") from the Veterans Health Administration ("VA") regarding its Community Care Network. If VACO is successful in its bid, we will acquire a fifteen percent (15%) membership interest in VACO. In addition, BioReference, our wholly-owned subsidiary, will provide laboratory services for the Community Care Network, a region which currently includes approximately 2,133,000 veterans in the states of Massachusetts, Maine, New Hampshire, Vermont, New York, Pennsylvania, New Jersey, Rhode Island, Connecticut, Maryland, Virginia, West Virginia, and North Carolina.

Pursuant to the Commitment Letter, we committed to provide, or to arrange from a third party lender, a line of credit for VACG in the amount of $50.0 million (the "Facility"). Funds drawn under the Facility would be contributed by VACG to VACO in order to satisfy the financial stability requirement of VACO in connection with its submission of the RFP. VACG would not be permitted to draw down on the Facility unless and until the VHA awards a contract to VACO. The Facility would have a maturity of five years. Interest on the Facility would be payable at a rate equal to 6.5% per annum, payable quarterly in arrears. The Facility is subject to the negotiation of definitive documentation conditions customary for transactions of such type and otherwise acceptable to VACG and the lender under the Facility.

We currently anticipate that a decision by the VHA with respect to the RFP will occur during the first half of 2019, although there can be no assurance that a decision will be made by such time or that, if favorable, such decision will not be challenged by participants in the RFP process or otherwise.

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review established accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new

information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For the matters referenced in the paragraph below, the amount of liability is not probable or the amount cannot be reasonably estimated; and, therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for matters which the likelihood of material loss is at least reasonably possible, we provide disclosure of the possible loss or range of loss; however, if a reasonable estimate cannot be made, we will provide disclosure to that effect.

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From time to time, we may receive inquiries, document requests, Civil Investigative Demands ("CIDs") or subpoenas from the Department of Justice, the Office of Inspector General and Office for Civil Rights ("OCR") of the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, various payors and fiscal intermediaries, and other state and federal regulators regarding investigations, audits and reviews. In addition to the matters discussed in this note, we are currently responding to CIDs, subpoenas or document requests for various matters relating to our laboratory operations. Some pending or threatened proceedings against us may involve potentially substantial amounts as well as the possibility of civil, criminal, or administrative fines, penalties, or other sanctions, which could be material. Settlements of suits involving the types of issues that we routinely confront may require monetary payments as well as corporate integrity agreements. Additionally, qui tam or "whistleblower" actions initiated under the civil False Claims Act may be pending but placed under seal by the court to comply with the False Claims Act's requirements for filing such suits. Also, from time to time, we may detect issues of non-compliance with federal healthcare laws pertaining to claims submission and reimbursement practices and/or financial relationships with physicians, among other things. We may avail ourselves of various mechanisms to address these issues, including participation in voluntary disclosure protocols. Participating in voluntary disclosure protocols can have the potential for significant settlement obligations or even enforcement action. The Company generally has cooperated, and intends to continue to cooperate, with appropriate regulatory authorities as and when investigations, audits and inquiries arise.

We are a party to other litigation in the ordinary course of business. We do not believe that any such litigation will have a material adverse effect on our business, financial condition, results of operations or cash flows.

In April 2017, the Civil Division of the United States Attorney's Office for the Southern District of New York (the "SDNY") informed BioReference that it believes that, from 2006 to the present, BioReference had, in violation of the False Claims Act, improperly billed Medicare and TRICARE (both are federal government healthcare programs) for clinical laboratory services provided to hospital inpatient beneficiaries at certain hospitals. BioReference is reviewing and assessing the allegations made by the SDNY, and, at this point, BioReference has not determined whether there is any merit to the SDNY's claims nor can it determine the extent of any potential liability. While management cannot predict the outcome of these matters at this time, the ultimate outcome could be material to our business, financial condition, results of operations, and cash flows.

We expect to continue to incur substantial research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that selling, general and administrative expenses will also increase as we expand our sales, marketing and administrative staff and add infrastructure, particularly as it relates to the launch of Rayaldee. We do not anticipate that we will generate substantial revenue from the sale of proprietary pharmaceutical products or certain of our diagnostic products for some time and we have generated only limited revenue from our pharmaceutical operations in Chile, Mexico, Israel, Spain, and Ireland, and from sale of the 4Kscore test. If we acquire additional assets or companies, fail to generate expected cash flow from BioReference, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions.

At September 30, 2018, we were committed to make future purchases for inventory and other items in 2018 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating $85.7 million.

NOTE 12 REVENUE RECOGNITION

Effective January 1, 2018, we adopted Accounting Standards Codification Topic 606, Revenue from Contracts with Customers. We generate revenues from services, products and intellectual property as follows:

Revenue from services

Revenue for laboratory services is recognized at the time test results are reported, which approximates when services are provided and the performance obligations are satisfied. Services are provided to patients covered by various third-party payor programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services are included in revenue net of allowances for contractual discounts, allowances for differences between the amounts billed and estimated program payment amounts, and implicit price concessions

provided to uninsured patients which are all elements of variable consideration.

The following are descriptions of our payors for laboratory services:

Healthcare Insurers. Reimbursements from healthcare insurers are based on negotiated fee-for-service schedules. Revenues consist of amounts billed, net of contractual allowances for differences between amounts billed and the estimated consideration we expect to receive from such payers, which considers historical denial and collection experience and the terms

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of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the third-party payers, are recorded upon settlement.

Government Payers. Reimbursements from government payers are based on fee-for-service schedules set by governmental authorities, including traditional Medicare and Medicaid. Revenues consist of amounts billed, net of contractual allowances for differences between amounts billed and the estimated consideration we expect to receive from such payers, which considers historical denial and collection experience and the terms of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the government payers, are recorded upon settlement.

Client Payers. Client payers include physicians, hospitals, employers, and other institutions for which services are performed on a wholesale basis, and are billed and recognized as revenue based on negotiated fee schedules.

Patients. Uninsured patients are billed based on established patient fee schedules or fees negotiated with physicians on behalf of their patients. Insured patients (including amounts for coinsurance and deductible responsibilities) are billed based on fees negotiated with healthcare insurers. Collection of billings from patients is subject to credit risk and ability of the patients to pay. Revenues consist of amounts billed net of discounts provided to uninsured patients in accordance with our policies and implicit price concessions. Implicit price concessions represent differences between amounts billed and the estimated consideration that we expect to receive from patients, which considers historical collection experience and other factors including current market conditions. Adjustments to the estimated allowances, based on actual receipts from the patients, are recorded upon settlement.

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, require us to estimate the potential for retroactive adjustments as an element of variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known. For the nine months ended September 30, 2018 and 2017, revenue reductions due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $23.4 million and $30.7 million, respectively, were recognized.

Third-party payers, including government programs, may decide to deny payment or recoup payments for testing they contend were improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. Our revenues may be subject to retroactive adjustment as a result of these factors among others, including without limitation, differing interpretations of billing and coding guidance and changes by government agencies and payors in interpretations, requirements, and “conditions of participation” in various programs. We have processed requests for recoupment from third-party payers in the ordinary course of our business, and it is likely that we will continue to do so in the future. If a third-party payer denies payment for testing or recoups money from us in a later period, reimbursement revenue for our testing could decline.

As an integral part of our billing compliance program, we periodically assess our billing and coding practices, respond to payor audits on a routine basis, and investigate reported failures or suspected failures to comply with federal and state healthcare reimbursement requirements, as well as overpayment claims which may arise from time to time without fault on the part of the Company. We may have an obligation to reimburse Medicare, Medicaid, and third-party payers for overpayments regardless of fault. We have periodically identified and reported overpayments, reimbursed payors for overpayments and taken appropriate corrective action.

Settlements with third-party payors for retroactive adjustments due to audits, reviews or investigations are also considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews, and investigations.

During the fourth quarter of 2017, a payor informed us it had overpaid BioReference due to an error on its part over a period of approximately ten years, including multiple years prior to the acquisition of BioReference by OPKO in August 2015. As of September 30, 2018 and December 31, 2017, we have liabilities of approximately $32.5 million

and $30.0 million within Accrued expenses related to reimbursements for payor overpayments.

The composition of Revenue from services by payor for the three and nine months ended September 30, 2018 and 2017 is as follows:

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	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	2018	2017	2018	2017
Healthcare insurers	$92,059	$92,978	$288,071	$313,065
Government payers	67,913	67,347	209,316	226,492
Client payers	37,772	34,724	116,123	106,499
Patients	5,067	5,827	16,670	17,277
Total	$202,811	$200,876	$630,180	$663,333

Revenue from products

We recognize revenue from product sales when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that we expect to receive in exchange for those goods or services. Our estimates for sales returns and allowances are based upon the historical patterns of product returns and allowances taken, matched against the sales from which they originated, and our evaluation of specific factors that may increase or decrease the risk of product returns. Product revenues are recorded net of estimated rebates, chargebacks, discounts, co-pay assistance and other deductions (collectively, “Sales Deductions”) as well as estimated product returns which are all elements of variable consideration. Allowances are recorded as a reduction of revenue at the time product revenues are recognized. The actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect Revenue from products in the period such variances become known.

We launched Rayaldee in the U.S. through our dedicated renal sales force in November 2016. Rayaldee is distributed in the U.S. principally through the retail pharmacy channel, which initiates with the largest wholesalers in the U.S. (collectively, “Rayaldee Customers”). In addition to distribution agreements with Rayaldee Customers, we have entered into arrangements with many healthcare providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of Rayaldee.

We recognize revenue for shipments of Rayaldee at the time of delivery to customers after estimating Sales Deductions and product returns as elements of variable consideration utilizing historical information and market research projections. For the three and nine months ended September 30, 2018, we recognized $5.8 million and $14.3 million in net product revenue from sales of Rayaldee. Amounts shipped prior to September 30, 2017 were insignificant and no revenue was recognized from sales of Rayaldee for the three and nine months ended September 30, 2017.

The following table presents an analysis of product sales allowances and accruals as contract liabilities for the nine months ended September 30, 2018:

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2017	$ 233	$ 348	$ 437	$1,018
Provision related to current period sales	3,835	5,929	—	9,764
Credits or payments made	(3,030)	(4,907)	(377)	(8,314)
Balance at September 30, 2018	$ 1,038	$ 1,370	$ 60	$2,468

Total gross Rayaldee sales	$24,074	
Provision for Rayaldee sales allowances and accruals as a percentage of gross Rayaldee sales	41	%

Taxes collected from customers related to revenues from services and revenues from products are excluded from revenues.

Revenue from intellectual property

We recognize revenues from the transfer of intellectual property generated through license, development, collaboration and/or commercialization agreements. The terms of these agreements typically include payment to us for one or more of the following: non-refundable, up-front license fees; development and commercialization milestone payments; funding of research

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and/or development activities; and royalties on sales of licensed products. Revenue is recognized upon satisfaction of a performance obligation by transferring control of a good or service to the customer.

For research, development and/or commercialization agreements that result in revenues, we identify all material performance obligations, which may include a license to intellectual property and know-how, and research and development activities. In order to determine the transaction price, in addition to any upfront payment, we estimate the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. We constrain (reduce) our estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur throughout the life of the contract. When determining if variable consideration should be constrained, we consider whether there are factors outside of our control that could result in a significant reversal of revenue. In making these assessments, we consider the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Upfront License Fees: If a license to our intellectual property is determined to be functional intellectual property distinct from the other performance obligations identified in the arrangement, we recognize revenue from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we apply an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments: Depending on facts and circumstances, we may conclude that it is appropriate to include the milestone in the estimated transaction price or that it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period that we conclude that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. We may record revenues from certain milestones in a reporting period before the milestone is achieved if we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We record a corresponding contract asset when this conclusion is reached. Milestone payments that have been fully constrained are not included in the transaction price to date. These milestones remain fully constrained until we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We re-evaluate the probability of achievement of such development milestones and any related constraint each reporting period. We adjust our estimate of the overall transaction price, including the amount of revenue recorded, if necessary.

Research and Development Activities: If we are entitled to reimbursement from our customers for specified research and development expenses, we account for them as separate performance obligations if distinct. We also determine whether the research and development funding would result in revenues or an offset to research and development expenses in accordance with provisions of gross or net revenue presentation. The corresponding revenues or offset to research and development expenses are recognized as the related performance obligations are satisfied.

Sales-based Milestone and Royalty Payments: Our customers may be required to pay us sales-based milestone payments or royalties on future sales of commercial products. We recognize revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the customer’s underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license to our intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

Other Potential Products and Services: Arrangements may include an option for license rights, future supply of drug substance or drug product for either clinical development or commercial supply at the licensee’s election. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the inception of the contract and revenue is recognized only if the option is exercised and products or

services are subsequently delivered or when the rights expire. If the promise is based on market terms and not considered a material right, the option is accounted for if and when exercised. If we are entitled to additional payments when the licensee exercises these options, any additional payments are generally recorded in license or other revenues when the licensee obtains control of the goods, which is upon delivery.

For the three and nine months ended September 30, 2018, revenue from transfer of intellectual property principally reflects $18.9 million and $49.9 million of revenue, respectively related to the Pfizer Transaction (as defined below). For the three and nine months ended September 30, 2017, revenue from transfer of intellectual property principally reflects and $21.8

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million and $54.2 million of revenue, respectively related to the Pfizer Transaction. Refer to Note 13. Total contract liabilities included in Accrued expenses and Other long-term liabilities was $89.8 million and $140.4 million at September 30, 2018 and December 31, 2017, respectively. The contract liability balance at September 30, 2018 relates primarily to the Pfizer Transaction.

NOTE 13 STRATEGIC ALLIANCES

Japan Tobacco Inc.

On October 12, 2017, EirGen, our wholly-owned subsidiary, and Japan Tobacco Inc. ("JT") entered into a Development and License Agreement (the "JT Agreement") granting JT the exclusive rights for the development and commercialization of Rayaldee in Japan (the "JT Territory"). The license grant to JT covers the therapeutic and preventative use of the product for (i) SHPT in non-dialysis and dialysis patients with CKD, (ii) rickets, and (iii) osteomalacia (the "JT Initial Indications"), as well as such additional indications as may be added to the scope of the license subject to the terms of the JT Agreement (the "JT Additional Indications" and together with the JT Initial Indications, the "JT Field").

In connection with the license, OPKO received an initial upfront payment of $6 million and received another $6 million upon the initiation of OPKO's Phase 2 study for Rayaldee in dialysis patients in the U.S. in September 2018. OPKO is also eligible to receive up to an additional aggregate amount of $31 million upon the achievement of certain regulatory and development milestones by JT for Rayaldee in the JT Territory, and $75 million upon the achievement of certain sales based milestones by JT in the JT Territory. OPKO will also receive tiered, double digit royalty payments at rates ranging from low double digits to mid-teens on net sales of Rayaldee within the JT Territory. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for Rayaldee in Japan and for all commercial activities pertaining to Rayaldee in Japan.

The JT Agreement provides for the following: (1) an exclusive license in the JT Territory in the JT Field for the development and commercialization of Rayaldee; and (2) at JT's option, EirGen will supply products to support the development, sale and commercialization of the products to JT in the JT Territory.

The initial consideration primarily includes the non-refundable $6 million upfront payment and the $6 million we received upon the initiation of our Phase 2 study for Rayaldee in dialysis patients in the U.S. The initial consideration will be recognized over the performance period through 2021, when we anticipate completing the transfer of license materials specified in the JT Agreement and our performance obligation is complete.

We are also eligible to receive up to $31 million in regulatory and development milestones and $75 million in sales milestones. Payments received for regulatory, development and sales milestones are non-refundable. The milestones are payable if and when the associated milestone is achieved and will be recognized as revenue in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. To date, no revenue has been recognized related to these milestones.

Vifor Fresenius Medical Care Renal Pharma Ltd

In May 2016, EirGen, our wholly-owned subsidiary, and Vifor Fresenius Medical Care Renal Pharma Ltd ("VFMCRP"), entered into a Development and License Agreement (the "VFMCRP Agreement") for the development and commercialization of Rayaldee (the "Product") worldwide, except for (i) the U.S., (ii) any country in Central America or South America (excluding Mexico), (iii) Russia, (iv) China, (v) Japan, (vi) Ukraine, (vii) Belorussia, (viii) Azerbaijan, (ix) Kazakhstan, and (x) Taiwan (the "VFMCRP Territory"). The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the Product in human patients (the "VFMCRP Field"), provided that initially the license is for the use of the Product for the treatment or prevention of SHPT related to patients with stage 3 or 4 CKD and vitamin D insufficiency/deficiency (the "VFMCRP Initial Indication").

Under the terms of the VFMCRP Agreement, EirGen granted to VFMCRP an exclusive license in the VFMCRP Territory in the VFMCRP Field to use certain EirGen patents and technology to make, have made, use, sell, offer for sale, and import Products and to develop, commercialize, have commercialized, and otherwise exploit the Product. EirGen received a non-refundable and non-creditable initial payment of $50 million, which was recognized in Revenue from the transfer of intellectual property and other in our Condensed Consolidated Statement of Operations in 2016. EirGen also received a $2.0 million payment triggered by the approval of Rayaldee in Canada for the treatment of SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency in July 2018. EirGen is also eligible

to receive up to an additional $35 million in regulatory milestones (“Regulatory Milestones”) and $195 million in launch and sales-based milestones (“Sales Milestones”), and will receive tiered

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royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon the commencement of sales of the Product within the VFMCRP Territory and in the VFMCRP Field.

We plan to share responsibility with VFMCRP for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. EirGen will lead the manufacturing activities within and outside the VFMCRP Territory and the commercialization activities outside the VFMCRP Territory and outside the VFMCRP Field in the VFMCRP Territory and VFMCRP will lead the commercialization activities in the VFMCRP Territory and the VFMCRP Field. For the initial development plan, the companies have agreed to certain cost sharing arrangements. VFMCRP will be responsible for all other development costs that VFMCRP considers necessary to develop the Product for the use of the Product for the VFMCRP Initial Indication in the VFMCRP Territory in the VFMCRP Field except as otherwise provided in the VFMCRP Agreement. The first of the clinical studies provided for in the development activities commenced in September 2018.

In connection with the VFMCRP Agreement, the parties entered into a letter agreement pursuant to which EirGen granted to VFMCRP an exclusive option (the "Option") to acquire an exclusive license under certain EirGen patents and technology to use, import, offer for sale, sell, distribute and commercialize the Product in the U.S. solely for the treatment of SHPT in dialysis patients with CKD and vitamin D insufficiency (the "Dialysis Indication"). Upon exercise of the Option, VFMCRP will reimburse EirGen for all of the development costs incurred by EirGen with respect to the Product for the Dialysis Indication in the U.S. VFMCRP would also pay EirGen up to an additional aggregate amount of $555 million of sales-based milestones upon the achievement of certain milestones and would be obligated to pay royalties at percentage rates that range from the mid-teens to the mid-twenties on sales of the Product in the U.S. for the Dialysis Indication. To date, VFMCRP has not exercised its option.

Payments received for Regulatory Milestones and Sales Milestones are non-refundable. The Regulatory Milestones are payable if and when VFMCRP obtains approval from certain regulatory authorities and will be recognized as revenue in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. We account for the Sales Milestones as royalties and Sales Milestones payments will be recognized as revenue in the period in which the associated milestone is achieved or sales occur, assuming all other revenue recognition criteria are met.

Pfizer Inc.

In December 2014, we entered into an exclusive worldwide agreement with Pfizer Inc. ("Pfizer") for the development and commercialization of our long-acting hGH-CTP for the treatment of growth hormone deficiency ("GHD") in adults and children, as well as for the treatment of growth failure in children born small for gestational age ("SGA") (the "Pfizer Transaction").

The Pfizer Transaction closed in January 2015 following the termination of the waiting period under the Hart-Scott-Rodino Act. Under the terms of the Pfizer Transaction, we received non-refundable and non-creditable upfront payments of $295.0 million and are eligible to receive up to an additional $275.0 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both hGH-CTP and Pfizer's Genotropin®.

The agreement with Pfizer will remain in effect until the last sale of the licensed product, unless earlier terminated as permitted under the agreement. In addition to termination rights for material breach and bankruptcy, Pfizer is permitted to terminate the Agreement in its entirety, or with respect to one or more world regions, without cause after a specified notice period. If the Agreement is terminated by us for Pfizer's uncured material breach, or by Pfizer without cause, provision has been made for transition of product and product responsibilities to us for the terminated regions, as well as continued supply of product by Pfizer or transfer of supply to us in order to support the terminated regions.

We are recognizing the non-refundable $295.0 million upfront payments as the research and development services are completed and had contract liabilities related to the Pfizer Transaction of $81.2 million at September 30, 2018, of

which $58.8 million was classified in Accrued expenses and $22.4 million was classified in Other long-term liabilities.

The Pfizer Transaction includes milestone payments of $275.0 million upon the achievement of certain milestones. The milestones range from $20.0 million to $90.0 million each and are based on achievement of regulatory approval in the U.S. and regulatory approval and price approval in other major markets. The milestone payments will be recognized as revenue in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. To date, no revenue has been recognized related to the achievement of the milestones.

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TESARO

In November 2009, we entered into an asset purchase agreement (the "NK-1 Agreement") under which we acquired VARUBI™ (rolapitant) and other neurokinin-1 ("NK-1") assets from Merck. In December 2010, we entered into an exclusive license agreement with TESARO, in which we out-licensed the development, manufacture, commercialization and distribution of our lead NK-1 candidate, VARUBI™ (the "TESARO License"). Under the terms of the license, we received a $6.0 million upfront payment from TESARO and we received $30 million of milestone payments from TESARO upon achievement of certain regulatory and commercial sale milestones and we are eligible to receive additional commercial milestone payments of up to $85 million if specified levels of annual net sales are achieved. The sales based milestone payments will be recognized as revenue in full in the period in which the associated sales occur. During the nine months ended September 30, 2018, no revenue was recognized related to the achievement of the milestones under the TESARO License. During the nine months ended September 30, 2017, $10.0 million of revenue was recognized related to the achievement of the milestones under the TESARO License.

TESARO is also obligated to pay us tiered royalties on annual net sales achieved in the U.S. and Europe at percentage rates that range from the low double digits to the low twenties, and outside of the U.S. and Europe at low double-digit percentage rates. Royalties will be recognized in the period the sales occur. TESARO assumed responsibility for clinical development and commercialization of licensed products at its expense. Under the NK-1 Agreement, we will continue to receive royalties on a country-by-country and product-by-product basis until the later of the date that all of the patent rights licensed from us and covering VARUBI™ expire, are invalidated or are not enforceable and 12 years from the first commercial sale of the product.

If TESARO elects to develop and commercialize VARUBI™ in Japan through a third-party licensee, TESARO will share equally with us all amounts it receives in connection with such activities, subject to certain exceptions and deductions.

The term of the license will remain in force until the expiration of the royalty term in each country, unless we terminate the license earlier for TESARO's material breach of the license or bankruptcy. TESARO has a right to terminate the license at any time during the term for any reason on three months' written notice.

TESARO announced during the first quarter of 2018 that it has elected to suspend further distribution of Varubi IV.

Pharmsynthez

In April 2013, we entered into a series of concurrent transactions with Pharmsynthez, a Russian pharmaceutical company traded on the Moscow Stock Exchange, pursuant to which we acquired an equity method investment in Pharmsynthez (ownership 9%). We also granted rights to certain technologies in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan (the "Pharmsynthez Territories") to Pharmsynthez and agreed to perform certain development activities. We will receive from Pharmsynthez royalties on net sales of products incorporating the technologies in the Pharmsynthez Territories, as well as a percentage of any sublicense income from third parties for the technologies in the Pharmsynthez Territories.

RXi Pharmaceuticals Corporation

In March 2013, we completed the sale to RXi of substantially all of our assets in the field of RNA interference (the "RNAi Assets") (collectively, the "Asset Purchase Agreement"). Pursuant to the Asset Purchase Agreement, RXi will be required to pay us up to $50.0 million in milestone payments upon the successful development and commercialization of each drug developed by RXi, certain of its affiliates or any of its or their licensees or sublicensees utilizing patents included within the RNAi Assets (each, a "Qualified Drug"). In addition, RXi will also be required to pay us royalties equal to: (a) a mid single-digit percentage of "Net Sales" (as defined in the Asset Purchase Agreement) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable "Royalty Period" (as defined in the Asset Purchase Agreement); and (b) a low single-digit percentage of net sales with respect to each Qualified Drug sold for a non-ophthalmologic use during the applicable Royalty Period.

Other

We have completed strategic deals with numerous institutions and commercial partners. In connection with these agreements, upon the achievement of certain milestones we are obligated to make certain payments and have royalty obligations upon sales of products developed under the license agreements. At this time, we are unable to estimate the timing and amounts of payments as the obligations are based on future development of the licensed products.

NOTE 14 SEGMENTS

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We manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of our pharmaceutical operations we acquired in Chile, Mexico, Ireland, Israel and Spain, Rayaldee product sales and our pharmaceutical research and development. The diagnostics segment primarily consists of our clinical laboratory operations we acquired through the acquisition of BioReference and our point-of-care operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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Information regarding our operations and assets for our operating segments and the unallocated corporate operations as well as geographic information are as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
(In thousands)	2018	2017	2018	2017
Revenue from services:				
Pharmaceutical	$—	$—	$—	$—
Diagnostics	202,811	200,876	630,180	663,333
Corporate	—	—	—	—
	$202,811	$200,876	$630,180	$663,333
Revenue from products:				
Pharmaceutical	$25,395	$22,795	$81,769	$73,992
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$25,395	$22,795	$81,769	$73,992
Revenue from transfer of intellectual property and other:				
Pharmaceutical	$21,609	$22,369	$56,463	$67,697
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$21,609	$22,369	$56,463	$67,697
Operating loss:				
Pharmaceutical	$(16,937)	$(10,823)	$(37,721)	$(42,080)
Diagnostics	(11,082)	(24,723)	(17,624)	(35,664)
Corporate	(5,445)	(12,219)	(25,839)	(41,067)
	$(33,464)	$(47,765)	$(81,184)	$(118,811)
Depreciation and amortization:				
Pharmaceutical	$7,021	$6,935	$20,514	$20,404
Diagnostics	16,880	18,430	52,855	56,183
Corporate	20	29	71	90
	$23,921	$25,394	$73,440	$76,677
Loss from investment in investees:				
Pharmaceutical	$(1,603)	$(3,661)	$(10,715)	$(10,784)
Diagnostics	(271)	(352)	(827)	(987)
Corporate	—	—	—	—
	$(1,874)	$(4,013)	$(11,542)	$(11,771)
Revenues:				
United States	$208,646	$201,059	$646,492	$674,073
Ireland	24,407	25,886	62,468	66,690
Chile	8,926	11,514	32,596	33,534
Spain	4,144	4,123	14,269	13,746
Israel	2,283	1,935	8,424	13,807
Mexico	1,382	1,483	4,105	3,072
Other	27	40	58	100
	$249,815	$246,040	$768,412	$805,022

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(In thousands)	September 30, 2018	December 31, 2017
Assets:		
Pharmaceutical	$ 1,257,043	$ 1,287,964
Diagnostics	1,176,798	1,241,388
Corporate	47,153	60,604
	$ 2,480,994	$ 2,589,956
Goodwill:		
Pharmaceutical	$ 260,842	$ 264,313
Diagnostics	452,787	452,786
Corporate	—	—
	$ 713,629	$ 717,099

No customer represented more than 10% of our total consolidated revenue during the three and nine months ended September 30, 2018 and 2017. As of September 30, 2018 and December 31, 2017, no customer represented more than 10% of our accounts receivable balance.

NOTE 15 SUBSEQUENT EVENTS

Private Placements of Common Stock

On November 8, 2018, we entered into stock purchase agreements with certain investors pursuant to which we agreed to sell to such investors in private placements an aggregate of approximately 26.5 million shares of our Common Stock (the “Shares”) at a purchase price of $3.49 per share, which was the closing bid price of our Common Stock on the NASDAQ Global Select Market (“NASDAQ”) on such date, for an aggregate purchase price of $92.5 million. The closing of the private placements is subject to obtaining requisite approval from NASDAQ for the listing of the Shares. The investors in the private placements include an affiliate of Dr. Phillip Frost, our Chairman and Chief Executive Officer ($70 million), and Dr. Jane Hsiao, our Vice Chairman and Chief Technical Officer ($2 million). We intend to use the proceeds from the private placements for general corporate purposes.The issuance of the Shares will be made in reliance on the exemption from registration provided in Section 4(a)(2) of the Securities Act based upon the representations made by the investors that they are “accredited investors” and that they are purchasing the Shares without a present view toward a distribution of the Shares.

Credit Agreement

On November 8, 2018, we entered into a credit agreement with an affiliate of Dr. Frost, pursuant to which the lender committed to provide us with an unsecured line of credit in the amount of $60 million. Borrowings under the line of credit will bear interest at a rate of 10% per annum and may be repaid and reborrowed at any time. The credit agreement includes various customary remedies for the lender following an event of default, including the acceleration of repayment of outstanding amounts under line of credit. The line of credit matures on November 8, 2023.

We have reviewed all subsequent events and transactions that occurred after the date of our September 30, 2018 Condensed Consolidated Balance Sheet date, through the time of filing this Quarterly Report on Form 10-Q.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

OVERVIEW

You should read this discussion together with the unaudited Condensed Consolidated Financial Statements, related Notes, and other financial information included elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2017 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part II, Item 1A of our Form 10-K for the year ended December 31, 2017, and described from time to time in our other reports filed with the Securities and Exchange Commission. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories ("BioReference"), the nation's third-largest clinical laboratory with a core genetic testing business and an almost 400-person sales and marketing team to drive growth and leverage new products, including the 4Kscore prostate cancer test and the Claros 1 in-office immunoassay platform (in development). Our pharmaceutical business features Rayaldee, an FDA-approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency (launched in November 2016), OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia, and OPK88003, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists (Phase 2b). Our pharmaceutical business also features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer).

We operate established pharmaceutical platforms in Spain, Ireland, Chile and Mexico, which are generating revenue and from which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. We have a development and commercial supply pharmaceutical company, as well as a global supply chain operation and holding company in Ireland, which we expect will play an important role in the development, manufacturing, distribution and approval of a wide variety of drugs with an emphasis on high potency products. We also own a specialty active pharmaceutical ingredients ("APIs") manufacturer in Israel, which we expect will facilitate the development of our pipeline of molecules and compounds for our proprietary molecular diagnostic and therapeutic products.

RECENT DEVELOPMENTS

In September 2018, we announced the initiation of a Phase 2 clinical trial to study the safety and efficacy of Rayaldee as a new treatment for SHPT in adults with vitamin D insufficiency and stage 5 CKD requiring hemodialysis. The trial will be conducted at multiple dialysis centers in the U.S. in two sequential cohorts. The first cohort of approximately 44 patients will be treated for 26 weeks in a randomized, open-label fashion with either Rayaldee or placebo to identify the appropriate dosing to be studied in the second cohort. Data readout for this first cohort is expected in 2019.

The second cohort of more than 200 patients will be treated for 26 weeks in a randomized, double-blind fashion with one of three different doses of Rayaldee or placebo. The primary efficacy endpoint will be correction of vitamin D insufficiency and control of SHPT. Patients will then be treated with Rayaldee for another 26 weeks in an open-label extension.

In July 2018, we announced that our partner Vifor Fresenius Medical Care Renal Pharma ("VFMCRP") has received approval from Health Canada to market Rayaldee in Canada for the treatment of SHPT in adults with CKD and vitamin D insufficiency.

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RESULTS OF OPERATIONS
FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

Effective January 1, 2018, we adopted Accounting Standards Codification Topic 606, Revenue from Contracts with Customers, using the full retrospective transition method. Under this method, we have revised our Condensed Consolidated Financial Statements for the years ended December 31, 2017 and 2016, and applicable interim periods within those years, as if Topic 606 had been effective for those periods. For further discussion on the impact of adopting Topic 606, refer to Note 2 to the Condensed Consolidated Financial Statements.

Revenues	For the three months ended September 30,		
(In thousands)	2018	2017	Change
Revenue from services	$202,811	$200,876	$1,935
Revenue from products	25,395	22,795	2,600
Revenue from transfer of intellectual property and other	21,609	22,369	(760)
Total revenues	$249,815	$246,040	$3,775

Revenue from services for the three months ended September 30, 2018 were negatively affected by $3.5 million as a result of reduction in test volumes, reduced reimbursement of $3.9 million for clinical testing due to the Protecting Access to Medicare Act of 2014 (“PAMA”), which came into effect in January 2018, reduced genomics reimbursement of $8.4 million and payor accruals of $2.0 million of amounts previously paid. Partially offsetting these decreases, Revenue from services increased by $8.4 million from improved collections for our clinical testing.

Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when estimating variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known based on actual collection experience. For the three months ended September 30, 2018 and 2017, changes to estimated collection amounts from third-party payors negatively affected revenue by $10.0 million and $21.4 million, respectively. The adjustments for the three months ended September 30, 2018 relate to both our clinical and genomics testing as a result of changes to payor medical and procedural requirements. The adjustments for the three months ended September 30, 2017 relate to payor claims processing adjustments due to changes to payor medical requirements for our clinical testing and delays in the billing cycle resulting from our implementation of a new clinical testing billing system in late 2016.

We may have an obligation to reimburse Medicare, Medicaid, and third-party payers for overpayments regardless of fault. We have periodically identified and reported overpayments, reimbursed payors for overpayments and taken appropriate corrective action. Settlements with third-party payors for retroactive adjustments due to audits, reviews or investigations are considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews, and investigations. During the fourth quarter of 2017, a payor informed us it had overpaid BioReference due to an error on its part over several years period, including multiple years prior to the acquisition of BioReference by OPKO in August 2015. As of September 30, 2018 and December 31, 2017, we have liabilities of approximately $32.5 million and $30.0 million within Accrued expenses related to reimbursements for payor overpayments.

The composition of Revenue from services by payor for the three months ended September 30, 2018 and 2017 is as follows:

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	Three months ended September 30,	
(In thousands)	2018	2017
Healthcare insurers	$92,059	$92,978
Government payers	67,913	67,347
Client payers	37,772	34,724
Patients	5,067	5,827
Total	$202,811	$200,876

The increase in Revenue from products is primarily attributable to $5.8 million of revenue from sales of Rayaldee, which was partially offset by a decrease in revenue at OPKO Chile. Revenue from transfer of intellectual property for the three months ended September 30, 2018 and 2017 principally reflects $18.9 million and $21.8 million, respectively, of revenue related to the Pfizer Transaction. Revenue from transfer of intellectual property for the three months ended September 30, 2018 also includes $2.0 million of revenue from a milestone payment from our licensee, VFMCRP.

Cost of revenue. Cost of revenue for the three months ended September 30, 2018 decreased $0.4 million compared to 2017. Cost of service revenue as a percentage of Revenue from services was consistent with the comparative period in 2017. The decrease in the cost of product revenue is attributable to changes in the product mix of items sold during the period compared to the prior year period. Cost of revenue for the three months ended September 30, 2018 and 2017 was as follows:

Cost of Revenue	For the three months ended September 30,		
(In thousands)	2018	2017	Change
Cost of service revenue	$137,347	$135,203	$2,144
Cost of product revenue	13,609	16,107	(2,498)
Total cost of revenue	$150,956	$151,310	$(354)

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2018 and 2017, were $84.1 million and $103.2 million, respectively. The decrease in selling, general and administrative expenses was primarily due to decreased expenses at BioReference due to planned cost reduction initiatives and to a decrease in corporate expenses. Selling, general and administrative expenses for the three months ended September 30, 2017 also reflect higher professional fees related to the implementation of a new billing system at BioReference. Selling, general and administrative expenses during the three months ended September 30, 2018 and 2017, include equity-based compensation expense of $3.4 million and $4.6 million, respectively.

Research and development expenses. Research and development expenses for the three months ended September 30, 2018 and 2017, were $30.2 million and $32.5 million, respectively. Research and development costs include external and internal expenses. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for Phase 3 clinical trials for drug approval and pre-market approvals (“PMAs”) for diagnostics tests, if any. Internal expenses include employee-related expenses including salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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The following table summarizes the components of our research and development expenses:

Research and Development Expenses	For the three months ended September 30,	
	2018	2017
External expenses:		
Phase 3 clinical trials	$4,357	$3,275
Manufacturing expense for biological products	12,772	10,827
PMA studies	—	249
Earlier-stage programs	4,630	1,479
Research and development employee-related expenses	1,216	6,178
Other internal research and development expenses	8,025	10,500
Third-party grants and funding from collaboration agreements	(840)	—
Total research and development expenses	$30,160	$32,508

The decrease in research and development expenses for the quarter is primarily due to research and development tax credits of approximately $5.2 million in Ireland recognized in 2018. Research and development expenses for the three months ended September 30, 2018 and 2017 include equity-based compensation expense of $1.0 million and $1.3 million, respectively. We expect our research and development expenses to increase as we continue to expand our research and development of potential future products.

Contingent consideration. Contingent consideration for the three months ended September 30, 2018 and 2017, were $1.2 million of expense and $11.2 million of income, respectively. The change in contingent consideration income (expense) was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal. The contingent consideration liabilities at September 30, 2018 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $16.9 million and $18.0 million, respectively, for the three months ended September 30, 2018 and 2017. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Our indefinite lived IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, the IPR&D assets will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Interest income. Interest income for the three months ended September 30, 2018 and 2017 was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

Interest expense. Interest expense for the three months ended September 30, 2018 and 2017 was $2.9 million and $1.8 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes, interest incurred on BioReference's outstanding debt under its credit facility and interest incurred on the 2023 Convertible Notes issued in February 2018. The increase in interest expense for the three months ended September 30, 2018 is primarily due to interest incurred on the the 2023 Convertible Notes and to higher outstanding debt and interest rates under BioReference's credit facility in 2018 compared to 2017.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended September 30, 2018 and 2017, was $0.2 million and $7.6 million of expense, respectively. Derivative income for the three months ended September 30, 2018 principally related to the change in fair value of warrants to purchase additional shares of Xenetic. Derivative expense for the three months ended September 30, 2017 principally related to the change in the fair value of the embedded derivatives in the 2033 Senior Notes.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2018 and 2017, were $0.8 million of expense and $0.6 million of income, respectively. Other income for the three months ended September 30, 2018 primarily consists of net unrealized losses recognized during the period on equity securities.

Income tax benefit. Our income tax benefit for the three months ended September 30, 2018 and 2017 was $11.6 million and $24.4 million, respectively, and reflects quarterly results using our expected effective tax rate. For the

three months ended September 30, 2018, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the valuation allowance against certain U.S. and non-U.S. deferred tax assets, the relative mix in earnings and losses in the U.S. versus foreign tax

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jurisdictions, and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report a net loss. Loss from investments in investees was $1.9 million and $4.0 million for the three months ended September 30, 2018 and 2017, respectively.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

Revenues	For the nine months ended September 30,		
(In thousands)	2018	2017	Change
Revenue from services	$630,180	$663,333	$(33,153)
Revenue from products	81,769	73,992	7,777
Revenue from transfer of intellectual property and other	56,463	67,697	(11,234)
Total revenues	$768,412	$805,022	$(36,610)

Revenue from services for the nine months ended September 30, 2018 were negatively affected by $21.9 million as a result of changes in clinical test volumes, reduced clinical reimbursement of $11.7 million due to PAMA which came into effect in January 2018, reduced genomics reimbursement of $11.4 million, and payor recoupment accruals of $2.0 million of amounts previously paid. Partially offsetting these decreases, Revenue from services increased by $1.6 million from higher volume for our genomics testing. Revenue from services also increased by $5.1 million from improved collections for our clinical testing resulting from improvements in our billing cycle.

For the nine months ended September 30, 2018 and 2017, adjustments to estimated collection amounts from third-party payors decreased revenue by $23.4 million and $30.7 million, respectively. The adjustments for the nine months ended September 30, 2018 primarily relate to our clinical testing and for 2017, primarily relate to our genomics testing.

During the fourth quarter of 2017, a payor informed us it had overpaid BioReference due to an error on its part over a period of approximately ten years, which was prior to the acquisition of BioReference by OPKO in August 2015. As of September 30, 2018 and December 31, 2017, we have liabilities of approximately $32.5 million and $30.0 million within Accrued expenses related to reimbursements for payor overpayments.

The composition of Revenue from services by payor for the nine months ended September 30, 2018 and 2017 is as follows:

	Nine months ended September 30,	
(In thousands)	2018	2017
Healthcare insurers	$288,071	$313,065
Government payers	209,316	226,492
Client payers	116,123	106,499
Patients	16,670	17,277
Total	$630,180	$663,333

The increase in Revenue from products is primarily attributable to $14.3 million of revenue from sales of Rayaldee, which was partially offset by a decrease in revenue at FineTech. Revenue from transfer of intellectual property for the nine months ended September 30, 2018 and 2017 principally reflects $49.9 million and $54.2 million, respectively, of revenue related to the Pfizer Transaction. Revenue from transfer of intellectual property for the nine months ended September 30, 2018 and 2017, also reflects $2.0 million and $10.0 million, respectively, of revenue from milestone payments from our licensees, VFMCRP and TESARO.

Cost of revenue. Cost of revenue for the nine months ended September 30, 2018 decreased $8.4 million compared to 2017. Cost of service revenue decreased in 2018 compared to 2017 due to a decrease in volume and employee related costs for

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clinical testing at BioReference. The decrease in the cost of product revenue is attributable to changes in the product mix of items sold during the period. Cost of revenue for the nine months ended September 30, 2018 and 2017 were as follows:

Cost of Revenue	For the nine months ended September 30,		
(In thousands)	2018	2017	Change
Cost of service revenue	$411,196	$419,070	$(7,874)
Cost of product revenue	43,909	44,441	(532)
Total cost of revenue	$455,105	$463,511	$(8,406)

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2018 and 2017, were $263.2 million and $318.7 million, respectively. The decrease in selling, general and administrative expenses was primarily due to decreased expenses at BioReference due to planned cost reduction initiatives and to a decrease in corporate expenses. Selling, general and administrative expenses for the nine months ended September 30, 2017 also reflect higher professional fees related to the implementation of a new billing system at BioReference. Selling, general and administrative expenses during the nine months ended September 30, 2018 and 2017, include equity-based compensation expense of $11.2 million and $16.7 million, respectively.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2018 and 2017, were $92.3 million and $92.2 million, respectively. Research and development costs include external and internal expenses. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for Phase 3 clinical trials for drug approval and PMAs for diagnostics tests, if any. Internal expenses include employee-related expenses including salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

The following table summarizes the components of our research and development expenses:

Research and Development Expenses	For the nine months ended September 30,	
	2018	2017
External expenses:		
Phase 3 clinical trials	$12,963	$11,354
Manufacturing expense for biological products	30,442	31,102
PMA studies	59	694
Earlier-stage programs	10,245	4,734
Research and development employee-related expenses	19,450	18,915
Other internal research and development expenses	19,939	25,394
Third-party grants and funding from collaboration agreements	(840)	—
Total research and development expenses	$92,258	$92,193

Overall research and development expenses in 2018 was consistent with the comparative period in 2017 as an increase in research and development expenses in 2018 related to a once or twice weekly oxyntomodulin for type 2 diabetes and to a selective androgen receptor modulator for benign prostatic hyperplasia were offset by research and development tax credits recognized in 2018. Research and development expenses for the nine months ended September 30, 2018 and 2017 include equity-based compensation expense of $3.3 million and $4.0 million, respectively. We expect our research and development expenses to increase as we continue to expand our research and development of potential future products.

Contingent consideration. Contingent consideration for the nine months ended September 30, 2018 and 2017, were $12.4 million and $4.5 million of income, respectively. The change in contingent consideration was primarily

attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal. Amortization of intangible assets. Amortization of intangible assets was $51.4 million and $53.9 million, respectively, for the nine months ended September 30, 2018 and 2017. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Our indefinite lived IPR&D assets will not be amortized until the underlying development

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programs are completed. Upon obtaining regulatory approval by the U.S. FDA, the IPR&D assets will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Interest income. Interest income for the nine months ended September 30, 2018 and 2017 was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

Interest expense. Interest expense for the nine months ended September 30, 2018 and 2017 was $7.9 million and $4.8 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes, interest incurred on BioReference's outstanding debt under its credit facility and interest incurred on the 2023 Convertible Notes issued in February 2018. The increase in interest expense for the nine months ended September 30, 2018 is primarily due to interest incurred on the 2023 Convertible Notes and to higher outstanding debt and interest rates under BioReference's credit facility in 2018 compared to 2017.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the nine months ended September 30, 2018 and 2017, was $3.5 million and $2.0 million of income, respectively. Derivative income for the nine months ended September 30, 2018 principally related to the change in fair value of warrants to purchase additional shares of Neovasc. Derivative income for the nine months ended September 30, 2017 principally related to the change in the fair value of the embedded derivatives in the 2033 Senior Notes.

Other income (expense), net. Other income (expense), net for the nine months ended September 30, 2018 and 2017, were $9.7 million and $3.1 million of income, respectively. Other income for the nine months ended September 30, 2018 primarily consists of net unrealized gains recognized during the period on equity securities. Other income for the nine months ended September 30, 2017 primarily consists of a $3.0 million gain on the sale of non-strategic assets at a wholly-owned BioReference subsidiary.

Income tax benefit. Our income tax benefit for the nine months ended September 30, 2018 and 2017 was $10.4 million and $42.3 million, respectively, and reflects results using our expected effective tax rate. For the nine months ended September 30, 2018, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the valuation allowance against certain U.S. and non-U.S. deferred tax assets, the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report a net loss. Loss from investments in investees was $11.5 million and $11.8 million for the nine months ended September 30, 2018 and 2017, respectively.

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LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2018, we had cash and cash equivalents of approximately $43.7 million. Cash used in operations of $74.5 million during 2018 principally reflects expenses related to general and administrative activities of our corporate operations, research and development activities and commercialization activities related to Rayaldee. Cash used in investing activities primarily reflects capital expenditures of $24.8 million. Cash provided by financing activities primarily reflects the issuance of $55.0 million of 2023 Convertible Notes in February 2018. We have not generated sustained positive cash flow sufficient to offset our operating and other expenses and our primary source of cash has been from the public and private placement of stock, the issuance of the 2033 Senior Notes and 2023 Convertible Notes and credit facilities available to us.

On November 8, 2018, we entered into stock purchase agreements with certain investors pursuant to which we agreed to sell to such investors in private placements an aggregate of approximately 26.5 million shares of our Common Stock (the "Shares") at a purchase price of $3.49 per share, which was the closing bid price of our Common Stock on the NASDAQ Global Select Market ("NASDAQ") on such date, for an aggregate purchase price of $92.5 million. The closing of the private placements is subject to obtaining requisite approval from NASDAQ for the listing of the Shares. The investors in the private placements include an affiliate of Dr. Phillip Frost, our Chairman and Chief Executive Officer ($70 million), and Dr. Jane Hsiao, our Vice Chairman and Chief Technical Officer ($2 million). We intend to use the proceeds from the private placements for general corporate purposes.

On November 8, 2018, we entered into a credit agreement with an affiliate of Dr. Frost, pursuant to which the lender committed to provide us with an unsecured line of credit in the amount of $60 million. Borrowings under the line of credit will bear interest at a rate of 10% per annum and may be repaid and reborrowed at any time. The credit agreement includes various customary remedies for the lender following an event of default, including the acceleration of repayment of outstanding amounts under line of credit. The line of credit matures on November 8, 2023.

In January 2013, we issued $175.0 million of the 2033 Senior Notes. The 2033 Senior Notes were sold in a private placement in reliance on exemptions from registration under the Securities Act. At September 30, 2018, $31.9 million principal amount of 2033 Senior Notes was outstanding. Holders of the 2033 Senior Notes may require us to repurchase the 2033 Senior Notes for 100% of their principal amount, plus accrued and unpaid interest, on February 1, 2019. Holders of the 2033 Senior Notes may require us to repurchase the 2033 Senior Notes for 100% of their principal amount, plus accrued and unpaid interest, on February 1, 2023 and February 1, 2028, or following the occurrence of a fundamental change as defined in the indenture governing the 2033 Senior Notes.

In August 2017, we entered into a Commitment Letter (the "Commitment Letter") with Veterans Accountable Care Group, LLC ("VACG") in connection with submission of a bid by its affiliate, the Veterans Accountable Care Organization, LLC ("VACO") in response to a request for proposal ("RFP") from the Veterans Health Administration ("VA") regarding its Community Care Network. If VACO is successful in its bid, we will acquire a fifteen percent (15%) membership interest in VACO. In addition, BioReference, our wholly-owned subsidiary, will provide laboratory services for the Community Care Network, a region which currently includes approximately 2,133,000 veterans in the states of Massachusetts, Maine, New Hampshire, Vermont, New York, Pennsylvania, New Jersey, Rhode Island, Connecticut, Maryland, Virginia, West Virginia, and North Carolina.

Pursuant to the Commitment Letter, we committed to provide, or to arrange from a third-party lender, a line of credit for VACG in the amount of $50.0 million (the "Facility"). Funds drawn under the Facility would be contributed by VACG to VACO in order to satisfy the financial stability requirement of VACO in connection with its submission of the RFP. VACG would not be permitted to draw down on the Facility unless and until the VHA awards a contract to VACO. The Facility would have a maturity of 5 years. Interest on the Facility would be payable at a rate equal to 6.5% per annum, payable quarterly in arrears. The Facility is subject to the negotiation of definitive documentation conditions customary for transactions of such type and otherwise acceptable to VACG and the lender under the Facility.

We currently anticipate that a decision by the VHA with respect to the RFP will occur during the first half of 2019, although there can be no assurance that a decision will be made by such time or that, if favorable, such decision will not be challenged by participants in the RFP process or otherwise.

As of September 30, 2018, the total availability under our Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain was $138.0 million, of which $109.7 million was used and outstanding as of September 30, 2018. The weighted average interest rate on these lines of credit is approximately 4.7%. These lines of credit are short-term and are used primarily as a source of working capital. The highest balance at any time during the nine months

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ended September 30, 2018, was $114.9 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

In February 2018, we issued the 2023 Convertible Notes in the aggregate principal amount of $55.0 million. The 2023 Convertible Notes mature 5 years from the date of issuance. Each holder of a 2023 Convertible Note has the option, from time to time, to convert all or any portion of the outstanding principal balance of such 2023 Convertible Note, together with accrued and unpaid interest thereon, into shares of our Common Stock, par value $0.01 per share, at a conversion price of $5.00 per share of Common Stock (the "Shares"). We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon, pro ratably among the holders, upon no fewer than 30 days, and no more than 60 days, notice to the holders. The 2023 Convertible Notes contain customary events of default and representations and warranties of OPKO. We are using the proceeds of the 2023 Convertible Notes for general corporate purposes.

The issuance of the 2023 Convertible Notes and the issuance of the Shares, if any, upon conversion thereof was not, and will not be, respectively, registered under the Securities Act, pursuant to the exemption provided by Section 4(a)(2) thereof, and we have not agreed to register the Shares if or when such Shares are issued. Purchasers of the 2023 Convertible Notes include an affiliate of Dr. Phillip Frost, M.D., our Chairman and Chief Executive Officer, and Dr. Jane H. Hsiao, Ph.D., MBA, our Vice-Chairman and Chief Technical Officer.

On October 12, 2017, EirGen, our wholly-owned subsidiary, and Japan Tobacco Inc. ("JT") entered into a Development and License Agreement (the "JT Agreement") granting JT the exclusive rights for the development and commercialization of Rayaldee in Japan (the "JT Territory"). The license grant to JT covers the therapeutic and preventative use of Rayaldee for (i) SHPT in non-dialysis and dialysis patients with CKD, (ii) rickets, and (iii) osteomalacia, as well as such additional indications as may be added to the scope of the license subject to the terms of the JT Agreement. In connection with the transaction, OPKO received an initial upfront payment of $6 million, and OPKO received another $6 million upon the initiation of OPKO's Phase 2 study for Rayaldee in dialysis patients in the U.S. in September 2018. OPKO is also eligible to receive up to an additional aggregate amount of $31 million upon the achievement of certain regulatory and development milestones by JT for Rayaldee in the JT Territory, and $75 million upon the achievement of certain sales based milestones by JT in the JT Territory. OPKO will also receive tiered, double digit royalty payments at rates ranging from low double digits to mid-teens on sales of Rayaldee within the JT Territory. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for Rayaldee in Japan and for all commercial activities pertaining to Rayaldee in Japan.

In May 2016, EirGen, our wholly-owned subsidiary, partnered with VFMCRP through a Development and License Agreement for the development and commercialization of Rayaldee in Europe, Canada, Mexico, Australia, South Korea and certain other international markets. The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the product in human patients, provided that initially the license is for the use of the product for the treatment or prevention of SHPT related to patients with stage 3 or 4 CKD and vitamin D insufficiency/deficiency ("VFMCRP Initial Indication"). We have received non-refundable and non-creditable payments of $52 million and are eligible to receive up to an additional $230 million upon the achievement of certain regulatory and sales-based milestones. In addition, we are eligible to receive tiered royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon commencement of sales of the product.

As part of the arrangement, the companies will share responsibility for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. For the initial development plan, the companies have agreed to certain cost sharing arrangements. VFMCRP will be responsible for all other development costs that VFMCRP considers necessary to develop the product for the VFMCRP Initial Indication in the VFMCRP Territory except as otherwise provided in the VFMCRP Agreement. EirGen also granted to VFMCRP an option to acquire an exclusive license to use, import, offer for sale, sell, distribute and commercialize the product in the U.S. for treatment of SHPT in dialysis patients with stage 5 CKD and vitamin D insufficiency (the "Dialysis Indication"). Upon exercise of the Option, VFMCRP will reimburse EirGen for all of the development costs

incurred by EirGen with respect to the product for the Dialysis Indication in the U.S. VFMCRP would also pay EirGen up to an additional aggregate amount of $555 million upon the achievement of certain milestones and would be obligated to pay royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon commencement of sales of the product.

In January 2015, we partnered with Pfizer through a worldwide agreement for the development and commercialization of our long-acting hGH-CTP for the treatment of GHD in adults and children, as well as for the treatment of growth failure in children born SGA. Under the terms of the agreements with Pfizer, we received non-refundable and non-creditable upfront payments of $295 million in 2015 and are eligible to receive up to an additional $275 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for Adult GHD with

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percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both hGH-CTP and Pfizer's Genotropin®.

We will lead the clinical activities and will be responsible for funding the development programs for the key indications, which includes Adult and Pediatric GHD and Pediatric SGA. Pfizer is responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer is required to fund the commercialization activities for all indications and lead the manufacturing activities covered by the global development plan. In December 2016, we announced preliminary topline data from our Phase 3, double blind, placebo controlled study of hGH-CTP in adults with GHD. Although there was no statistically significant difference between hGH-CTP and placebo on the primary endpoint of change in trunk fat mass from baseline to 26 weeks, after unblinding the study, we identified an exceptional value of trunk fat mass reduction in the placebo group that may have affected the primary outcome.

We have completed post-hoc sensitivity analyses to evaluate the influence of outliers on the primary endpoint results using multiple statistical approaches. Analyses that excluded outliers showed a statistically significant difference between hGH-CTP and placebo on the change in trunk fat mass. Additional analyses that did not exclude outliers showed mixed results. Following completion of the analyses, OPKO and Pfizer agreed that OPKO may proceed to discuss a possible BLA submission with the FDA. We believe there is a path for submission in which the FDA would assess the totality of the data, including all relevant efficacy and safety data in adult and pediatric patients. We will continue to assess the regulatory strategy for the adult indication going forward, including the timing of a possible submission.

In August 2018, we announced that we had completed enrollment in a global Phase 3 study of hGH-CTP in growth hormone deficient children. The development project for hGH-CTP will exceed our original estimates and could result in additional expenses beyond our estimates.

We are constructing a research, development and manufacturing center in Waterford, Ireland, for which we will incur between $40 million and $45 million for the construction and validation of the facility. Construction of the facility began in the fourth quarter of 2016 with expected completion in 2019. Currently, we plan to fund the project from cash on hand or from third party funding sources that may be available to us. Through September 30, 2018, the cumulative expenditures we incurred to date on the construction of the facility was approximately $38.8 million.

In connection with our acquisitions of CURNA, OPKO Diagnostics and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events, including up to an additional $19.1 million in shares of our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones; and up to an additional $125.0 million in either shares of our Common Stock or cash, at our option subject to the achievement of certain milestones, to the former shareholders of OPKO Renal.

In November 2015, BioReference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. ("CB"), as lender and administrative agent, as amended (the "Credit Agreement"). The Credit Agreement provides for a $175.0 million secured revolving credit facility and includes a $20.0 million sub-facility for swingline loans and a $20.0 million sub-facility for the issuance of letters of credit. BioReference may increase the credit facility to up to $275.0 million on a secured basis, subject to the satisfaction of specified conditions. The Credit Agreement matures on November 5, 2020 and is guaranteed by all of BioReference's domestic subsidiaries. The Credit Agreement is also secured by substantially all assets of BioReference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in BioReference. Availability under the Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein.

We expect to continue to incur substantial research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that selling, general and administrative expenses will also increase as we expand our sales, marketing and administrative staff and add infrastructure.

We believe that the cash and cash equivalents on hand at September 30, 2018, the amounts available to be borrowed under our lines of credit and the proceeds from the private placement of our common stock in November 2018 are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to

use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements will depend on a number of factors, including our relationship with Pfizer, the commercial success of Rayaldee, BioReference's financial performance, possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, our success in developing markets for our product candidates and results of government investigations, payor claims, and legal

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proceedings that may arise. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions or reduce our marketing or sales efforts or cease operations.

The following table provides information as of September 30, 2018, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining three months ending December 31, 2018	2019	2020	2021	2022	Thereafter	Total
Open purchase orders	$ 81,465	$4,195	$60	$—	$—	$ —	$85,720
Operating leases	4,889	16,701	10,575	7,196	3,597	3,792	46,750
Capital leases	895	2,982	2,551	1,845	757	645	9,675
2033 Senior Notes and 2023 Convertible Notes	—	31,850	—	—	—	55,000	86,850
Deferred payments	5,000	5,000	—	—	—	—	10,000
Mortgages and other debts payable	1,165	1,128	495	459	357	4,733	8,337
Lines of credit	4,543	—	104,025	—	—	—	108,568
Interest commitments	255	215	1,045	30	16	13,911	15,472
Total	$ 98,212	$62,071	$118,751	$9,530	$4,727	$ 78,081	$371,372

The preceding table does not include information where the amounts of the obligations are not currently determinable, including the following:

- Contractual obligations in connection with clinical trials, which span over two years, and that depend on patient enrollment. The total amount of expenditures is dependent on the actual number of patients enrolled and as such, the contracts do not specify the maximum amount we may owe.
- Product license agreements effective during the lesser of 15 years or patent expiration whereby payments and amounts are determined by applying a royalty rate on uncapped future sales.
- Contingent consideration that includes payments upon achievement of certain milestones including meeting development milestones such as the completion of successful clinical trials, NDA approvals by the FDA and revenue milestones upon the achievement of certain revenue targets all of which are anticipated to be paid within the next seven years and are payable in either shares of our Common Stock or cash, at our option, and that may aggregate up to $159.1 million.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Accounting estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from these estimates.

Goodwill and intangible assets. Goodwill and other intangible assets, including IPR&D, acquired in business combinations, licensing and other transactions at both September 30, 2018 and December 31, 2017 was $2.0 billion, representing approximately 80% of total assets at September 30, 2018.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. We determined the fair value of intangible assets, including IPR&D, using the "income method." This method starts with a forecast of net cash flows, risk adjusted for estimated probabilities of technical and regulatory success (for IPR&D) and adjusted to present value using an appropriate discount rate that reflects the risk associated with the cash flow streams. All assets are valued from a market participant view which might be different than our specific views. The valuation process is very complex and requires significant input and judgment using internal and external sources. Although a valuation is required to be finalized within a one-year period, it must consider all and only those facts and evidence which existed at the acquisition date. The most complex and judgmental matters applicable to the valuation process are summarized below:

- Unit of account – Most intangible assets are valued as single global assets rather than multiple assets for each jurisdiction or indication after considering the development stage, expected levels of incremental costs to obtain additional approvals, risks associated with further development, amount and timing of benefits expected to be derived in the future, expected patent lives in various jurisdictions and the intention to promote the asset as a global brand.
- Estimated useful life – The asset life expected to contribute meaningful cash flows is determined after considering all pertinent matters associated with the asset, including expected regulatory approval dates (if unapproved), exclusivity periods and other legal, regulatory or contractual provisions as well as the effects of any obsolescence, demand, competition, and other economic factors, including barriers to entry.
- Probability of Technical and Regulatory Success ("PTRS") Rate – PTRS rates are determined based upon industry averages considering the respective program's development stage and disease indication and adjusted for specific information or data known at the acquisition date. Subsequent clinical results or other internal or external data obtained could alter the PTRS rate and materially impact the estimated fair value of the intangible asset in subsequent periods leading to impairment charges.
- Projections – Future revenues are estimated after considering many factors such as initial market opportunity, pricing, sales trajectories to peak sales levels, competitive environment and product evolution. Future costs and expenses are estimated after considering historical market trends, market participant synergies and the timing and level of additional development costs to obtain the initial or additional regulatory approvals, maintain or further enhance the product. We generally assume initial positive cash flows to commence shortly after the receipt of expected regulatory approvals which typically may not occur for a number of years. Actual cash flows attributed to the project are likely to be different than those assumed since projections are subjected to multiple factors including trial results and regulatory matters which could materially change the ultimate commercial success of the asset as well as significantly alter the costs to develop the respective asset into commercially viable products.
- Tax rates – The expected future income is tax effected using a market participant tax rate. In determining the tax rate, we consider the jurisdiction in which the intellectual property is held and location of research and manufacturing infrastructure. We also consider that any repatriation of earnings would likely have U.S. tax consequences.
- Discount rate – Discount rates are selected after considering the risks inherent in the future cash flows; the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

Goodwill was $713.6 million and $717.1 million, respectively, at September 30, 2018 and December 31, 2017. Goodwill is tested at least annually for impairment or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value. Examples of qualitative factors include our share price, our

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financial performance compared to budgets, long-term financial plans, macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test previously performed.

The estimated fair value of a reporting unit is highly sensitive to changes in projections and assumptions; therefore, in some instances, changes in these assumptions could potentially lead to impairment. We perform sensitivity analyses around our assumptions in order to assess the reasonableness of the assumptions and the results of our testing. Ultimately, future potential changes in these assumptions may impact the estimated fair value of a reporting unit and cause the fair value of the reporting unit to be below its carrying value. We believe that our estimates are consistent with assumptions that marketplace participants would use in their estimates of fair value. However, if actual results are not consistent with our estimates and assumptions, we may be exposed to an impairment charge that could be material.

Intangible assets, net were $1.3 billion, including IPR&D of $646.3 million and $647.3 million, respectively, at September 30, 2018 and December 31, 2017. Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the project is completed or abandoned. Upon obtaining regulatory approval, the IPR&D asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the IPR&D asset is charged to expense.

IPR&D is tested for impairment by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying amount. If the carrying amount of the IPR&D exceeds its fair value, an impairment loss shall be recognized in an amount equal to that excess. Intangible assets with defined lives are tested for impairment by a comparison of the carrying amount of the asset to its estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products and IPR&D. These assets are initially measured at fair value and therefore any reduction in expectations used in the valuations could potentially lead to impairment. Some of the more common potential risks leading to impairment include competition, earlier than expected loss of exclusivity, pricing pressures, adverse regulatory changes or clinical trial results, delay or failure to obtain regulatory approval and additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes.

Considering the high risk nature of research and development and the industry’s success rate of bringing developmental compounds to market, IPR&D impairment charges are likely to occur in future periods. IPR&D is closely monitored and assessed each period for impairment indicators.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense was $51.4 million and $53.9 million for the nine months ended September 30, 2018 and 2017, respectively.

Revenue recognition. Effective January 1, 2018, we adopted Accounting Standards Codification Topic 606, Revenue from Contracts with Customers. We generate revenues from services, products and intellectual property as follows:

Revenue from services. Revenue for laboratory services is recognized at the time test results are reported, which approximates when services are provided and the performance obligations are satisfied. Services are provided to patients covered by various third-party payor programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services are included in revenue net of allowances for contractual discounts, allowances for differences between the amounts billed and estimated program payment amounts, and implicit price concessions provided to uninsured patients which are all elements of variable consideration.

The following are descriptions of our payors for laboratory services:

Healthcare Insurers. Reimbursements from healthcare insurers are based on negotiated fee-for-service schedules. Revenues consist of amounts billed, net of contractual allowances for differences between amounts billed and the

estimated consideration we expect to receive from such payers, which considers historical denial and collection experience and the terms of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the third-party payers, are recorded upon settlement.

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Government Payers. Reimbursements from government payers are based on fee-for-service schedules set by governmental authorities, including traditional Medicare and Medicaid. Revenues consist of amounts billed, net of contractual allowances for differences between amounts billed and the estimated consideration we expect to receive from such payers, which considers historical denial and collection experience and the terms of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the government payers, are recorded upon settlement.

Client Payers. Client payers include physicians, hospitals, employers, and other institutions for which services are performed on a wholesale basis, and are billed and recognized as revenue based on negotiated fee schedules.

Patients. Uninsured patients are billed based on established patient fee schedules or fees negotiated with physicians on behalf of their patients. Insured patients (including amounts for coinsurance and deductible responsibilities) are billed based on fees negotiated with healthcare insurers. Collection of billings from patients is subject to credit risk and ability of the patients to pay. Revenues consist of amounts billed net of discounts provided to uninsured patients in accordance with our policies and implicit price concessions. Implicit price concessions represent differences between amounts billed and the estimated consideration that we expect to receive from patients, which considers historical collection experience and other factors including current market conditions. Adjustments to the estimated allowances, based on actual receipts from the patients, are recorded upon settlement.

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, require us to estimate the potential for retroactive adjustments as an element of variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known. For the nine months ended September 30, 2018 and 2017, revenue reductions of $23.4 million and $30.7 million, respectively, were recognized due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods.

Third-party payers, including government programs, may decide to deny payment or recoup payments for testing they contend were improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. Our revenues may be subject to retroactive adjustment as a result of these factors among others, including without limitation, differing interpretations of billing and coding guidance and changes by government agencies and payors in interpretations, requirements, and “conditions of participation” in various programs. We have processed requests for recoupment from third-party payers in the ordinary course of our business, and it is likely that we will continue to do so in the future. If a third-party payer denies payment for testing or recoups money from us in a later period, reimbursement revenue for our testing could decline.

As an integral part of our billing compliance program, we periodically assess our billing and coding practices, respond to payor audits on a routine basis, and investigate reported failures or suspected failures to comply with federal and state healthcare reimbursement requirements, as well as overpayment claims which may arise from time to time without fault on the part of the Company. We may have an obligation to reimburse Medicare, Medicaid, and third-party payers for overpayments regardless of fault. We have periodically identified and reported overpayments, reimbursed payors for overpayments and taken appropriate corrective action.

Settlements with third-party payors for retroactive adjustments due to audits, reviews or investigations are also considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews, and investigations.

Revenue from products. We recognize revenue from product sales when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that we expect to receive in exchange for those goods or services. Our estimates for sales returns and allowances are based upon the historical patterns of product returns and allowances taken, matched against the sales from which they originated, and our evaluation of specific factors that may increase or decrease the risk of product returns. Product revenues are recorded net of

estimated rebates, chargebacks, discounts, co-pay assistance and other deductions (collectively, “Sales Deductions”) as well as estimated product returns which are all elements of variable consideration. Allowances are recorded as a reduction of revenue at the time product revenues are recognized. The actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect Revenue from products in the period such variances become known.

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We launched Rayaldee in the U.S. through our dedicated renal sales force in November 2016. Rayaldee is distributed in the U.S. principally through the retail pharmacy channel, which initiates with the largest wholesalers in the U.S. (collectively, "Rayaldee Customers"). In addition to distribution agreements with Rayaldee Customers, we have entered into arrangements with many healthcare providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of Rayaldee.

We recognize revenue for shipments of Rayaldee at the time of delivery to customers after estimating Sales Deductions and product returns as elements of variable consideration utilizing historical information and market research projections. For the three and nine months ended September 30, 2018, we recognized $5.8 million and $14.3 million in net product revenue from sales of Rayaldee. Amounts shipped prior to September 30, 2017 were insignificant and no revenue was recognized from sales of Rayaldee for the nine months ended September 30, 2017.

The following table presents an analysis of product sales allowances and accruals as contract liabilities for the nine months ended September 30, 2018:

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2017	$ 233	$ 348	$ 437	$1,018
Provision related to current period sales	3,835	5,929	—	9,764
Credits or payments made	(3,030)	(4,907)	(377)	(8,314)
Balance at September 30, 2018	$ 1,038	$ 1,370	$ 60	$2,468

Total gross Rayaldee sales	$24,074	
Provision for Rayaldee sales allowances and accruals as a percentage of gross Rayaldee sales	41	%

Taxes collected from customers related to revenues from services and revenues from products are excluded from revenues.

Revenue from intellectual property. We recognize revenues from the transfer of intellectual property generated through license, development, collaboration and/or commercialization agreements. The terms of these agreements typically include payment to us for one or more of the following: non-refundable, up-front license fees; development and commercialization milestone payments; funding of research and/or development activities; and royalties on sales of licensed products. Revenue is recognized upon satisfaction of a performance obligation by transferring control of a good or service to the customer.

For research, development and/or commercialization agreements that result in revenues, we identify all material performance obligations, which may include a license to intellectual property and know-how, and research and development activities. In order to determine the transaction price, in addition to any upfront payment, we estimate the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. We constrain (reduce) our estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur throughout the life of the contract. When determining if variable consideration should be constrained, we consider whether there are factors outside of our control that could result in a significant reversal of revenue. In making these assessments, we consider the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Upfront License Fees: If a license to our intellectual property is determined to be functional intellectual property distinct from the other performance obligations identified in the arrangement, we recognize revenue from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined

performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we apply an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments: Depending on facts and circumstances, we may conclude that it is appropriate to include the milestone in the estimated transaction price or that it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period that we conclude that it is probable that recording

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revenue in the period will not result in a significant reversal in amounts recognized in future periods. We may record revenues from certain milestones in a reporting period before the milestone is achieved if we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We record a corresponding contract asset when this conclusion is reached. Milestone payments that have been fully constrained are not included in the transaction price to date. These milestones remain fully constrained until we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We re-evaluate the probability of achievement of such development milestones and any related constraint each reporting period. We adjust our estimate of the overall transaction price, including the amount of revenue recorded, if necessary.

Research and Development Activities: If we are entitled to reimbursement from our customers for specified research and development expenses, we account for them as separate performance obligations if distinct. We also determine whether the research and development funding would result in revenues or an offset to research and development expenses in accordance with provisions of gross or net revenue presentation. The corresponding revenues or offset to research and development expenses are recognized as the related performance obligations are satisfied.

Sales-based Milestone and Royalty Payments: Our customers may be required to pay us sales-based milestone payments or royalties on future sales of commercial products. We recognize revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the customer's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license to our intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

Other Potential Products and Services: Arrangements may include an option for license rights, future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's election. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the inception of the contract and revenue is recognized only if the option is exercised and products or services are subsequently delivered or when the rights expire. If the promise is based on market terms and not considered a material right, the option is accounted for if and when exercised. If we are entitled to additional payments when the licensee exercises these options, any additional payments are generally recorded in license or other revenues when the licensee obtains control of the goods, which is upon delivery.

For the three and nine months ended September 30, 2018, revenue from transfer of intellectual property principally reflects $18.9 million and $49.9 million of revenue, respectively related to the Pfizer Transaction. For the three and nine months ended September 30, 2017, revenue from transfer of intellectual property principally reflects and $21.8 million and $54.2 million of revenue, respectively related to the Pfizer Transaction. Refer to Note 13. Total contract liabilities included in Accrued expenses and Other long-term liabilities was $89.8 million and $140.4 million at September 30, 2018 and December 31, 2017, respectively. The contract liability balance at September 30, 2018 relates primarily to the Pfizer Transaction.

Concentration of credit risk and allowance for doubtful accounts. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of accounts receivable. Substantially all of our accounts receivable are with either companies in the healthcare industry or patients. However, credit risk is limited due to the number of our clients as well as their dispersion across many different geographic regions.

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk since the related healthcare programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. At September 30, 2018 and December 31, 2017, receivable balances (net of contractual adjustments) from Medicare and Medicaid were 15.2% and 15.8%, respectively, of our consolidated Accounts receivable, net.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At September 30, 2018 and December 31, 2017, receivables due from patients represent approximately 3.2% and 3.2%, respectively, of our consolidated Accounts receivable, net.

We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current

economic conditions and trends that may affect a customer's ability to pay. Actual results could differ from those estimates. Our reported net income (loss) is directly affected by our estimate of the collectability of accounts receivable. The allowance for doubtful accounts was $1.7 million and $1.4 million at September 30, 2018 and December 31, 2017, respectively.

Income taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are

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recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment. Valuation allowances on certain U.S. deferred tax assets and non-U.S. deferred tax assets are established, because realization of these tax benefits through future taxable income does not meet the more-likely-than-not threshold.

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the "Tax Act") was enacted into law and the new legislation contains several key tax provisions, including a reduction of the corporate income tax rate from 35% to 21% effective January 1, 2018, and a one-time mandatory transition tax on accumulated foreign earnings, among others. We are required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring our U.S. deferred tax assets and liabilities, as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Act ("SAB 118"), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Through September 30, 2018, we did not have any significant adjustments to our provisional amounts. As we continue to perform our analysis of the Tax Act, and interpret any additional accounting guidance issued by the FASB, the U.S. Department of the Treasury and the IRS, we may make adjustments to these provisional amounts.

Effective January 1, 2018, the Tax Act provides for a new global intangible low-taxed income (GILTI) provision. Under the GILTI provision, certain foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets are included in U.S. taxable income. We are now subject to GILTI but have not triggered an income inclusion as of September 30, 2018. Any future inclusion is expected to be offset by net operating loss carry forwards in the U.S. We are still evaluating, pending further interpretive guidance, whether to make a policy election to treat the GILTI tax as a period expense or to provide U.S. deferred taxes on foreign temporary differences that are expected to generate GILTI income when they reverse in future years.

We anticipate future impacts at a U.S. state and local tax level related to the Tax Act; however, the limited amount of statutory and interpretive guidance available from applicable state and local tax authorities is not sufficient to reasonably estimate the impact. Consequently, for those jurisdictions, we have not recorded provisional amounts and have continued to apply ASC 740 based on the provisions of the tax laws that were in effect immediately prior to Tax Act enactment.

Equity-based compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options, as cash flows from operations. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. We estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the "Black-Scholes Model." The Black-Scholes Model requires the use of several variables to estimate the grant-date fair value of stock options including expected term, expected volatility, expected dividends and risk-free interest rate. We perform analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model and to estimate forfeitures of equity-based awards. We are required to adjust our forfeiture estimates on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates which may have a material impact on our Condensed Consolidated Financial Statements.

Inventories. Inventories are valued at the lower of cost and net realizable value. Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such

inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost and net realizable value. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories. Inventory obsolescence expense for the nine months ended September 30, 2018 and 2017 was $1.5 million and $5.0 million, respectively.

Contingent consideration. Each period we revalue the contingent consideration obligations associated with certain prior acquisitions to their fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as a reduction in contingent consideration expense. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and the discount rate used to estimate the fair value of the liability. Contingent consideration may

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change significantly as our development programs progress, revenue estimates evolve and additional data is obtained, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value which may have a material impact on our results from operations and financial position.

RECENT ACCOUNTING PRONOUNCEMENTS

Recently adopted accounting pronouncements.

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers." ASU 2014-09, as amended and codified into Topic 606, clarifies the principles for recognizing revenue and develops a common revenue standard for GAAP that removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. As required, we adopted ASU 2014-09 on January 1, 2018 using the full retrospective approach, and have elected to use the following practical expedients that are permitted under the rules of the adoption, which have been applied consistently to all contracts within all reporting periods presented:

- For all reporting periods presented before January 1, 2018, we have not restated revenue from contracts that begin and are completed within the same annual reporting period.
- For all reporting periods presented before January 1, 2018, we have not disclosed the amount of the transaction price allocated to the remaining performance obligations or an explanation of when we expect to recognize that amount as revenue.
- We have applied the practical expedient provided for by Topic 606 by not adjusting the transaction price for significant financing components for periods less than one year.

As a result of adopting ASU 2014-09 on January 1, 2018 using the full retrospective approach, we revised our comparative financial statements for the prior years as if Topic 606 had been effective for those periods. As a result, the following financial statement line items for 2017 were affected:

Condensed Consolidated Statement of Operations

	For the three months ended September 30, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Revenue from services	$200,876	$229,035	$(28,159)
Revenue from transfer of intellectual property and other	22,369	11,665	10,704
Selling, general and administrative	103,177	131,336	(28,159)
Research and development	32,508	32,329	179

	For the nine months ended September 30, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Revenue from services	$663,333	$740,992	$(77,659)
Revenue from transfer of intellectual property and other	67,697	58,819	8,878

Selling, general and administrative	318,700	396,359	(77,659)
Research and development	92,193	90,944	1,249

Condensed Consolidated Balance Sheet

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	December 31, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Other current assets and prepaid expenses	$42,513	$37,113	$5,400
Accrued expenses	230,301	215,102	15,199
Other long-term liabilities, principally contract liabilities, contingent consideration and line of credit	239,955	219,954	20,001
Accumulated deficit	(1,036,959)	(1,007,159)	(29,800)

Condensed Consolidated Statement of Cash Flows

	For the nine months ended September 30, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Net loss	$(87,336)	$(94,965)	$7,629
Contract liabilities	(49,771)	(42,142)	(7,629)

The most significant change above relates to amounts in our clinical laboratory operations that were historically classified as provision for bad debts, primarily related to patient responsibility, which are considered an element of variable consideration as an implicit price concession in determining revenues under Topic 606. Accordingly, we report uncollectible balances associated with individual patients as a reduction of the transaction price and therefore as a reduction in Revenue from services when historically these amounts were classified as provision for bad debts within Selling, general and administrative expenses.

In addition, under Topic 606, the upfront consideration received for a license and contract services combined performance obligation is recognized as revenue to the extent of costs incurred based on the length of the expected performance period and the subjectivity in estimating progress towards satisfaction of the performance obligation. Under previous accounting, we recognized revenue over the expected performance period. The adoption of Topic 606 resulted in a cumulative revenue reduction of $29.8 million and an increase of our accumulated deficit balance as of December 31, 2017; with a corresponding increase in our contract liabilities. For the nine months ended September 30, 2017, Revenue from the transfer of intellectual property and other was increased by $7.6 million for the change in accounting. For a further discussion of the adoption of Topic 606, refer to Note 12, “Revenue Recognition.”

In January 2016, the FASB issued ASU No. 2016-01, “Financial Instruments - Overall (Subtopic 825-10),” which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The ASU requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. As a result of the required adoption of ASU 2016-01 on January 1, 2018, we recorded a cumulative-effect adjustment to reclassify our net unrealized gains on our equity securities of $4.9 million as of January 1, 2018 from Accumulated other comprehensive loss to Accumulated deficit in our Condensed Consolidated Balance Sheet. Changes in the fair value of our equity securities subsequent to the adoption of ASU 2016-01 on January 1, 2018 will be recognized in net income.

In August 2016, the FASB issued ASU No. 2016-15, “Statement of Cash Flows (Topic 230),” which addresses the classification of eight specific cash flow issues with the objective of reducing the existing diversity in practice. The required adoption of ASU 2016-15 in the first quarter of 2018 did not have a significant impact on our Condensed Consolidated Financial Statements.

In January 2017, the FASB issued ASU No. 2017-01, “Business Combinations (Topic 805),” which clarifies the definition of a business to assist entities in evaluating whether transactions should be accounted for acquisitions (or disposals) of assets or businesses. The required adoption of ASU 2017-01 in the first quarter of 2018 did not have a significant impact on our Condensed Consolidated Financial Statements.

Pending accounting pronouncements.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” which will require organizations that lease

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assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. ASU 2016-02, as amended, requires new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements. In July 2018, the FASB issued an ASU to provide an additional transition method to adopt the guidance by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative effect to the opening balance of retained earnings.

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles - Goodwill and Other (Topic 350),” which simplifies how an entity is required to test for goodwill impairment. ASU 2017-04 will be effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019, with early adoption permitted after January 1, 2017. We are currently evaluating the impact of this new guidance on our Consolidated Financial Statements.

In June 2018, the FASB issued ASU No. 2018-07, “Compensation - Stock Compensation (Topic 718),” which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 will be effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

In the normal course of doing business, we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

Foreign Currency Exchange Rate Risk – We operate globally and, as such, we are subject to foreign exchange risk in our commercial operations as portions of our revenues are exposed to changes in foreign currency exchange rates, primarily the Chilean Peso, the Mexican Peso, the Euro and the New Israeli Shekel.

Although we do not speculate in the foreign exchange market, we may from time to time manage exposures that arise in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. Certain firmly committed transactions may be hedged with foreign exchange forward contracts. As exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. Both the exposed transactions and the hedging contracts are translated and fair valued, respectively, at current spot rates, with gains and losses included in earnings.

Our derivative activities, which consist of foreign exchange forward contracts, are initiated to economically hedge forecasted cash flows that are exposed to foreign currency risk. The foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity dates. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the Condensed Consolidated Statements of Operations and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. If the counterparties to the exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. Our foreign exchange forward contracts primarily hedge exchange rates on the Chilean Peso to the U.S. dollar. If Chilean Pesos were to strengthen or weaken in relation to the U.S. dollar, our loss or gain on hedged foreign currency cash-flows would be offset by the derivative contracts, with a net effect of zero.

We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or "other than trading" instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price, or equity price risk.

Interest Rate Risk – Our exposure to interest rate risk relates to our cash and investments and to our borrowings. We generally maintain an investment portfolio of money market funds and marketable securities. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment.

At September 30, 2018, we had cash and cash equivalents of $43.7 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2018 was less than 1%. As of September 30, 2018, the principal outstanding balance under our Credit Agreement with JPMorgan Chase Bank, N.A. and our Chilean and Spanish lines of credit was $109.7 million in the aggregate at a weighted average interest rate of approximately 4.7%.

Our $31.9 million aggregate principal amount of our 2033 Senior Notes has a fixed interest rate of 3% and our $55.0 million aggregate principal amount of our 2023 Convertible Notes has a fixed interest rate of 5%, and therefore are not subject to fluctuations in market interest rates.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we may invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and money market funds that invest in such debt instruments, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than three months.

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Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, management concluded that our disclosure controls and procedures were effective as of September 30, 2018.

Changes to the Company's Internal Control Over Financial Reporting

We have implemented new controls as part of our effort to adopt Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers." The adoption of the ASU requires the implementation of new accounting processes which necessitates changes to our internal controls over financial reporting.

These changes to the Company's internal control over financial reporting that occurred since the beginning of 2018 have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are, from time to time, party to various legal proceedings arising out of our business. During the reporting period, except as set forth below, there have been no material changes to the description of legal proceedings set forth in our Annual Report on Form 10-K for the year ended December 31, 2017.

On September 7, 2018, the Securities and Exchange Commission ("SEC") filed a lawsuit in the Southern District of New York (the "SEC Complaint") against a number of individuals and entities (the "Defendants"), including the Company and its CEO and Chairman, Phillip Frost. The SEC alleges that the Company (i) aided and abetted an illegal "pump and dump" scheme perpetrated by a number of the Defendants, and (ii) failed to file required Schedules 13D or 13G with the SEC. The Complaint also alleges that Dr. Frost participated in the alleged "pump and dump" scheme with respect to two companies, failed to file required Schedules 13D or 13G with the SEC, and unlawfully sold securities without registering the sales with the SEC. The SEC seeks final judgments permanently enjoining the Company and Dr. Frost from future violations of the charged provisions of the federal securities laws with respect to both OPKO and Dr. Frost, Sections 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 13d-1(a) thereunder relating to the alleged failure to make the appropriate filings on Schedules 13D or 13G,Section 20(e) of the Exchange Act and Section 15(b) of the Securities Act of 1933 (the "Securities Act") relating to allegations that OPKO and Dr. Frost aided and abetted the alleged "pump and dump" schemes, and, with respect to Dr. Frost alone, Sections 5(a) and (c) of the Securities Act alleging that Dr. Frost failed to register certain securities transactions, and Section 10(b) of the Exchange Act and Rule 10b-5 thereunder as well as Section 17(a)(2) of the Securities Act relating to the alleged commission of fraud. The complaint makes no allegations about OPKO's financial statements or business practices. Following the SEC's announcement of the SEC Complaint, a number of class actions and derivative suits were filed concerning the allegations in the SEC Complaint and related matters.

On or about September 12, 2018, Jason Kerznowski ("Kerznowski"), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the District of New Jersey against the Company and certain of its current and former executive officers (the "Kerznowski Lawsuit"). This lawsuit was brought by Kerznowski both individually and on behalf of a putative class of the Company's stockholders, claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Kerznowski Lawsuit seeks to declare the action to be a class action and certify Kerznowski as the class representative, monetary damages, including prejudgment and post judgment interest, an award of reasonable attorneys' fees, expert fees, and other costs, and such other relief as the Court may deem just and proper.

On or about September 14, 2018, Charles Steinberg ("Steinberg"), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the Southern District of Florida against the Company and certain of its current and former executive officers (the "Steinberg Lawsuit"). This lawsuit was brought by Steinberg both individually and on behalf of a putative class of the Company's stockholders claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Steinberg Lawsuit seeks to declare the action to be a class action, monetary damages, including prejudgment and post judgment interest, an award of reasonable attorneys' fees and expert fees and other costs, and such additional or different relief as the interests of law or equity may require.

On or about September 17, 2018, Adsport, Inc. ("Adsport"), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the Southern District of New York against the Company and Dr. Frost (the "Adsport Lawsuit"). This lawsuit was brought by Adsport individually and on behalf of a putative class of the Company's stockholders, claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Adsport Lawsuit seeks to declare the action to be a proper class action, monetary damages, including interest, an award of reasonable costs, and such equitable/injunctive relief as the Court may deem proper.

On or about September 21, 2018, Michael Brennan (“Brennan”), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the Southern District of Florida against the Company and certain of its current and former executive officers (the “Brennan Lawsuit”). This lawsuit was brought by Brennan individually and on behalf of a putative class of the Company’s stockholders, claiming that in connection with the facts and circumstances underlying the

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allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Brennan Lawsuit seeks to declare the action to be a class action and certify Brennan as the class representative, monetary damages, including prejudgment and post judgment interest, an award of reasonable costs, including attorneys' fees, expert fees and other costs, and such other relief as the Court may deem proper.

On or about September 27, 2018, Frank Lipsius ("Lipsius"), a purported stockholder, filed a shareholder derivative complaint in the Circuit Court of the Eleventh Judicial Circuit of Florida serving Miami-Dade Countyagainst the Company as a nominal defendant, certain of the Company's current and former executive officers, and members of its Board of Directors (the "Lipsius Lawsuit"). This lawsuit was brought by Lipsius and alleges breach of fiduciary duty against the officers and directors named therein, based on the allegations raised by the SEC in the SEC Lawsuit that the Company made misleading statements, and failed to maintain proper internal controls. The Lipsius Lawsuit seeks to declare that Lipsius maintain the action on behalf of the Company and that Lipsius is a proper and adequate representative of the Company, to direct the Company to improve its corporate governance and internal procedures, monetary damages, restitution, an award of reasonable attorneys' fees and expert fees and other costs, and such additional or different relief as the interests of law or equity may require.

On or about September 13, 2018, Idan Sharon filed an Application for Approval of a Class Action in the Tel Aviv Israel District Court against the Company and certain of its current and former executive officers, and certain members of its Board of Directors (the "Sharon Claim"). This application was filed by a purported stockholder, both individually and on behalf of a putative class of the Company's stockholders, claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Sharon Claim seeks to declare the action to be a class action and monetary damages.

On or about September 16, 2018, Dalia Avraham filed an Application for Approval of a Class Action in the Tel Aviv Israel District Court against the Company and Dr. Frost. This application was filed by a purported stockholder, both individually and on behalf of a putative class of the Company's stockholders (the "Avraham Claim"). The Avraham Claim alleges a negligent and/or deliberate act related to the trade of the Company's shares on the Tel Aviv Stock Exchange ("TASE") which was intended to or which in fact caused damage to the Company's investors based on the Company's decision to delist from TASE in April 2018 and its subsequent decision to continue to be listed on TASE. The Avraham Claim seeks to declare the action to be a class action and an estimated NIS 20 million in damages.

On or about October 2, 2018 Andy Yu ("Yu"), a purported stockholder, filed a shareholder derivative complaint in the United States District Court for the Southern District of Florida against the Company as a nominal defendant, certain of the Company's current and former executive officers, certain current and former members of its Board of Directors, and Frost Gamma Investments Trust (the "Yu Lawsuit"). The Yu Lawsuit alleges breach of fiduciary duty against the officers and directors named therein based on the allegations raised by the SEC in the SEC Complaint, unjust enrichment, and that the Company made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading and failed to maintain effective internal controls. The Yu Lawsuit seeks to declare that Yu maintain the action on behalf of the Company and that Yu is a proper and adequate representative of the Company, to direct the Company to improve its corporate governance and internal procedures, monetary damages, restitution, an award of reasonable attorneys' fees and expert fees and other costs, and such additional or different relief as the interests of law or equity may require.

On or about October 8, 2018 Paul Camhi ("Camhi"), a purported stockholder, filed a putative class action lawsuit in the United States District Court for the Southern District of Florida against the Company and Dr. Frost (the "Camhi Lawsuit"). The Camhi Lawsuit was brought by Camhi individually and on behalf of a putative class of the Company's stockholders, claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Camhi Lawsuit seeks to declare the action to be a class action,to certify Camhi as the class representative, and to award monetary damages, including prejudgment and post judgment interest, an award of reasonable attorneys' fees, and such other relief as the

Court may deem just and proper.

On or about October 15, 2018 Richard Tunick (“Tunick”), a purported stockholder, filed a shareholder derivative complaint in the Court of Chancery of the State of Delaware against the Company as a nominal defendant, Dr. Frost and the Company’s Board of Directors (the “Tunick Lawsuit”). The Tunick Lawsuit alleges breach of fiduciary duty based on the allegations raised by the SEC in the SEC Complaint. The lawsuit seeks to declare the action a proper derivative action,monetary damages, equitable and injunctive relief, to direct the Company to improve its internal controls and Board oversight , an award of reasonable attorneys’ fees and expert fees, and such other and further relief as the Court deems just and proper.

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On or about October 31, 2018, Lisette Demetriades ("Demetriades"), a purported stockholder, filed a shareholder derivative complaint in the United States District Court for the Southern District of Florida against the Company, certain of the Company's current and former executive officers, certain current and former members of its Board of Directors, and Frost Gamma Investment Trust (the "Demetriades Lawsuit"). The Demetriades Lawsuit alleges breach of fiduciary duty against the officers and directors named therein, based on the allegations raised by the SEC in the SEC Lawsuit, and that the Company made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading, and failed to maintain effective internal controls. The lawsuit seeks to declare the action a proper derivative action, monetary damages, to direct the Company to improve its internal controls and Board oversight concerning investments and self-dealing, restitution and disgorgement of profits, an award of reasonable attorneys' fees and experts' fees, and such other and further relief as the Court deems just and proper.

On or about November 7, 2018, Esther Susan Lutzker ("Lutzker"), a purported stockholder, filed a shareholder derivative complaint in the Court of Chancery of the State of Delaware against the Company as a nominal defendant and certain members of the Company's Board of Directors (the "Lutzker Lawsuit"). This lawsuit was brought by Lutzker and alleges breach of fiduciary duty against the directors named therein, based on the allegations raised by the SEC in the SEC Complaint. The Lutzker Lawsuit seeks to declare that Lutzker maintain the action on behalf of the Company, that Lutzker is a proper and adequate representative of the Company, monetary damages, appropriate equitable relief, an award of costs and disbursements, including reasonable attorneys', accountants', and experts' fees costs and expenses, and such other and further relief as the Court may deem just and proper.
The Company intends to vigorously defend itself against the class action and derivative claims. Based on the early stages of these legal proceedings, at this time, the Company is not able to reasonably estimate a possible range of loss, if any, that may result from these allegations.

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Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common and capital stock. Other than as set forth below, there have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2017.

We will continue to require additional funding, which may not be available to us on acceptable terms, or at all.

As of September 30, 2018, we had cash and cash equivalents of approximately $43.7 million. We have not generated sustained positive cash flows sufficient to offset our operating and research and development expenses and our primary source of cash has been from the public and private placement of stock, the issuance of the 2033 Senior Notes and 2023 Convertible Notes and credit facilities available to us.

On November 8, 2018, we entered into stock purchase agreements with certain investors pursuant to which we agreed to sell to such investors in private placements (the "Private Placements") an aggregate of approximately 26.5 million shares of our Common Stock (the "Shares") at a purchase price of $3.49 per share, which was the closing bid price of our Common Stock on the NASDAQ Global Select Market ("NASDAQ") on such date, for an aggregate purchase price of $92.5 million. The closing of the Private Placements is subject to obtaining requisite approval from NASDAQ for the listing of the Shares. In addition, we entered into a credit agreement with an affiliate of Dr. Frost, pursuant to which the lender committed to provide us with an unsecured line of credit in the amount of $60 million. Borrowings under the line of credit will bear interest at a rate of 10% per annum and may be repaid and reborrowed at any time. The line of credit matures on November 8, 2023.

We believe that the cash and cash equivalents on hand at September 30, 2018, together with the amounts we expect to receive in the Private Placements referenced above and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service within the next 12 months.

Because of the numerous risks and uncertainties associated with the development and commercialization of our products and product candidates, the success of our relationships with Pfizer, VFMCRP and JT and the success of our integration of BioReference and other acquisitions, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and our expanded commercial operations. Our future capital requirements will depend on a number of factors, including the successful commercialization of Rayaldee, our relationships with Pfizer, VFMCRP, and JT, cash flow generated by BioReference and costs associated with the integration of the BioReference and other acquisitions, the continued progress of our research and development of product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our products and product candidates. Until we can generate a sufficient amount of product and service revenue to finance our cash requirements for research, development and operations, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, or strategic collaborations.

Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control. Disruptions in the U.S. and global financial markets may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Economic conditions have been, and continue to be, volatile. Continued instability in these market conditions may limit our ability to replace, in

a timely manner, maturing liabilities and access the capital necessary to fund and grow our business. Additionally, our continuing operating losses and the recent lawsuits involving the Company and its CEO and Chairman by the SEC and other parties increase the difficulty in obtaining additional capital.

There can be no assurance that additional capital will be available to us on acceptable terms, or at all, which could adversely impact our business, results of operations, liquidity, capital resources and financial condition. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or cease operations altogether. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants and other onerous terms. To the extent that we raise additional funds through collaboration and

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licensing arrangements, it may be necessary to relinquish some rights to our technologies or our products and product candidates or grant licenses on terms that may not be favorable to us.

Our success is dependent to a significant degree upon the involvement, efforts and reputation of our Chairman and Chief Executive Officer, Phillip Frost, M.D.

Our success is dependent to a significant degree upon the efforts of our Chairman and Chief Executive Officer, Phillip Frost, M.D., who is essential to our business. The departure of our CEO for whatever reason or the inability of our CEO to continue to serve in his present capacity could have a material adverse effect upon our business, financial condition, and results of operations. Our CEO has a highly regarded reputation in the pharmaceutical and medical industry and attracts business opportunities and assists both in negotiations with acquisition targets, investment targets, and potential joint venture partners. Our CEO has also provided financing to the Company, both in terms of a credit agreement and equity investments. If we lost his services or if his reputation was damaged for whatever reason, including, but not limited to, as a result of the allegations underlying various SEC and shareholder lawsuits against the Company and Dr. Frost, our relationships with acquisition and investment targets, joint ventures, customers and investors, as well as our ability to obtain additional funding on acceptable terms, or at all, may suffer and could cause a material adverse impact on our operations, financial condition, and the value of our Common Stock.

Adverse results in material litigation matters or governmental inquiries could have a material adverse effect upon our business and financial condition.

We may from time to time become subject in the ordinary course of business to material legal action related to, among other things, intellectual property disputes, professional liability, contractual and employee-related matters, as well as inquiries from governmental agencies and Medicare or Medicaid carriers requesting comment and information on allegations of billing irregularities and other matters that are brought to their attention through billing audits, third parties or other sources. The health care industry is subject to substantial federal and state government regulation and audit. Additionally, as of September 30, 2018, the Company is subject to multiple lawsuits with respect to alleged violations of securities laws, as set forth in the “Legal Proceedings” section in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. Legal actions could result in substantial monetary damages, negatively impact our ability to obtain additional funding on acceptable terms, or at all, and damage to the Company’s reputation with customers, business partners, and other third parties, all of which could have a material adverse effect upon our results of operations and financial position . Further, the legal actions could damage our reputation with investors and adversely affect our stock price.

If our products are not covered and eligible for reimbursement from government and third party payors, we may not be able to generate significant revenue or achieve or sustain profitability.
The coverage and reimbursement status of newly approved or cleared drugs, diagnostic and laboratory tests is uncertain, and failure of our pharmaceutical products, diagnostic tests or laboratory tests to be adequately covered by insurance and eligible for adequate reimbursement could limit our ability to market any future product candidates we may develop and decrease our ability to generate revenue from any of our existing and future product candidates that may be approved or cleared. The commercial success of our existing and future products in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations, and other third-party payors, as well as our ability to obtain in network status with such payors. The government and other third-party payors are increasingly attempting to contain health care costs by limiting both insurance coverage and the level of reimbursement for new drugs and diagnostic tests and restricting in network status of laboratory providers. As a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our products are less safe, less effective, or less cost-effective than existing or later-introduced products. These payors

may also conclude that the overall cost of the procedure using one of our devices exceeds the overall cost of the competing procedure using another type of device, and third-party payors may not approve our products for insurance coverage and adequate reimbursement or approve our laboratory for in network status.

The failure to obtain coverage and adequate or any reimbursement for our products, or health care cost containment initiatives that limit or restrict reimbursement for our products, may reduce any future product revenue. Even though a drug (not administered by a physician) may be approved by the FDA, this does not mean that a Prescription Drug Plan ("PDP"), a private insurer operating under Medicare Part D, will list that drug on its formulary or will set a reimbursement level. PDPs are not required to make every FDA-approved drug available on their formularies. If our drug products are not listed on sufficient number of PDP formularies or if the PDPs' levels of reimbursement are inadequate, our business, results of operations, and financial condition could be materially adversely affected. Private health plans, such as managed care plans and pharmacy

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benefit management (PBM) programs may also not include our products on formularies, use other techniques that may restrict access to our products or set a lower reimbursement rate than anticipated.

On May 18, 2018, Novitas Solutions, Inc., the Medicare Administrative Contractor for a jurisdiction that includes the State of New Jersey, where our 4Kscore test samples are processed, issued a draft local coverage determination (LCD) that proposed no coverage for our 4Kscore test. We submitted comments to the draft LCD during the public comment period, which ended on July 5, 2018. Novitas continues to reimburse us for our 4Kscore test. However, in the event that Novitas issues a final LCD for no coverage or limited coverage of our 4Kscore test or Novitas ceasing reimbursing the test for any reason, a portion of our revenues would be lost, which could have a material adverse effect on our cash flows, results of operations, net income and financial conditions.

Additionally, our failure to comply with applicable Medicare, Medicaid and other governmental payor rules could result in our inability to participate in a governmental payor program, our returning funds already paid to us, civil monetary penalties, criminal penalties and/or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payor program, a substantial portion of our revenues would be lost, which would adversely affect our results of operations and financial condition.

Denial of insurance coverage with respect to securities litigation claims could significantly affect our financial position. Further, the frequency and magnitude of material litigation claims and the related expenses could significantly affect the cost and availability of insurance to us.

On September 7, 2018, the SEC filed a lawsuit against the Company and our CEO and Chairman, among others. Following the SEC's announcement of the lawsuit, a number of class actions and derivative suits were filed against the Company and certain of its directors and officers, during, and subsequent to, the quarter ended September 30, 2018, concerning the allegations in the SEC lawsuit and related matters. See the "Legal Proceedings" section in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. If any of our third-party insurers deny, cancel, or refuse coverage, or are otherwise unable to provide us with adequate insurance coverage for all or any of these lawsuits, then our overall risk exposure and operational expenses would increase and the management of our business operations would be disrupted, which could cause a material adverse impact on our business, operations and financial condition. Further, an unusually large liability claim or a string of claims, like these lawsuits, could potentially exceed our available insurance coverage. In addition, the availability of, and our ability to collect on, insurance coverage can be subject to factors beyond our control.

As our current insurance policies expire, increased premiums for renewed or new coverage, if such coverage can be secured at all, may increase our insurance expense and/or require us to increase our self-insured retention or deductibles. If the number of claims or the dollar amounts of any such claims rise in any policy year, we could suffer additional costs associated with accessing excess coverage policies. Also, an increase in the loss amounts attributable to such claims could expose us to uninsured damages if we are unable or elect not to insure against certain claims because of increased premiums or other reasons. These lawsuits or the resolution of such lawsuits may affect the availability or cost of some of our insurance coverage, which could materially adversely impact our business, results of operations and cash flows and potentially expose us to increased risks that would be uninsured.

The market price of our Common Stock may fluctuate significantly.

The market price of our Common Stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- the announcement of new products or product enhancements by us or our competitors;
- results of our clinical trials and other development efforts;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our Common Stock is covered by analysts;

- developments in the biotechnology, pharmaceutical, diagnostic, and medical device industry;
- the announcement and/or commencement and/or settlement of lawsuits or similar claims against the Company or any of its officers, directors and affiliates;
- the results of product liability or intellectual property lawsuits;
- future issuances of our Common Stock or other securities, including debt;
- purchases and sales of our Common Stock by our officers, directors or affiliates;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments, or strategic alliances; and

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- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for biotechnology, pharmaceutical, diagnostic, and medical device companies in particular, has experienced extreme price and volume fluctuations in recent years. Continued market fluctuations could result in extreme volatility in the price of our Common Stock, which could cause a decline in the value of our Common Stock.

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

None.

Item 3. Defaults Upon Senior Securities
None.
Item 4. Mine Safety Disclosures
Not Applicable.
Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit 3.1(1)	Amended and Restated Certificate of Incorporation.
Exhibit 3.2(2)	Amended and Restated By-Laws.
Exhibit 3.3(3)	Certificate of Designation of Series D Preferred Stock.
Exhibit 4.3(4)	Indenture, dated as of January 30, 2013, between OPKO Health, Inc. and Wells Fargo Bank, National Association.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2018.
Exhibit 31.2	Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2018.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2018.
Exhibit 32.2	Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2018.
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2013 for the Company's three month period ended September 30, 2013, and incorporated herein by reference.

(2) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008, and incorporated herein by reference.

(3) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2009, and incorporated herein by reference.

(4) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2013, and incorporated herein by reference.

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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.

Date: November 9, 2018 OPKO Health, Inc.

/s/ Adam Logal
Adam Logal
Senior Vice President, Chief Financial Officer,
Chief Accounting Officer and Treasurer