
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017.

OR

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

For the transition period from _____ to _____.

Commission file number 001-33528

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

75-2402409
(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. ☒ YES ☐ NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). ☒ YES ☐ NO

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

Large accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Accelerated filer ☐

Smaller reporting company ☐

Emerging growth company ☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ YES ☒ NO

As of October 31, 2017, the registrant had 559,404,941 shares of Common Stock outstanding.

TABLE OF CONTENTS**PART I. FINANCIAL INFORMATION**

	<u>Page</u>
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016 (unaudited)</u>	<u>6</u>
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017 and 2016 (unaudited)</u>	<u>7</u>
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2017 and 2016 (unaudited)</u>	<u>8</u>
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and 2016 (unaudited)</u>	<u>9</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>11</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>40</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>55</u>
<u>Item 4. Controls and Procedures</u>	<u>56</u>

PART II. OTHER INFORMATION

<u>Item 1. Legal Proceedings</u>	<u>57</u>
<u>Item 1A. Risk Factors</u>	<u>57</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>57</u>
<u>Item 3. Defaults Upon Senior Securities</u>	<u>57</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>57</u>
<u>Item 5. Other Information</u>	<u>57</u>
<u>Item 6. Exhibits</u>	<u>58</u>
<u>Signatures</u>	<u>59</u>

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, and Section 21E of the Securities Exchange Act of 1934, as amended. 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, 2016, and described from time to time in our other reports filed with the Securities and Exchange Commission. 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;
- 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;
- that we may fail to obtain regulatory approval for hGH-CTP or successfully commercialize *Royaldee* and hGH-CTP;
- that we may not generate profits or cash flow from our laboratory operations or substantial revenue from 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;
- changes in regulation and policies in the United States 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;
- failure to timely or accurately bill for our services;
- failure in our information technology systems, including cybersecurity attacks or other data security 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;
- 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;
- our need for, and ability to obtain, additional financing;
- adverse results in material litigation matters or governmental inquiries;
- 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.

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, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 100,362	\$ 168,733
Accounts receivable, net	233,916	220,284
Inventory, net	46,954	47,228
Other current assets and prepaid expenses	49,324	47,356
Total current assets	430,556	483,601
Property, plant and equipment, net	142,437	122,831
Intangible assets, net	714,552	763,976
In-process research and development	648,377	644,713
Goodwill	715,573	704,603
Investments	32,196	41,139
Other assets	38,299	5,756
Total assets	\$ 2,721,990	\$ 2,766,619
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 66,536	\$ 53,360
Accrued expenses	176,300	197,955
Current portion of lines of credit and notes payable	16,112	11,981
Total current liabilities	258,948	263,296
2033 Senior Notes, net of discount	28,590	43,701
Deferred tax liabilities, net	118,799	165,331
Other long-term liabilities, principally deferred revenue, contingent consideration and line of credit	226,617	202,483
Total long-term liabilities	374,006	411,515
Total liabilities	632,954	674,811
Equity:		
Common Stock - \$0.01 par value, 750,000,000 shares authorized; 559,955,118 and 558,576,051 shares issued at September 30, 2017 and December 31, 2016, respectively	5,600	5,586
Treasury Stock - 549,907 and 586,760 shares at September 30, 2017 and December 31, 2016, respectively	(1,791)	(1,911)
Additional paid-in capital	2,883,026	2,845,096
Accumulated other comprehensive loss	(5,422)	(27,009)
Accumulated deficit	(792,377)	(729,954)
Total shareholders' equity	2,089,036	2,091,808
Total liabilities and equity	\$ 2,721,990	\$ 2,766,619

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

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,	
	2017	2016	2017	2016
Revenues:				
Revenue from services	\$ 229,035	\$ 259,025	\$ 740,992	\$ 777,559
Revenue from products	22,795	20,569	73,992	63,275
Revenue from transfer of intellectual property and other	11,665	18,441	58,819	105,338
Total revenues	263,495	298,035	873,803	946,172
Costs and expenses:				
Cost of service revenue	135,203	138,554	419,070	417,121
Cost of product revenue	16,107	12,626	44,441	35,033
Selling, general and administrative	131,336	124,845	396,359	370,358
Research and development	32,329	24,424	90,944	83,594
Contingent consideration	(11,213)	3,093	(4,475)	15,604
Amortization of intangible assets	18,023	18,116	53,904	47,337
Total costs and expenses	321,785	321,658	1,000,243	969,047
Operating loss	(58,290)	(23,623)	(126,440)	(22,875)
Other income and (expense), net:				
Interest income	249	163	634	341
Interest expense	(1,840)	(2,018)	(4,771)	(6,022)
Fair value changes of derivative instruments, net	(7,550)	(5,701)	1,969	(5,889)
Other income (expense), net	597	(2,972)	3,105	3,543
Other income and (expense), net	(8,544)	(10,528)	937	(8,027)
Loss before income taxes and investment losses	(66,834)	(34,151)	(125,503)	(30,902)
Income tax benefit	24,405	19,988	42,309	24,626
Net loss before investment losses	(42,429)	(14,163)	(83,194)	(6,276)
Loss from investments in investees	(4,013)	(814)	(11,771)	(5,147)
Net loss	\$ (46,442)	\$ (14,977)	\$ (94,965)	\$ (11,423)
Loss per share, basic and diluted:				
Loss per share	\$ (0.08)	\$ (0.03)	\$ (0.17)	\$ (0.02)
Weighted average common shares outstanding, basic and diluted	559,405,309	552,229,266	559,065,232	548,550,641

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

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,	
	2017	2016	2017	2016
Net loss	\$ (46,442)	\$ (14,977)	\$ (94,965)	\$ (11,423)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss)	8,557	2,796	21,646	5,306
Available for sale investments:				
Change in unrealized loss, net of tax	(6)	449	(749)	(2,955)
Less: reclassification adjustments for losses included in net loss, net of tax	96	3,902	690	3,902
Comprehensive loss	<u>\$ (37,795)</u>	<u>\$ (7,830)</u>	<u>\$ (73,378)</u>	<u>\$ (5,170)</u>

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

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

	For the nine months ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (94,965)	\$ (11,423)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	76,677	72,612
Non-cash interest	1,944	2,063
Amortization of deferred financing costs	168	175
Losses from investments in investees	11,771	5,147
Equity-based compensation – employees and non-employees	22,292	34,939
Realized loss (gain) on equity securities and disposal of fixed assets	(2,683)	943
Change in fair value of derivative instruments	(1,969)	5,889
Change in fair value of contingent consideration	(4,475)	15,604
Deferred income tax benefit	(46,366)	(30,982)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	(13,594)	(28,974)
Inventory, net	1,729	(2,726)
Other current assets and prepaid expenses	(2,857)	(24,310)
Other assets	(449)	(402)
Accounts payable	12,013	(16,141)
Foreign currency measurement	608	(433)
Deferred revenue	(42,142)	(56,256)
Accrued expenses and other liabilities	(11,892)	36,015
Net cash provided by (used in) operating activities	(94,190)	1,740
Cash flows from investing activities:		
Investments in investees	(4,625)	(9,171)
Acquisition of businesses, net of cash	—	15,878
Purchase of marketable securities	(6)	(15,631)
Maturities of short-term marketable securities	—	15,634
Proceeds from the sale of property, plant and equipment	3,979	1,082
Acquisition of intangible assets	—	(5,000)
Capital expenditures	(32,061)	(17,015)
Net cash used in investing activities	(32,713)	(14,223)
Cash flows from financing activities:		
Proceeds from the exercise of Common Stock options and warrants	1,916	6,112
Borrowings on lines of credit	75,544	15,816
Repayments of lines of credit	(20,643)	(58,901)
Net cash provided by (used in) financing activities	56,817	(36,973)

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

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

	For the nine months ended September 30,	
	2017	2016
Effect of exchange rate changes on cash and cash equivalents	1,715	504
Net decrease in cash and cash equivalents	(68,371)	(48,952)
Cash and cash equivalents at beginning of period	168,733	193,598
Cash and cash equivalents at end of period	\$ 100,362	\$ 144,646
SUPPLEMENTAL INFORMATION:		
Interest paid	\$ 1,409	\$ 2,519
Income taxes paid, net	\$ 5,899	\$ 8,045
Non-cash financing:		
Shares issued upon the conversion of:		
Common Stock options and warrants, surrendered in net exercise	\$ 1,546	\$ 350
Issuance of capital stock for contingent consideration settlement:		
Transition Therapeutics, Inc.	\$ —	\$ 58,530
OPKO Health Europe	\$ 303	\$ 313
OPKO Renal	\$ —	\$ 25,986
Issuance of stock for investment in Xenetic	\$ —	\$ 4,856

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

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 a 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 and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO in November 2015 and IV formulation approved October 2017), 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), and OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia and other urologic and metabolic conditions. Our pharmaceutical business also features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a once-daily Factor VIIa drug for hemophilia (Phase 2a). We are incorporated in Delaware and our principal executive offices are located in leased offices in Miami, Florida.

In August 2016, we completed the acquisition of Transition Therapeutics, Inc. (“Transition Therapeutics”), a clinical stage biotechnology company developing OPK88003, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity, and OPK88004, a selective androgen receptor modulator for androgen deficiency indications. Holders of Transition Therapeutics common stock received 6,431,899 shares of OPKO Common Stock. The transaction was valued at approximately \$58.5 million, based on a closing price per share of our Common Stock of \$9.10 as reported by NASDAQ on the closing date.

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.

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 United States (“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, 2017, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2017 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, 2016.

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, 2017 and 2016 was \$5.0 million and \$0.2 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 and arose from our acquisitions. 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, 2017 and December 31, 2016 was \$2.1 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 reclassified \$187.6 million of IPR&D related to *Royaldee* from In-process research and development to Intangible assets, net in our Condensed Consolidated Balance Sheets upon the FDA's approval of *Royaldee* in June 2016. The assets are being amortized on a straight-line basis over their estimated useful life of approximately 12 years.

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 \$53.9 million and \$47.3 million for the nine months ended September 30, 2017 and 2016, 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 available for sale as of September 30, 2017 and December 31, 2016 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 Sheets at their fair value and recognize the changes in the fair value in our Condensed Consolidated Statements 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, 2017 and December 31, 2016, 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 Statements 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, automobiles and aircraft - 3-15 years. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation expense was \$22.7 million and \$25.3 million for the nine months ended September 30, 2017 and 2016, respectively. Assets held under capital leases are included within Property, plant and equipment, net in our Condensed Consolidated Balance Sheets 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 operate in various countries and tax jurisdictions globally. For interim reporting purposes, we record income taxes based on the expected annual effective income tax rate taking into consideration global forecasted tax results. For the three and nine months ended September 30, 2017, the tax rate differed from the U.S. federal statutory rate of 35% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

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. On December 29, 2016, the Israeli Parliament reduced the standard corporate income tax rate from 25% to 24%, effective January 1, 2017 and 23% effective January 1, 2018. The new rates have been used in determining Income tax benefit in 2017.

Revenue recognition. Revenue for laboratory services is recognized at the time test results are reported, which approximates when services are provided. Services are provided to patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in revenue net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue. For the nine months ended September 30, 2017, approximately 31% of our revenues were derived directly from the Medicare and Medicaid programs.

We recognize revenue from product sales when persuasive evidence of an arrangement exists, delivery has occurred, collectability is reasonably assured, and the price to the buyer is fixed or determinable, which is generally when goods are shipped and title and risk of loss transfer to our customers. 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. Allowances are recorded as a reduction of revenue at the time product revenues are recognized.

We launched *Royaldee* in the U.S. through our dedicated renal sales force in November 2016. *Royaldee* is distributed in the U.S. principally through the retail pharmacy channel, which initiates with the largest wholesalers in the U.S. (collectively, "*Royaldee* Customers"). In addition to distribution agreements with *Royaldee* 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 *Royaldee*.

We lack the experiential data which would allow us to estimate Sales Deductions and product returns. Therefore, as of September 30, 2017, we have determined that we do not yet meet the criteria for the recognition of revenue for shipments of *Royaldee* at the time of shipment to *Royaldee* Customers as allowances for Sales Deductions and product returns are not known or cannot be reasonably estimated. We will not recognize revenue upon shipment until such time as we can reasonably estimate and record provisions for Sales Deductions and product returns utilizing historical information and market research projections.

During the nine months ended September 30, 2017, we did not recognize any product revenues related to *Royaldee* sales. Payments received from *Royaldee* Customers in advance of recognition of revenue are recorded as deferred revenue included in Accrued expenses in our Condensed Consolidated Balance Sheets. The related deferred revenue balance as of September 30, 2017 was \$6.5 million. The corresponding costs of product revenues for which we have not recognized product revenue have similarly not yet been reflected in our Condensed Consolidated Statements of Operations.

Revenue from transfer of intellectual property includes revenue related to the sale, license or transfer of intellectual property such as upfront license payments, license fees, milestone and royalty payments received through our license, and collaboration and commercialization agreements. We analyze our multiple-element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting.

Non-refundable license fees for the out-license of our technology are recognized depending on the provisions of each agreement. We recognize non-refundable upfront license payments as revenue upon receipt if the license has standalone value and qualifies for treatment as a separate unit of accounting under multiple-element arrangement guidance. License fees with ongoing involvement or performance obligations that do not have standalone value are recorded as deferred revenue, included in Accrued expenses or Other long-term liabilities, when received and generally are recognized ratably over the period of such performance obligations only after both the license period has commenced and we have delivered the technology.

The assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the

relevant time period of research and development on a periodic basis. For the three and nine months ended September 30, 2017, revenue from transfer of intellectual property includes \$11.2 million and \$46.5 million of revenue, respectively related to the Pfizer Transaction. For the three and nine months ended September 30, 2016, revenue from transfer of intellectual property includes \$17.7 million and \$53.0 million of revenue, respectively related to the Pfizer Transaction. Refer to Note 12.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as Revenue from transfer of intellectual property upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; there was substantive uncertainty at the date of entering into the arrangement that the milestone would be achieved; the milestone payment is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item by us; the milestone relates solely to past performance; and the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions are not met, the milestone payments are not considered to be substantive and are, therefore, deferred and recognized as Revenue from transfer of intellectual property over the term of the arrangement as we complete our performance obligations.

Total deferred revenue included in Accrued expenses and Other long-term liabilities was \$120.4 million and \$162.4 million at September 30, 2017 and December 31, 2016, respectively. The deferred revenue balance at September 30, 2017 relates primarily to the Pfizer Transaction. 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, 2017 and December 31, 2016, receivable balances (net of contractual adjustments) from Medicare and Medicaid were 22.0% and 22.9%, 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, 2017 and December 31, 2016, receivables due from patients represent approximately 2.4% and 4.1%, 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 \$57.6 million and \$36.3 million at September 30, 2017 and December 31, 2016, respectively. The provision for bad debts for the nine months ended September 30, 2017 and 2016 was \$78.3 million and \$62.5 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 Statements 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, 2017 and 2016, we recorded \$22.3 million and \$34.9 million, respectively, of equity-based compensation expense.

Research and development expenses. Research and development expenses include external and internal expenses, partially offset by third-party grants and fundings arising from collaboration agreements. 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.

We record expense 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 and our pharmaceutical research and development. The diagnostics segment primarily consists of 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.

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 investments available for sale based on our percentage of ownership and whether we have significant influence over the operations of the investees. Investments for which it is not practical to estimate fair value and which we do not have significant influence are accounted for as cost method investments. 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 Statements of Operations. Refer to Note 5. For investments classified as available for sale, we record changes in their fair value as unrealized gain or loss in Other comprehensive income (loss) based on their closing price per share at the end of each reporting period. Refer to Note 5.

Recent accounting pronouncements. In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers.” ASU 2014-09, as amended, 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. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Companies can choose to apply the ASU using either the full retrospective approach or a modified retrospective approach.

We have commenced our implementation analysis, including identification of revenue streams and reviews of customer contracts under ASU 2014-09’s framework. Our analysis includes reviewing current accounting policies and practices to identify potential differences that would result from applying the requirements under this new standard. The Company has reviewed certain contracts with its customers that the Company believes are representative of its revenue streams and continues to review additional contracts across its global business units. ASU 2014-09 requires increased disclosure which in turn is expected to require certain new processes. The determination of the impact of adoption of ASU 2014-09 on our financial condition, results of operations, cash flows and disclosures, is ongoing, and, as such, we have not yet concluded on a transition method and are not able to reasonably estimate the effect that the adoption of the new standard will have on our financial statements. Based on our preliminary assessment of this ASU, however, the majority of the amounts that were historically classified as provision for bad debts, primarily related to patient responsibility, will be considered an implicit price concession in determining net revenues. Accordingly, we will report uncollectible balances associated with individual patients as a reduction of the transaction price and therefore as a reduction in net revenues when historically these amounts were classified as provision for bad debts within Selling, general and administrative expenses.

In July 2015, the FASB issued ASU No. 2015-11, “Inventory (Topic 330): Simplifying the Measurement of Inventory,” which changes the measurement principle for entities that do not measure inventory using the last-in, first-out (“LIFO”) or retail inventory method from the lower of cost or market to lower of cost and net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. The adoption of ASU 2015-11 in the first quarter of 2017 did not have a significant impact on our Condensed Consolidated Financial Statements.

In November 2015, the FASB issued ASU No. 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes,” which requires deferred tax liabilities and assets to be classified as noncurrent in a classified statement of financial position. The adoption of this ASU simplifies the presentation of deferred income taxes and reduces complexity without decreasing the usefulness of information provided to users of financial statements. We early adopted the provisions of this ASU prospectively in the fourth quarter of 2015, and did not retrospectively adjust the prior periods. The adoption of ASU 2015-17 did not have a significant impact on our Condensed Consolidated Financial Statements.

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. ASU 2016-01 will be effective for fiscal years beginning after December 15, 2017, 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 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. The ASU will also require 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 March 2016, the FASB issued ASU No. 2016-09, “Compensation - Stock Compensation (Topic 718),” which simplifies several aspects of the accounting for share-based payment award transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and accounting for forfeitures. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We adopted this standard in the first quarter of 2017. As required by ASU 2016-09, excess tax benefits are classified as an operating activity in our Condensed Consolidated Statement of Cash Flows and we have applied this provision prospectively. In addition, we have elected to estimate forfeitures over the course of a vesting period, rather than account for forfeitures as they occur. We adjust our forfeiture estimates based on the number of share-based awards that ultimately vest on at least an annual basis. Upon the adoption of ASU 2016-09 in 2017, we recorded a cumulative-effect adjustment to increase our deferred tax assets and reduce our accumulated deficit by \$32.5 million with respect to excess tax benefits recognized in our Condensed Consolidated Balance Sheets.

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. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, 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 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.

NOTE 3 EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing our net income (loss) by the weighted average number of shares outstanding during the period. For diluted earnings per share, the dilutive impact of stock options, warrants and, for periods in 2016, conversion options of the 2033 Senior Notes is determined by applying the “treasury stock” 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 (defined in Note 6) in the dilutive computation.

A total of 1,016,090 and 1,636,706 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2017, 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, 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.

During the three months ended September 30, 2016, 660,921 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 658,357 shares of Common Stock. Of the 660,921 Common Stock options and Common Stock warrants exercised, 2,564 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, 2016, 2,899,458 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 2,771,514 shares of Common Stock. Of the 2,899,458 Common Stock options and Common Stock warrants exercised, 127,944 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	September 30, 2017	December 31, 2016
Accounts receivable, net:		
Accounts receivable	\$ 291,560	\$ 256,552
Less: allowance for doubtful accounts	(57,644)	(36,268)
	<u>\$ 233,916</u>	<u>\$ 220,284</u>
Inventories, net:		
Consumable supplies	\$ 19,446	\$ 23,448
Finished products	22,882	16,143
Work in-process	4,087	3,896
Raw materials	6,984	4,686
Less: inventory reserve	(6,445)	(945)
	<u>\$ 46,954</u>	<u>\$ 47,228</u>
Other current assets and prepaid expenses:		
Taxes recoverable	17,581	16,187
Other receivables	12,318	13,021
Prepaid supplies	12,269	6,952
Prepaid insurance	3,276	3,688
Other	3,880	7,508
	<u>\$ 49,324</u>	<u>\$ 47,356</u>
Intangible assets, net:		
Customer relationships	\$ 447,699	\$ 443,560
Technologies	340,861	340,397
Trade names	50,520	50,442
Licenses	23,518	23,506
Covenants not to compete	16,373	16,348
Product registrations	10,857	7,641
Other	5,742	5,289
Less: accumulated amortization	(181,018)	(123,207)
	<u>\$ 714,552</u>	<u>\$ 763,976</u>
Accrued expenses:		
Deferred revenue	\$ 52,403	\$ 73,434
Employee benefits	46,237	43,792
Clinical trials	7,606	5,935
Taxes payable	4,590	4,430
Contingent consideration	2,011	259
Capital leases short-term	3,483	3,025
Milestone payment	9,819	4,865
Professional fees	2,584	4,035
Other	47,567	58,180
	<u>\$ 176,300</u>	<u>\$ 197,955</u>

(In thousands)	September 30, 2017	December 31, 2016
Other long-term liabilities:		
Deferred revenue	\$ 68,011	\$ 89,016
Line of credit	93,311	38,809
Contingent consideration	38,290	44,817
Mortgages and other debts payable	1,162	717
Capital leases long-term	8,435	7,216
Other	17,408	21,908
	<u>\$ 226,617</u>	<u>\$ 202,483</u>

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.

At September 30, 2017, the changes in value of the intangible assets and goodwill 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, 2017.

	2017		
(In thousands)	Balance at January 1	Foreign exchange and other	Balance at September 30th
Pharmaceuticals			
CURNA	\$ 4,827	\$ —	\$ 4,827
EirGen	78,358	9,639	87,997
FineTech	11,698	—	11,698
OPKO Chile	4,785	217	5,002
OPKO Biologics	139,784	—	139,784
OPKO Health Europe	6,936	853	7,789
OPKO Renal	2,069	—	2,069
Transition Therapeutics	3,360	261	3,621
Diagnostics			
BioReference	401,821	—	401,821
OPKO Diagnostics	17,977	—	17,977
OPKO Lab	32,988	—	32,988
	<u>\$ 704,603</u>	<u>\$ 10,970</u>	<u>\$ 715,573</u>

NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

Transition Therapeutics acquisition

In August 2016, we completed the acquisition of Transition Therapeutics, a clinical stage biotechnology company. Holders of Transition Therapeutics common stock received 6,431,899 shares of OPKO Common Stock. The transaction was valued at approximately \$58.5 million, based on a closing price per share of our Common Stock of \$9.10 as reported by NASDAQ on the closing date.

The following table summarizes the purchase price allocation and the fair value of the net assets acquired and liabilities assumed at the date of acquisition:

(In thousands)	Transition Therapeutics
Cash and cash equivalents	\$ 15,878
IPR&D assets	41,000
Goodwill	3,453
Other assets	634
Accounts payable and other liabilities	(1,035)
Deferred tax liability	(1,400)
Total purchase price	<u>\$ 58,530</u>

Goodwill from the acquisition of Transition Therapeutics principally relates to intangible assets that do not qualify for separate recognition (for instance, Transition Therapeutics' assembled workforce) and the deferred tax liability generated as a result of the transaction. Goodwill is not tax deductible for income tax purposes and was assigned to the pharmaceutical reporting segment.

Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval, the IPR&D assets are then accounted for as finite-lived intangible assets and amortized on a straight-line basis over its estimated useful life.

Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of September 30, 2017:

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	\$ 24,101	\$ 23,910
Variable interest entity, equity method	361	—
Available for sale investments	3,108	
Cost method investment	2,606	
Warrants and options	2,020	
Total carrying value of investments	<u>\$ 32,196</u>	

Equity method investments

Our equity method investments consist of investments in Pharmsynthez (ownership 9%), Cocrystal Pharma, Inc. ("COCP") (9%), Sevion Therapeutics, Inc. ("Sevion") (31%), Non-Invasive Monitoring Systems, Inc. ("NIMS") (1%), Neovasc (4%), VBI Vaccines Inc. ("VBI") (15%), InCellDx, Inc. (28%), 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, 2017 were \$415.4 million, \$(203.2) million, and \$(106.1) 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 Statements 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, 2017 is \$67.4 million.

Available for sale investments

Our available for sale investments consist of investments in RXi Pharmaceuticals Corporation (“RXi”) (ownership 2%), ChromaDex Corporation (1%), MabVax Therapeutics Holdings, Inc. (“MabVax”) (4%), and ARNO Therapeutics, Inc. (“ARNO”) (5%). We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of our available for sale investments. Accordingly, we account for our investment in these entities as available for sale, and we record changes in these investments as an unrealized gain or loss in Other comprehensive income (loss) each reporting period.

Based on our evaluation of the value of our investment in Xenetic, including Xenetic’s decreasing stock price during the nine months ended September 30, 2017, we determined that the decline in fair value of our Xenetic common shares was other-than-temporary and recorded an impairment charge of \$0.6 million in Other income (expense), net in our Condensed Consolidated Statements of Operations for the nine months ended September 30, 2017 to write our investment in Xenetic down to its fair value as of September 30, 2017.

Based on our evaluation of the value of our investments in Xenetic and RXi, including their decreasing stock price during the nine months ended September 30, 2016, we determined that the decline in fair value of our common shares in Xenetic and RXi was other-than-temporary and recorded an impairment charge of \$3.9 million in Other income (expense), net in our Condensed Consolidated Statements of Operations for the nine months ended September 30, 2016 to write our investments in Xenetic and RXi down to their respective fair values as of September 30, 2016.

Cost method investments

Our cost method investments consist primarily of our investment in Eloxx Pharmaceuticals (“Eloxx”) (ownership 3%). Investments for which it is not practical to estimate fair value and with which we do not have significant influence, are accounted for as cost method investments.

Sales of investments

Gains (losses) included in earnings from sales of our investments are recorded in Other income (expense), net in our Condensed Consolidated Statements of Operations. We did not have any such activity in the nine months ended September 30, 2017 and 2016. The cost of securities sold is based on the specific identification method.

Warrants and options

In addition to our equity method investments and available for sale investments, we hold options to purchase 1.0 million additional shares of Neovasc, which are fully vested as of September 30, 2017, options to purchase 5.0 million additional shares of BioCardia, none of which are vested as of September 30, 2017, and 1.0 million, 0.3 million, 0.2 million, 0.7 million, 0.5 million and 0.2 million of warrants to purchase additional shares of COCP, Sevion, MabVax, InCellDx, Inc., Xenetic and RXi, 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 Statements of Operations. We also recorded the fair value of the options and warrants in Investments, net in our Condensed Consolidated Balance Sheets. 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, 2017). 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.

Other

In March 2016, we entered into an agreement with Relative Core pursuant to which we delivered \$5.0 million cash to Relative Core in exchange for a \$5.0 million promissory note ("Relative Note") which bears interest at 10% and is due in 2018. The Relative Note is secured by 122,446 shares of common stock of Xenetic and 494,462 shares of OPKO common stock. We recorded the Relative Note within Other current assets and prepaid expenses in our Condensed Consolidated Balance Sheets.

NOTE 6 DEBT

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 of 1933, as amended (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 our Condensed Consolidated Balance Sheets as of September 30, 2017:

(In thousands)	Embedded conversion option	2033 Senior Notes	Discount	Debt Issuance Cost	Total
Balance at December 31, 2016	\$ 16,736	\$ 31,850	\$ (4,612)	\$ (273)	\$ 43,701
Amortization of debt discount and debt issuance costs	—	—	1,514	111	1,625
Change in fair value of embedded derivative	(3,185)	—	—	—	(3,185)
Reclassification of embedded derivatives to equity	(13,551)	—	—	—	(13,551)
Balance at September 30, 2017	\$ —	\$ 31,850	\$ (3,098)	\$ (162)	\$ 28,590

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) and holders who convert upon the occurrence of certain specific events prior to February 1, 2017 (other than in connection with a make-whole fundamental change). 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.

On or after February 1, 2017 and 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 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 for periods prior to February 1, 2017 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, prior to 2017 we combined these embedded derivatives and valued them together as one unit of accounting.

On February 1, 2017, certain terms of the embedded derivatives expired pursuant to the original agreement and we determined that the embedded derivatives no longer met the criteria to be separated from the host contract and, as a result, the embedded derivatives are no longer required to be valued separate and apart from the 2033 Senior Notes and are not required to be measured at fair value subsequent to February 1, 2017.

The change in derivative income for the period from January 1, 2017 to February 1, 2017 related to the embedded derivatives was \$3.2 million and the fair value at that date was \$13.6 million. For financial reporting purposes, we had remeasured the embedded derivatives subsequent to February 1, 2017 and recorded derivative income of \$4.9 million and \$5.1 million for the three months ended March 31, 2017 and June 30, 2017, respectively. In the three and nine months ended September 30, 2017, we reversed aggregate derivative income of \$6.8 million to correct the derivative to its value as of February 1, 2017. The adjustment of previously recorded derivative income for the three months ended March 31, 2017 and June 30, 2017 were not significant to those previous periods and increased our basic loss per share by \$(0.01) for the three months ended September 30, 2017 in the consolidated statements of operations. In addition, because the embedded derivatives are no longer required to be accounted for separately each period, in September 2017 the embedded derivative fair value of \$13.6 million as of February 1, 2017 was reclassified to additional paid in capital.

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.

On April 1, 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, and may be convertible thereafter, 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.

Through February 1, 2017, we used a binomial lattice model in order to estimate the fair value of the embedded derivative in the 2033 Senior Notes. A binomial lattice model generates two probable outcomes — one up and another down — arising at each point in time, starting from the date of valuation until the maturity date. A lattice model was initially used to determine if the 2033 Senior Notes would be converted, called or held at each decision point. Within the lattice model, the following assumptions are made: (i) the 2033 Senior Notes will be converted early if the conversion value is greater than the holding value; or (ii) the 2033 Senior Notes will be called if the holding value is greater than both (a) the redemption price (as defined in the Indenture) and (b) the conversion value plus the coupon make-whole payment at the time. If the 2033 Senior Notes are called, then the holders will maximize their value by finding the optimal decision between (1) redeeming at the redemption price and (2) converting the 2033 Senior Notes.

Using this lattice model, we had valued the embedded derivatives using the “with-and-without method,” where the value of the 2033 Senior Notes including the embedded derivatives is defined as the “with,” and the value of the 2033 Senior Notes excluding the embedded derivatives is defined as the “without.” This method estimated the value of the embedded derivatives by looking at the difference in the values between the 2033 Senior Notes with the embedded derivatives and the value of the 2033 Senior Notes without the embedded derivatives.

The lattice model requires the following inputs: (i) price of our Common Stock; (ii) Conversion Rate (as defined in the Indenture); (iii) Conversion Price (as defined in the Indenture); (iv) maturity date; (v) risk-free interest rate; (vi) estimated stock volatility; and (vii) estimated credit spread for the Company.

The following table sets forth the inputs to the lattice model used to value the embedded derivative as of February 1, 2017:

	February 1, 2017
Stock price	\$8.63
Conversion Rate	141.4827
Conversion Price	\$7.07
Maturity date	February 1, 2033
Risk-free interest rate	1.22%
Estimated stock volatility	49%
Estimated credit spread	761 basis points

On November 5, 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”), which replaced BioReference’s prior credit facility. 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. 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.

On March 17, 2017, BioReference and certain of its subsidiaries entered into Amendment No. 3 to Credit Agreement, which amended the Credit Agreement to permit BioReference and its subsidiaries to dividend cash to the Company in the form of an intercompany loan, in an aggregate amount not to exceed \$55,000,000. On August 7, 2017, BioReference and certain of its subsidiaries entered into Amendment No. 4 to Credit Agreement, which amended the Credit Agreement to permit BioReference and its subsidiaries to dividend cash to the Company in the form of an additional intercompany loan, in an aggregate amount not to exceed \$35,000,000. The other terms of the Credit Agreement remain unchanged.

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, 2017 were approximately \$1.0 billion, which includes goodwill of \$401.8 million and intangible assets of \$457.0 million.

In addition to the Credit Agreement with CB, we have line of credit agreements with eleven other financial institutions as of September 30, 2017 and ten other financial institutions as of December 31, 2016 in United States, 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 Bio Reference, Chilean and Spanish lines of credit:

(Dollars in thousands)		Balance Outstanding		
Lender	Interest rate on borrowings at September 30, 2017	Credit line capacity	September 30, 2017	December 31, 2016
JPMorgan Chase	3.36%	\$ 175,000	\$ 93,311	\$ 38,809
Itau Bank	5.50%	1,810	374	419
Bank of Chile	6.60%	3,800	2,687	1,619
BICE Bank	5.50%	2,500	1,720	1,538
BBVA Bank	5.50%	3,250	2,164	1,063
Estado Bank	5.50%	3,500	2,559	1,870
Santander Bank	5.50%	4,500	2,133	1,196
Scotiabank	5.00%	1,800	986	789
Corpbanca	5.00%	—	—	18
Banco Bilbao Vizcaya	2.90%	295	—	—
Santander Bank	2.67%	354	—	—
Total		\$ 196,809	\$ 105,934	\$ 47,321

At September 30, 2017 and December 31, 2016, the weighted average interest rate on our lines of credit was approximately 4.5% and 4.7%, respectively.

At September 30, 2017 and December 31, 2016, we had notes payable and other debt (excluding the 2033 Senior Notes, the Credit Agreement and amounts outstanding under lines of credit) as follows:

(In thousands)	September 30, 2017	December 31, 2016
Current portion of notes payable	\$ 3,726	\$ 3,681
Other long-term liabilities	2,085	2,090
Total	\$ 5,811	\$ 5,771

The notes and other debt mature at various dates ranging from 2017 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, 2017 and December 31, 2016, was 2.9% and 3.2%, respectively. The notes payable are secured by our office space in Barcelona.

NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

For the nine months ended September 30, 2017, 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, 2016	\$ (28,128)	\$ 1,119	\$ (27,009)
Other comprehensive income (loss) before reclassifications	21,646	(749)	20,897
Reclassification adjustments for losses included in net loss, net of tax		690	690
Net other comprehensive income (loss)	21,646	(59)	21,587
Balance at September 30, 2017	\$ (6,482)	\$ 1,060	\$ (5,422)

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.

A summary of our investments classified as available for sale and carried at fair value, is as follows:

(In thousands)	As of September 30, 2017			
	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Fair value
Common stock investments, available for sale	\$ 2,048	\$ 1,308	\$ (248)	\$ 3,108
Total assets	\$ 2,048	\$ 1,308	\$ (248)	\$ 3,108

(In thousands)	As of December 31, 2016			
	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Fair value
Common stock investments, available for sale	\$ 3,409	\$ 1,313	\$ (194)	\$ 4,528
Total assets	\$ 3,409	\$ 1,313	\$ (194)	\$ 4,528

Any future fluctuation in fair value related to our available for sale investments that is judged to be temporary, and any recoveries of previous temporary write-downs, will be recorded in Accumulated other comprehensive income (loss). If we determine that any future valuation adjustment was other-than-temporary, we will record a loss during the period such determination is made.

As of September 30, 2017, we have money market funds that qualify as cash equivalents, 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 agreements with Neovasc and BioCardia, we record the related Neovasc and BioCardia options at fair value as well as the warrants from COCP, Sevion, MabVax, InCellDx, Inc., Xenetic and RXi.

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

Fair value measurements as of September 30, 2017				
(In thousands)	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	\$ 12,621	\$ —	\$ —	\$ 12,621
Common stock investments, available for sale	3,108	—	—	3,108
Common stock options/warrants	—	2,020	—	2,020
Total assets	\$ 15,729	\$ 2,020	\$ —	\$ 17,749
Liabilities:				
Forward contracts	—	264	—	264
Contingent consideration	—	—	40,301	40,301
Total liabilities	\$ —	\$ 264	\$ 40,301	\$ 40,565

Fair value measurements as of December 31, 2016				
(In thousands)	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	\$ 5,314	\$ —	\$ —	\$ 5,314
Common stock investments, available for sale	4,528	—	—	4,528
Common stock options/warrants	—	4,017	—	4,017
Forward contracts	—	39	—	39
Total assets	\$ 9,842	\$ 4,056	\$ —	\$ 13,898
Liabilities:				
Embedded conversion option	\$ —	\$ —	\$ 16,736	\$ 16,736
Contingent consideration	—	—	45,076	45,076
Total liabilities	\$ —	\$ —	\$ 61,812	\$ 61,812

The carrying amount and estimated fair value of our 2033 Senior Notes with the embedded conversion option, as well as the applicable fair value hierarchy tiers, are contained in the table below. The fair value of the 2033 Senior Notes is determined using a binomial lattice approach in order to estimate the fair value of the embedded derivative in the 2033 Senior Notes. Refer to Note 6.

September 30, 2017					
(In thousands)	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2033 Senior Notes	\$ 28,590	\$ 37,011	\$ —	\$ —	\$ 37,011

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, 2017 and December 31, 2016, the carrying value of our other financial instrument assets and liabilities 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, 2017:

	September 30, 2017	
(In thousands)	Contingent consideration	Embedded conversion option
Balance at December 31, 2016	\$ 45,076	\$ 16,736
Total losses for the period:		
Included in results of operations	(4,475)	(3,185)
Foreign currency impact	3	—
Payments	(303)	—
Reclassification of embedded derivatives to equity	—	(13,551)
Balance at September 30, 2017	<u>\$ 40,301</u>	<u>\$ —</u>

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 \$2.4 million. As of September 30, 2017, of the \$40.3 million of contingent consideration, \$2.0 million is recorded in Accrued expenses and \$38.3 million is recorded in Other long-term liabilities. As of December 31, 2016, of the \$45.1 million of contingent consideration, \$0.3 million is recorded in Accrued expenses and \$44.8 million is recorded in Other long-term liabilities.

NOTE 9 DERIVATIVE CONTRACTS

The following table summarizes the fair values and the presentation of our derivative financial instruments in the Condensed Consolidated Balance Sheets:

(In thousands)	Balance Sheet Component	September 30, 2017	December 31, 2016
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	\$ 2,020	\$ 4,017
Embedded conversion option	2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	\$ —	\$ (16,736)
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.	\$ (264)	\$ 39

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, 2017 and December 31, 2016, 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 Statements of Operations. The following table summarizes the losses and gains recorded for the nine months ended September 30, 2017 and 2016:

(In thousands)	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Derivative gain (loss):				
Common Stock options/warrants	\$ (342)	\$ (12)	\$ (854)	\$ (4,728)
2033 Senior Notes	(6,829)	(5,795)	3,185	(1,061)
Forward contracts	(379)	106	(362)	(100)
Total	\$ (7,550)	\$ (5,701)	\$ 1,969	\$ (5,889)

NOTE 10 RELATED PARTY TRANSACTIONS

We hold investments in Zebra (ownership 29%), Sevion (31%), Neovasc (4%), ChromaDex Corporation (1%), MabVax (4%), COCP (9%) ARNO (5%), NIMS (1%), BioCardia (5%) and Eloxx (3%). 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 June 2017, we invested \$1.5 million in Eloxx for 99,915 Preferred C Shares and in July 2017, we invested an additional \$1.5 million in Sevion for 10,000,000 shares of Sevion common stock. An entity controlled by Dr. Frost also made an investment in Eloxx and committed to investing additional funds in Sevion by December 31, 2017. Sevion and Eloxx entered into an acquisition agreement on May 31, 2017 under which Eloxx will become a wholly owned subsidiary of Sevion. Upon completion of the transaction, Sevion will change its name to Eloxx Pharmaceuticals, Inc. Previously, in November 2016, we made a \$0.2 million loan to Sevion, and in February 2017, we entered into an agreement with Sevion pursuant to which we delivered \$0.3 million cash to Sevion in exchange for a promissory note. The loan and promissory note were converted into 4.1 million shares of Sevion common stock in August 2017. In September 2017, we converted 66,667 shares of Series C Preferred Stock of Sevion into 1,250,006 shares of common stock. The agreements with Sevion were considered related party transactions as a result of our executive management's ownership interests and board representation in Sevion.

In July 2017, we invested an additional \$0.1 million in MabVax for 152,143 shares of common stock and in May 2017, we invested an additional \$0.5 million in MabVax for 285,714 shares of Series G Preferred Stock and 322,820 shares of Series I Preferred Stock. We had also invested an additional \$1.0 million in MabVax in August 2016 for 207,900 shares of its common stock and warrants to purchase 415,800 shares of its common stock.

In April 2017, we invested an additional \$1.0 million in COCP for 4,166,667 shares of its common stock, and in August 2016, we had invested an additional \$2.0 million in COCP for 4,878,050 shares of its common stock.

In January 2016, we invested an additional \$0.3 million in ARNO for 714,285 shares of its common stock, and in August 2016, we had invested an additional \$0.3 million in ARNO for 714,285 shares of its common stock and warrants to purchase 357,142 shares of its common stock.

In October 2016, we entered into a consulting agreement to provide strategic advisory services to BioCardia. In connection with the consulting agreement, BioCardia granted us 5,027,726 common stock options. In December 2016, we purchased 19,230,769 shares of BioCardia from Dr. Frost for \$2.5 million. We have also purchased shares of BioCardia in the open market. BioCardia is a related party as a result of our executive management's ownership interest and board representation in BioCardia and its predecessor, Tiger X Medical, Inc. In October 2016, BioCardia completed its merger with Tiger X Medical, Inc., to which Tiger X Medical, Inc. was the surviving entity and the name of the issuer was changed to BioCardia.

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 28% 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, 2017, we recognized approximately \$168 thousand and \$309 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2016, we recognized approximately \$154 thousand and \$274 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

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, 2017, we recorded \$40.3 million as contingent consideration, with \$2.0 million recorded within Accrued expenses and \$38.3 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

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 (5) years. Interest on the Facility would be payable at a rate equal to six and one-half percent (6.5%) per annum, payable quarterly in arrears.

We currently anticipate that a decision by the VHA with respect to the RFP will occur during the fourth quarter of 2017, although there can be no assurance that a decision will be made by such time or that, if made, such decision will not be challenged by participants in the RFP process or otherwise.

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 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 these 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.

From time to time, we may receive inquiries, document requests, 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 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 Laboratories (“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 *Royaldee*. 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, 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.

We have employment agreements with certain executives of BioReference which provide for compensation and certain other benefits and for severance payments under certain circumstances. During the nine months ended September 30, 2017 and 2016, we recognized \$3.7 million and \$17.9 million, respectively, of severance costs pursuant to these employment agreements as a component of Selling, general and administrative expense.

At September 30, 2017, we were committed to make future purchases for inventory and other items in 2017 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating \$106.6 million.

NOTE 12 STRATEGIC ALLIANCES

Vifor Fresenius Medical Care Renal Pharma Ltd

We plan to develop a portfolio of product candidates through a combination of internal development and external partnerships. 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 *Royaldee* (the "Product") worldwide, except for (i) the United States, (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 chronic kidney disease 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. EirGen is also eligible to receive up to an additional \$37 million in regulatory milestones ("Regulatory Milestones") and \$195 million in launch and sales-based milestones ("Sales Milestones"), and will 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 the commencement of sales of the Product within the VFMCRP Territory and in the VFMCRP Field.

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. 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 VFMCRP Agreement will remain in effect with respect to the Product in each country of the VFMCRP Territory, on a country by country basis, until the date on which VFMCRP shall have no further payment obligations to EirGen under the terms of the VFMCRP Agreement, unless earlier terminated pursuant to the VFMCRP Agreement. VFMCRP's royalty

obligations expire on a country-by-country and product-by-product basis on the later of (i) expiration of the last to expire valid claim covering the Product sold in such country, (ii) expiration of all regulatory and data exclusivity applicable to the Product in the country of sale, and (iii) ten (10) years after the Product first commercial sale in such country. In addition to termination rights for material breach and bankruptcy, VFMCPR is permitted to terminate the VFMCPR Agreement in its entirety, or with respect to one or more countries in the VFMCPR Territory, after a specified notice period, provided that VFMCPR shall not have the right to terminate the VFMCPR Agreement with respect to certain major countries without terminating the entire VFMCPR Agreement. If the VFMCPR Agreement is terminated by EirGen or VFMCPR, provision has been made for transition of product and product responsibilities to EirGen.

In connection with the VFMCPR Agreement, the parties entered into a letter agreement (the “Letter Agreement”) pursuant to which EirGen granted to VFMCPR 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 United States solely for the treatment of secondary hyperparathyroidism in dialysis patients with chronic kidney disease and vitamin D insufficiency (the “Dialysis Indication”). Upon exercise of the Option, VFMCPR will reimburse EirGen for all of the development costs incurred by EirGen with respect to the Product for the Dialysis Indication in the United States. VFMCPR 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 at percentage rates that range from the mid-teens to the mid-twenties on sales of the Product in the United States for the Dialysis Indication.

The Option is exercisable until the earlier of (i) the date that EirGen submits a new drug application or supplemental new drug application or their then equivalents to the U.S. Food and Drug Administration for the Product for the Dialysis Indication in the United States, (ii) the parties mutually agree to discontinue development of Product for the Dialysis Indication, or (iii) VFMCPR provides notice to OPKO that it has elected not to exercise the Option.

OPKO has guaranteed the performance of certain of EirGen’s obligations under the VFMCPR Agreement and the Letter Agreement.

For revenue recognition purposes, we evaluated the various agreements with VFMCPR to determine whether there were multiple deliverables in the arrangement. The VFMCPR Agreement provides for the following: (1) an exclusive license in the VFMCPR Territory in the VFMCPR Field to use certain 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; (2) EirGen will supply Products to support the development, sale and commercialization of the Products to VFMCPR in the VFMCPR Territory (the “Manufacturing Services”); and (3) 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 United States solely for the Dialysis Indication. Based on our evaluation, the exclusive license is the only deliverable at the outset of the arrangement. We concluded the Manufacturing Services were a contingent deliverable dependent on the future regulatory and commercial action by VFMCPR and the Option was substantive and not considered a deliverable under the license arrangement.

We recognized the \$50.0 million upfront license payment in Revenue from transfer of intellectual property in our Condensed Consolidated Statements of Operations in the second quarter of 2016. Revenues related to the Manufacturing Services will be recognized as Product is sold to VFMCPR. No revenue related to the Option will be recognized unless and until VFMCPR exercises its Option under the Letter Agreement.

We determined that the cost sharing arrangement for development of the Dialysis Indication is not a deliverable in the VFMCPR Agreement. Payments for the Dialysis Indication will be recorded as Research and development expense as incurred.

EirGen is also eligible to receive up to an additional \$37 million in Regulatory Milestones and \$195 million in Sales Milestones. Payments received for Regulatory Milestones and Sales Milestones are non-refundable. The Regulatory Milestones are payable if and when VFMCPR 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 full 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.

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 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 will be responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer will fund the commercialization activities for all indications and lead the manufacturing activities covered by the global development plan.

For revenue recognition purposes, we viewed the Pfizer Transaction as a multiple-element arrangement. Multiple-element arrangements are analyzed to determine whether the various performance obligations, or elements, can be separated or whether they must be accounted for as a single unit of accounting. We evaluated whether a delivered element under an arrangement has standalone value and qualifies for treatment as a separate unit of accounting. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. For a single unit of accounting, payments received are recognized in a manner consistent with the final deliverable. We determined that the deliverables under the Pfizer Transaction, including the licenses granted to Pfizer, as well as our obligations to provide various research and development services, will be accounted for as a single unit of account. This determination was made because the ongoing research and development services to be provided by us are essential to the overall arrangement as we have significant knowledge and technical know-how that is important to realizing the value of the licenses granted. The performance period over which the revenue will be recognized is expected to continue from the first quarter of 2015 through 2020, when we anticipate completing the various research and development services that are specified in the Pfizer Transaction and our performance obligations are completed. We will continue to review the timing of when our research and development services will be completed in order to assess that the estimated performance period over which the revenue is to be recognized is appropriate. Any significant changes in the timing of the performance period will result in a change in the revenue recognition period. We increased the expected performance period over which the revenue will be recognized in the third quarter of 2017 by approximately one year.

We are recognizing the non-refundable \$295.0 million upfront payments on a straight-line basis over the performance period. We recognized \$46.5 million of revenue related to the Pfizer Transaction in Revenue from transfer of intellectual property in our Condensed Consolidated Statements of Operations during the nine months ended September 30, 2017, and had deferred revenue related to the Pfizer Transaction of \$112.3 million at September 30, 2017. As of September 30, 2017, \$44.9 million of deferred revenue related to the Pfizer Transaction was classified in Accrued expenses and \$67.4 million was classified in Other long-term liabilities in our Condensed Consolidated Balance Sheets.

The Pfizer Transaction includes milestone payments totaling \$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. We evaluated each of these milestone payments and believe that all of the milestones are substantive as (i) there is substantive uncertainty at the close of the Pfizer Transaction that the milestones would be achieved as approval from a regulatory authority must be received to achieve the milestones which would be commensurate with the enhancement of value of the underlying intellectual property, (ii) the milestones relate solely to past performance and (iii) the amount of the milestone is reasonable in relation to the effort expended and the risk associated with the achievement of the milestone. The milestone payments will be recognized as revenue in full 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.

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. 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. During the nine months ended September 30, 2016, no 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 United States and Europe at percentage rates that range from the low double digits to the low twenties, and outside of the United States and Europe at low double-digit percentage rates. 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.

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.

In July 2015, we entered into a Note Purchase Agreement with Pharmsynthez pursuant to which we delivered \$3.0 million to Pharmsynthez in exchange for a \$3.0 million note (the “Pharmsynthez Note Receivable”). The Pharmsynthez Note Receivable will be settled in 2017 and Pharmsynthez may satisfy the note either in cash or shares of its capital stock. We recorded the Pharmsynthez Note Receivable within Other current assets and prepaid expenses in our Condensed Consolidated Balance Sheets.

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 13 SEGMENTS

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 and our pharmaceutical research and development. The diagnostics segment primarily consists of our clinical laboratory operations we acquired through the acquisitions of BioReference and OPKO Lab 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.

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

(In thousands)	For the three months ended September 30,		For the nine months ended September 30,	
	2017	2016	2017	2016
Revenue from services:				
Pharmaceutical	\$ —	\$ —	\$ —	\$ —
Diagnostics	229,035	259,025	740,992	777,559
Corporate	—	—	—	—
	<u>\$ 229,035</u>	<u>\$ 259,025</u>	<u>\$ 740,992</u>	<u>\$ 777,559</u>
Revenue from products:				
Pharmaceutical	\$ 22,795	\$ 20,569	\$ 73,992	\$ 63,275
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	<u>\$ 22,795</u>	<u>\$ 20,569</u>	<u>\$ 73,992</u>	<u>\$ 63,275</u>
Revenue from transfer of intellectual property:				
Pharmaceutical	\$ 11,665	\$ 18,441	\$ 58,819	\$ 105,338
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	<u>\$ 11,665</u>	<u>\$ 18,441</u>	<u>\$ 58,819</u>	<u>\$ 105,338</u>
Operating loss:				
Pharmaceutical	\$ (18,452)	\$ (18,593)	\$ (49,709)	\$ 15,422
Diagnostics	(27,619)	3,098	(35,664)	11,117
Corporate	(12,219)	(8,128)	(41,067)	(49,414)
	<u>\$ (58,290)</u>	<u>\$ (23,623)</u>	<u>\$ (126,440)</u>	<u>\$ (22,875)</u>
Depreciation and amortization:				
Pharmaceutical	\$ 6,935	\$ 6,994	\$ 20,404	\$ 12,841
Diagnostics	18,430	18,818	56,183	59,711
Corporate	29	20	90	60
	<u>\$ 25,394</u>	<u>\$ 25,832</u>	<u>\$ 76,677</u>	<u>\$ 72,612</u>
Income (loss) from investment in investees:				
Pharmaceutical	\$ (3,661)	\$ 399	\$ (10,784)	\$ (5,643)
Diagnostics	(352)	(1,213)	(987)	496
Corporate	—	—	—	—
	<u>\$ (4,013)</u>	<u>\$ (814)</u>	<u>\$ (11,771)</u>	<u>\$ (5,147)</u>
Revenues:				
United States	\$ 229,218	\$ 259,221	\$ 751,732	\$ 777,703
Ireland	15,182	20,594	57,812	114,526
Chile	11,514	9,936	33,534	26,516
Spain	4,123	3,910	13,746	12,257
Israel	1,935	3,699	13,807	12,862
Mexico	1,483	675	3,072	2,308
Other	40	—	100	—
	<u>\$ 263,495</u>	<u>\$ 298,035</u>	<u>\$ 873,803</u>	<u>\$ 946,172</u>

(In thousands)	September 30, 2017	December 31, 2016
Assets:		
Pharmaceutical	\$ 1,309,650	\$ 1,294,916
Diagnostics	1,339,401	1,408,522
Corporate	72,939	63,181
	<u>\$ 2,721,990</u>	<u>\$ 2,766,619</u>
Goodwill:		
Pharmaceutical	\$ 262,786	\$ 251,817
Diagnostics	452,787	452,786
Corporate	—	—
	<u>\$ 715,573</u>	<u>\$ 704,603</u>

Two customers represented more than 10% of our total consolidated revenue during the three and nine months ended September 30, 2017. As of September 30, 2017, one customer represented more than 10% of our accounts receivable balance. As of December 31, 2016, one customer represented more than 10% of our accounts receivable balance.

NOTE 14 SUBSEQUENT EVENTS

On October 12, 2017, EirGen, our wholly-owned subsidiary, and Japan Tobacco Inc. (“JT”) entered into a Development and License Agreement granting JT the exclusive rights for the development and commercialization of *Royaldee* 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 Agreement (the “JT Additional Indications”, and together with the JT Initial Indications, the “JT Field”).

OPKO will receive an initial upfront payment of \$6 million. OPKO will receive another \$6 million upon the initiation of OPKO’s planned phase 2 study for *Royaldee* in dialysis patients in the U.S. 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 the Product 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 Product sales within the JT Territory and in the JT Field. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for *Royaldee* in Japan and for all commercial activities pertaining to *Royaldee* in Japan, except for certain preclinical expenses which OPKO has agreed to reimburse JT up to a capped amount.

We have reviewed all subsequent events and transactions that occurred after the date of our September 30, 2017 Condensed Consolidated Balance Sheet date, through the time of filing this Quarterly Report on Form 10-Q.

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, 2016 (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, 2016, 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 a 400-person sales and marketing team to drive growth and leverage new products, including the *4Kscore* prostate cancer test and the *Claros I* in-office immunoassay platform (in development). Our pharmaceutical business features *Royaldee*, 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), and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO in November 2015 and IV formulation approved October 2017), 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), and OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia and other urologic and metabolic conditions. Our pharmaceutical business also features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a once-daily Factor VIIa drug for hemophilia (Phase 2a).

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. EirGen, our specialty pharmaceutical manufacturing and development site in Ireland, is focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products. In addition, we operate 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 products.

RECENT DEVELOPMENTS

On October 12, 2017, EirGen, our wholly-owned subsidiary, and Japan Tobacco Inc. ("JT") entered into a Development and License Agreement granting JT the exclusive rights for the development and commercialization of *Royaldee* 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 Agreement (the "JT Additional Indications", and together with the JT Initial Indications, the "JT Field").

OPKO will receive an initial upfront payment of \$6 million. OPKO will receive another \$6 million upon the initiation of OPKO's planned phase 2 study for *Royaldee* in dialysis patients in the U.S. 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 the Product 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 Product sales within the JT Territory and in the JT Field. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for *Royaldee* in Japan and for all commercial activities pertaining to *Royaldee* in Japan, except for certain preclinical expenses which OPKO has agreed to reimburse JT up to a capped amount.

RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016

Revenues (In thousands)	For the three months ended September 30,		
	2017	2016	Change
Revenue from services	\$ 229,035	\$ 259,025	\$ (29,990)
Revenue from products	22,795	20,569	2,226
Revenue from transfer of intellectual property and other	11,665	18,441	(6,776)
Total revenues	<u>\$ 263,495</u>	<u>\$ 298,035</u>	<u>\$ (34,540)</u>

The decrease in Revenue from services is attributable to decreased pricing at BioReference's GeneDx division. The increase in Revenue from products principally reflects an increase in revenue from OPKO Chile and EirGen. Revenue from transfer of intellectual property for the three months ended September 30, 2017 and 2016 principally reflects \$11.2 million and \$17.7 million, respectively, of revenue related to the Pfizer Transaction.

Cost of revenue. Cost of revenue for the three months ended September 30, 2017 increased \$0.1 million compared to the prior year period. The decrease in cost of service revenue is attributable to cost savings initiatives at BioReference. The increase in cost of product revenue is attributable to an increase in revenue at OPKO Chile and EirGen. Cost of revenue for the three months ended September 30, 2017 and 2016 were as follows:

Cost of Revenue (In thousands)	For the three months ended September 30,		
	2017	2016	Change
Cost of service revenue	\$ 135,203	\$ 138,554	\$ (3,351)
Cost of product revenue	16,107	12,626	3,481
Total cost of revenue	<u>\$ 151,310</u>	<u>\$ 151,180</u>	<u>\$ 130</u>

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2017 and 2016, were \$131.3 million and \$124.8 million, respectively. The increase in selling, general and administrative expenses was primarily due to costs related to the launch of *Royaldee* and increased selling, general and administrative expenses at BioReference. Selling, general and administrative expenses during the three months ended September 30, 2017 and 2016, include equity-based compensation expense of \$4.6 million and \$6.4 million, respectively.

Research and development expenses. Research and development expenses for the three months ended September 30, 2017 and 2016, were \$32.3 million and \$24.4 million, respectively. Research and development costs include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. 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.

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

Research and Development Expenses	For the three months ended September 30,	
	2017	2016
External expenses:		
Phase 3 clinical trials	\$ 3,275	\$ 2,647
Manufacturing expense for biological products	10,827	6,951
PMA studies	249	—
Earlier-stage programs	1,479	1,910
Research and development employee-related expenses	6,177	6,718
Other internal research and development expenses	10,500	6,797
Third-party grants and funding from collaboration agreements	(178)	(599)
Total research and development expenses	<u>\$ 32,329</u>	<u>\$ 24,424</u>

The increase in research and development expenses is due to an increase in research and development expenses related to hGH-CTP, a long acting human growth hormone which was outlicensed to Pfizer in 2015, and to the acquisition of Transition Therapeutics in August 2016. In addition, during the three months ended September 30, 2017 and 2016, we recorded, as an offset to research and development expenses, \$0.2 million and \$0.6 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the three months ended September 30, 2017 and 2016 include equity-based compensation expense of \$1.3 million and \$2.0 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 income (expense) for the three months ended September 30, 2017 and 2016, were \$11.2 million of income and \$3.1 million of expense, respectively. The change in contingent consideration income (expense) was attributable to contingent consideration income for OPKO Renal during the three months ended September 30, 2017 due to changes in assumptions regarding the timing of successful achievement of future milestones of *Royaldee*. The contingent consideration liabilities at September 30, 2017 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 \$18.0 million and \$18.1 million, respectively, for the three months ended September 30, 2017 and 2016. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, IPR&D assets will then 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, 2017 and 2016 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, 2017 and 2016 was \$1.8 million and \$2.0 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes including amortization of related deferred financing costs and to interest incurred on BioReference's outstanding debt under its credit facility.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended September 30, 2017 and 2016, was \$7.6 million and \$5.7 million of expense, respectively. The change in derivative instruments principally related to non-cash expense related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes of \$6.8 million and \$5.8 million of expense for the three months ended September 30, 2017 and 2016, respectively.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2017 and 2016, were \$0.6 million of income and \$3.0 million of expense, respectively. Other expense for the three months ended September 30, 2016 primarily consists of a \$3.9 million other-than-temporary impairment charge to write our investments in Xenetic and RXi down to their respective fair values.

Income tax benefit. Our income tax benefit for the three months ended September 30, 2017 and 2016 was \$24.4 million and \$20.0 million, respectively, and reflects quarterly results using our expected effective tax rate for the full year. The change in income taxes is primarily due to changes in the geographic mix of revenues and expenses.

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 \$4.0 million and \$0.8 million for the three months ended September 30, 2017 and 2016, respectively. The increase in Loss from investments in investees is attributable to losses recognized on our investment in Pharmsynthez.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016

Revenues

(In thousands)	Nine months ended September 30,		
	2017	2016	Change
Revenue from services	\$ 740,992	\$ 777,559	\$ (36,567)
Revenue from products	73,992	63,275	10,717
Revenue from transfer of intellectual property and other	58,819	105,338	(46,519)
Total revenues	<u>\$ 873,803</u>	<u>\$ 946,172</u>	<u>\$ (72,369)</u>

The decrease in Revenue from services is attributable to decreased pricing at BioReference's GeneDx division. The increase in Revenue from products principally reflects an increase in revenue from OPKO Chile and EirGen. Revenue from transfer of intellectual property decreased as a result of the \$50.0 million of revenue from the initial payment under the VFMCPRP agreement included in the nine months ended September 30, 2016, partially offset by \$10.0 million of revenue from a milestone payment from our licensee, TESARO, for the nine months ended September 30, 2017. Revenue from transfer of intellectual property for the nine months ended September 30, 2017 and 2016 also reflects \$46.5 million and \$53.0 million, respectively, of revenue related to the Pfizer Transaction.

Cost of revenue. Cost of revenue for the nine months ended September 30, 2017 increased \$11.4 million compared to the prior year period. The increase in cost of service revenue is attributable to BioReference. The increase in cost of product revenue is attributable to an increase in revenue at OPKO Chile and EirGen. Included in cost of product revenue for the nine months ended September 30, 2017 is \$5.0 million of inventory obsolescence expense related primarily to the launch of *Royaldee*. Cost of revenue for the nine months ended September 30, 2017 and 2016 were as follows:

Cost of Revenue

(In thousands)	Nine months ended September 30,		
	2017	2016	Change
Cost of service revenue	\$ 419,070	\$ 417,121	\$ 1,949
Cost of product revenue	44,441	35,033	9,408
Total cost of revenue	<u>\$ 463,511</u>	<u>\$ 452,154</u>	<u>\$ 11,357</u>

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2017 and 2016, were \$396.4 million and \$370.4 million, respectively. The increase in selling, general and administrative expenses was primarily due to costs related to the launch of *Royaldee* and increased selling, general and administrative expenses at BioReference, which was partially offset by a decrease in severance costs. Included in selling, general and administrative expenses for the nine months ended September 30, 2017 and 2016 are \$3.7 million and \$17.9 million, respectively, of net severance costs for certain BioReference executives. These severance costs include \$2.8 million and \$8.9 million of expense related to the acceleration of stock option vesting for certain BioReference executives in 2017 and 2016, respectively.

Selling, general and administrative expenses during the nine months ended September 30, 2017 and 2016, include equity-based compensation expense of \$16.7 million and \$27.7 million, respectively, including the expense related to the acceleration of stock option vesting for certain BioReference executives.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2017 and 2016, were \$90.9 million and \$83.6 million, respectively. Research and development costs include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. 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	Nine months ended September 30,	
	2017	2016
External expenses:		
Phase 3 clinical trials	\$ 11,354	\$ 8,436
Manufacturing expense for biological products	31,102	30,484
PMA studies	694	—
Earlier-stage programs	4,734	4,949
Research and development employee-related expenses	18,915	21,266
Other internal research and development expenses	25,394	20,525
Third-party grants and funding from collaboration agreements	(1,249)	(2,066)
Total research and development expenses	<u>\$ 90,944</u>	<u>\$ 83,594</u>

The increase in research and development expenses is primarily due to a increase in research and development expenses related to hGH-CTP, a long acting human growth hormone which was outlicensed to Pfizer in 2015, and to the acquisition of Transition Therapeutics in August 2016.. In addition, during the nine months ended September 30, 2017 and 2016, we recorded, as an offset to research and development expenses, \$1.2 million and \$2.1 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the nine months ended September 30, 2017 and 2016 include equity-based compensation expense of \$4.0 million and \$6.0 million, respectively. We expect our research and development expense to increase as we continue to expand our research and development of potential future products.

Contingent consideration. Contingent consideration income (expense) for the nine months ended September 30, 2017 and 2016, were \$4.5 million of income and \$15.6 million of expense, respectively. The change in contingent consideration income (expense) was attributable to contingent consideration income for OPKO Renal during the nine months ended September 30, 2017 due to changes in assumptions regarding the timing of successful achievement of future milestones of *Royaldee*. The contingent consideration liabilities at September 30, 2017 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 \$53.9 million and \$47.3 million, respectively, for the nine months ended September 30, 2017 and 2016. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the nine months ended September 30, 2017 includes \$12.0 million of amortization expense related to intangible assets for *Royaldee*. Upon the FDA's approval of *Royaldee* in June 2016, we reclassified \$187.6 million of IPR&D related to *Royaldee* from In-process research and development to Intangible assets, net in our Condensed Consolidated Balance Sheets and began to amortize that asset. Our 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 then 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, 2017 and 2016, 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, 2017 and 2016, was \$4.8 million and \$6.0 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes including amortization of related deferred financing costs and to interest incurred on BioReference's outstanding debt under its credit

facility. The decrease in interest expense for the nine months ended September 30, 2017 is attributable to lower interest rates on borrowings in 2017 compared to 2016.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the nine months ended September 30, 2017 and 2016, was \$2.0 million of income and \$5.9 million of expense, respectively. Fair value changes of derivative instruments, net nine months ended September 30, 2017 principally related to non-cash income of \$3.2 million related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes. For the nine months ended September 30, 2017, we observed a decrease in the market price of our Common Stock which resulted in the decrease in the estimated fair value of our embedded derivatives in the 2033 Senior Notes through the last valuation on February 1, 2017. Fair value changes of derivative instruments, net for the nine months ended September 30, 2016 principally reflects \$4.0 million of expense related to the change in fair value of options to purchase additional shares of NeoVasc.

Other income (expense), net. Other income (expense), net for the nine months ended September 30, 2017 and 2016, were \$3.1 million and \$3.5 million of income, respectively. 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. Other income for the nine months ended September 30, 2016 primarily consisted of a \$2.5 million gain recognized in connection with the merger of STI and VBI Vaccines Inc. and a \$2.9 million gain recognized in connection with the settlement of a legal matter, which was partially offset by a \$3.9 million other-than-temporary impairment charge to write our investments in Xenetic and RXi down to their respective fair values.

Income tax benefit. Our income tax benefit for the nine months ended September 30, 2017 and 2016 was \$42.3 million and \$24.6 million, respectively, and reflects quarterly results using our expected effective tax rate for the full year. The change in income taxes is primarily due to changes in the geographic mix of revenues and expenses.

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 \$11.8 million and \$5.1 million for the nine months ended September 30, 2017 and 2016, respectively. The increase in Loss from investments in investees is attributable to losses recognized on our investment in Pharmsynthez.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2017, we had cash and cash equivalents of approximately \$100.4 million. Cash used in operations during 2017 principally reflects expenses related to general and administrative activities of our corporate operations, research and development activities and our launch activities related to *Royaldee*. Cash used in investing activities primarily reflects capital expenditures of \$32.1 million. Cash provided by financing activities primarily reflects net borrowings on lines of credit of \$54.9 million. 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 credit facilities available to us.

On October 12, 2017, EirGen, our wholly-owned subsidiary, and Japan Tobacco Inc. (“JT”) entered into a Development and License Agreement granting JT the exclusive rights for the development and commercialization of *Royaldee* 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 Agreement (the “JT Additional Indications”, and together with the JT Initial Indications, the “JT Field”).

OPKO will receive an initial upfront payment of \$6 million. OPKO will receive another \$6 million upon the initiation of OPKO’s planned phase 2 study for *Royaldee* in dialysis patients in the U.S. 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 the Product 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 Product sales within the JT Territory and in the JT Field. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for *Royaldee* in Japan and for all commercial activities pertaining to *Royaldee* in Japan, except for certain preclinical expenses which OPKO has agreed to reimburse JT up to a capped amount.

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 (5) years. Interest on the Facility would be payable at a rate equal to six and one-half percent (6.5%) per annum, payable quarterly in arrears.

We currently anticipate that a decision by the VHA with respect to the RFP will occur during the fourth quarter of 2017, although there can be no assurance that a decision will be made by such time or that, if made, such decision will not be challenged by participants in the RFP process or otherwise.

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.

In November 2016, we launched commercial sales for *Royaldee* in the U.S. market. The FDA approved *Royaldee* extended release capsules in June 2016 for the treatment of SHPT in adults with stage 3 or 4 CKD and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. We have a highly specialized sales and marketing team dedicated to the launch and commercialization of *Royaldee*, and we have increased the sales and marketing team in the second half of 2017 as market access improves and prescription trends increase.

In August 2016, we completed the acquisition of Transition Therapeutics, a clinical stage biotechnology company. Holders of Transition Therapeutics common stock received 6,431,899 shares of OPKO Common Stock. The transaction was valued at approximately \$58.5 million, based on a closing price per share of our Common Stock of \$9.10 as reported by NASDAQ on the closing date.

In May 2016, EirGen, our wholly-owned subsidiary, partnered with VFMCRP through a Development and License Agreement for the development and commercialization of *Royaldee* 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 chronic kidney disease and vitamin D insufficiency/deficiency (“VFMCRP Initial Indication”). We received a non-refundable and non-creditable upfront payment of \$50 million and are eligible to receive up to an additional \$232 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 United States 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 United States. 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.

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 \$295.0 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 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 will be responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer will 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 now 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 have agreed that OPKO may proceed with a pre-BLA meeting with the FDA to discuss a submission plan. OPKO intends to carry out an additional study in adults using a pen device.

We are constructing a research, development and manufacturing center in Waterford, Ireland, for which we expect to 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.

Our licensee, TESARO, received approval by the U.S. FDA in September 2015 for oral VARUBI™, a neurokinin-1 receptor antagonist for the prevention of chemotherapy-induced nausea and vomiting. In November 2015, TESARO announced the commercial launch of VARUBI™ in the United States. We received \$30.0 million of milestone payments from TESARO upon achievement of certain regulatory and commercial sale milestones, which includes a \$10.0 million milestone payment we received for the nine months ended September 30, 2017, and we are eligible to receive additional commercial milestone payments of up to \$85.0 million if specified levels of annual net sales are achieved. TESARO is also obligated to pay us tiered royalties on annual net sales achieved in the United States and Europe at percentage rates that range from the low double digits to the low twenties, and outside of the United States and Europe at low double-digit percentage rates.

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, 2017, \$31.9 million principal amount of 2033 Senior Notes was outstanding.

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.

On November 5, 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.

On March 17, 2017, BioReference and certain of its subsidiaries entered into Amendment No. 3 to Credit Agreement, which amended the Credit Agreement to permit BioReference and its subsidiaries to dividend cash to the Company in the form of an intercompany loan, in an aggregate amount not to exceed \$55,000,000. On August 7, 2017, BioReference and certain of its subsidiaries entered into Amendment No. 4 to Credit Agreement, which amended the Credit Agreement to permit BioReference and its subsidiaries to dividend cash to the Company in the form of an additional intercompany loan, in an aggregate amount not to exceed \$35,000,000. The other terms of the Credit Agreement remain unchanged.

As of September 30, 2017, the total availability under our Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain was \$130.6 million, of which \$105.9 million was used and outstanding as of September 30, 2017. The weighted average interest rate on these lines of credit is approximately 4.5%. 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 ended September 30, 2017, was \$105.9 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.

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, 2017, 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 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, success of the commercial launch 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, and our success in developing markets for our product candidates. 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.

The following table provides information as of September 30, 2017, 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, 2017	2018	2019	2020	2021	Thereafter	Total
Open purchase orders	\$ 97,863	\$ 8,446	\$ 274	\$ 34	\$ —	\$ —	\$ 106,617
Operating leases	5,271	18,231	15,027	9,388	6,164	6,853	60,934
Capital leases	887	3,404	3,026	2,367	1,438	800	11,922
2033 Senior Notes	—	—	31,850	—	—	—	31,850
Deferred payments	5,000	5,000	5,000	—	—	—	15,000
Mortgages and other debts payable	3,412	416	410	409	409	755	5,811
Lines of credit	12,623	—	—	93,311	—	—	105,934
Severance payments	5,101	—	—	—	—	—	5,101
Interest commitments	257	1,019	291	39	37	23	1,666
Total	<u>\$ 130,414</u>	<u>\$ 36,516</u>	<u>\$ 55,878</u>	<u>\$ 105,548</u>	<u>\$ 8,048</u>	<u>\$ 8,431</u>	<u>\$ 344,835</u>

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.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Accounting 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.

Goodwill and intangible assets. Goodwill and other intangible assets, including IPR&D, acquired in business combinations, licensing and other transactions at both September 30, 2017 and December 31, 2016 was \$2.1 billion, representing approximately 76% of total assets.

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 \$715.6 million and \$704.6 million, respectively, at September 30, 2017 and December 31, 2016. 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

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 \$1.4 billion, including IPR&D of \$648.4 million and \$644.7 million, respectively, at September 30, 2017 and December 31, 2016. 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.

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. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation.

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.

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 \$53.9 million and \$47.3 million for the nine months ended September 30, 2017 and 2016, respectively.

Revenue recognition. Revenue for laboratory services is recognized at the time test results are reported, which approximates when services are provided. Services are provided to patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in revenue net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue. For the nine months ended September 30, 2017, approximately 31% of our revenues were derived directly from the Medicare and Medicaid programs.

We recognize revenue from product sales when persuasive evidence of an arrangement exists, delivery has occurred, collectability is reasonably assured, and the price to the buyer is fixed or determinable, which is generally when goods are shipped and title and risk of loss transfer to our customers. 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. Allowances are recorded as a reduction of revenue at the time product revenues are recognized.

We launched *Royaldee* in the U.S. through our dedicated renal sales force in November 2016. *Royaldee* is distributed in the U.S. principally through the retail pharmacy channel, which initiates with the largest wholesalers in the U.S. (collectively, "*Royaldee* Customers"). In addition to distribution agreements with *Royaldee* 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 *Royaldee*.

We lack the experiential data which would allow us to estimate Sales Deductions and product returns. Therefore, as of September 30, 2017, we have determined that we do not yet meet the criteria for the recognition of revenue for shipments of *Royaldee* at the time of shipment to *Royaldee* Customers as allowances for Sales Deductions and product returns are not known

or cannot be reasonably estimated. We will not recognize revenue upon shipment until such time as we can reasonably estimate and record provisions for Sales Deductions and product returns utilizing historical information and market research projections.

During the nine months ended September 30, 2017, we did not recognize any product revenues related to *Royaldee* sales. Payments received from *Royaldee* Customers in advance of recognition of revenue are recorded as deferred revenue included in Accrued expenses in our Condensed Consolidated Balance Sheets. The related deferred revenue balance as of September 30, 2017 was \$6.5 million. The corresponding costs of product revenues for which we have not recognized product revenue have similarly not yet been reflected in our Condensed Consolidated Statements of Operations.

Revenue from transfer of intellectual property includes revenue related to the sale, license or transfer of intellectual property such as upfront license payments, license fees, milestone and royalty payments received through our license, and collaboration and commercialization agreements. We analyze our multiple-element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting.

Non-refundable license fees for the out-license of our technology are recognized depending on the provisions of each agreement. We recognize non-refundable upfront license payments as revenue upon receipt if the license has standalone value and qualifies for treatment as a separate unit of accounting under multiple-element arrangement guidance. License fees with ongoing involvement or performance obligations that do not have standalone value are recorded as deferred revenue, included in Accrued expenses or Other long-term liabilities, when received and generally are recognized ratably over the period of such performance obligations only after both the license period has commenced and we have delivered the technology.

The assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the relevant time period of research and development on a periodic basis.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as Revenue from transfer of intellectual property upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; there was substantive uncertainty at the date of entering into the arrangement that the milestone would be achieved; the milestone payment is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item by us; the milestone relates solely to past performance; and the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions are not met, the milestone payments are not considered to be substantive and are, therefore, deferred and recognized as Revenue from transfer of intellectual property over the term of the arrangement as we complete our performance obligations.

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, 2017 and December 31, 2016, receivable balances (net of contractual adjustments) from Medicare and Medicaid were 22.0% and 22.9%, 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, 2017 and December 31, 2016, receivables due from patients represent approximately 2.4% and 4.1%, 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 \$57.6 million and \$36.3 million at September 30, 2017 and December 31, 2016, respectively.

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.

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 Statements 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 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.

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.

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.

RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers.” ASU 2014-09, as amended, 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. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Companies can choose to apply the ASU using either the full retrospective approach or a modified retrospective approach.

We have commenced our implementation analysis, including identification of revenue streams and reviews of customer contracts under ASU 2014-09’s framework. Our analysis includes reviewing current accounting policies and practices to identify potential differences that would result from applying the requirements under this new standard. The Company has reviewed certain contracts with its customers that the Company believes are representative of its revenue streams and continues to review additional contracts across its global business units. ASU 2014-09 requires increased disclosure which in turn is

expected to require certain new processes. The determination of the impact of adoption of ASU 2014-09 on our financial condition, results of operations, cash flows and disclosures, is ongoing, and, as such, we have not yet concluded on a transition method and are not able to reasonably estimate the effect that the adoption of the new standard will have on our financial statements. Based on our preliminary assessment of this ASU, however, the majority of the amounts that were historically classified as provision for bad debts, primarily related to patient responsibility, will be considered an implicit price concession in determining net revenues. Accordingly, we will report uncollectible balances associated with individual patients as a reduction of the transaction price and therefore as a reduction in net revenues when historically these amounts were classified as provision for bad debts within Selling, general and administrative expenses.

In July 2015, the FASB issued ASU No. 2015-11, “Inventory (Topic 330): Simplifying the Measurement of Inventory,” which changes the measurement principle for entities that do not measure inventory using the last-in, first-out (“LIFO”) or retail inventory method from the lower of cost or market to lower of cost and net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. The adoption of ASU 2015-11 in the first quarter of 2017 did not have a significant impact on our Condensed Consolidated Financial Statements.

In November 2015, the FASB issued ASU No. 2015-17, “Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes,” which requires deferred tax liabilities and assets to be classified as noncurrent in a classified statement of financial position. The adoption of this ASU simplifies the presentation of deferred income taxes and reduces complexity without decreasing the usefulness of information provided to users of financial statements. We early adopted the provisions of this ASU prospectively in the fourth quarter of 2015, and did not retrospectively adjust the prior periods. The adoption of ASU 2015-17 did not have a significant impact on our Condensed Consolidated Financial Statements.

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. ASU 2016-01 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 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. The ASU will also require 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 March 2016, the FASB issued ASU No. 2016-09, “Compensation - Stock Compensation (Topic 718),” which simplifies several aspects of the accounting for share-based payment award transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and accounting for forfeitures. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We adopted this standard in the first quarter of 2017. As required by ASU 2016-09, excess tax benefits are classified as an operating activity in our Condensed Consolidated Statement of Cash Flows and we have applied this provision prospectively. In addition, we have elected to estimate forfeitures over the course of a vesting period, rather than account for forfeitures as they occur. We adjust our forfeiture estimates based on the number of share-based awards that ultimately vest on at least an annual basis. Upon the adoption of ASU 2016-09 in 2017, we recorded a cumulative-effect adjustment to increase our deferred tax assets and reduce our accumulated deficit by \$32.5 million with respect to excess tax benefits recognized in our Condensed Consolidated Balance Sheets.

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. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, 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 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.

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 a significant portion 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 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, 2017, we had cash and cash equivalents of \$100.4 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2017 was less than 1%. As of September 30, 2017, the principal outstanding balance under our Credit Agreement with JPMorgan Chase Bank, N.A. and our Chilean and Spanish lines of credit was \$105.9 million in the aggregate at a weighted average interest rate of approximately 4.5%.

Our \$31.9 million aggregate principal amount of our 2033 Senior Notes has a fixed interest rate, and therefore is 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.

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, 2017.

Changes to the Company's Internal Control Over Financial Reporting

In connection with the acquisition of Transition Therapeutics in August 2016, we began implementing standards and procedures at Transition Therapeutics, including establishing controls over accounting systems and establishing controls over the preparation of financial statements in accordance with generally accepted accounting principles to ensure that we have in place appropriate internal control over financial reporting at Transition Therapeutics. We are continuing to integrate the acquired operations of Transition Therapeutics into our overall internal control over financial reporting process.

We are in the process of implementing a new comprehensive enterprise resource planning ("ERP") system on a company-wide basis, which is one of the systems used for financial reporting. The implementation of the ERP system involves changes to our financial systems and other systems and accordingly, necessitated changes to our internal controls over financial reporting.

These changes to the Company's internal control over financial reporting that occurred during the most recent quarter ended September 30, 2017 have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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, 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, 2016 and our Quarterly Report on Form 10-Q for the quarters ended March 31, 2017 and June 30, 2017.

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, 2016, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common and capital stock. There have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2016.

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

On November 8, 2017, BioReference and certain of its subsidiaries entered into Amendment No. 5 to Credit Agreement, which amended the Credit Agreement to, among other things, ease certain thresholds that require increased reporting by BioReference and reduce the pro forma availability condition for BioReference to make certain cash dividends to the Company. The other terms of the Credit Agreement remain unchanged.

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 10.1*	Amendment No. 4 to Credit Agreement by and between Bio-Reference Laboratories, Inc. and certain of its subsidiaries and JPMorgan Chase Bank, N.A. dated August 7, 2017
Exhibit 10.2*	Commitment Letter by and between OPKO Health, Inc. and Veterans Accountable Care Group, LLC, dated August 15, 2017
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, 2017.
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, 2017.
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, 2017.
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, 2017.
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

* Filed herewith.

- (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.

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 8, 2017

OPKO Health, Inc.

/s/ Adam Logal

Adam Logal

Senior Vice President, Chief Financial Officer,
Chief Accounting Officer and Treasurer

EXECUTION VERSION**AMENDMENT NO. 4 TO CREDIT AGREEMENT**

AMENDMENT NO. 4 TO CREDIT AGREEMENT (this "Amendment"), dated as of August 7, 2017, is entered into among BIO-REFERENCE LABORATORIES, INC., a New Jersey corporation ("Company"), the Subsidiary Borrowers party hereto ("Subsidiary Borrowers," and together with Company, each a "Borrower" and, collectively, the "Borrowers"), the other Loan Parties party hereto, the Lenders party hereto, and JPMORGAN CHASE BANK, N.A., as the administrative agent for the Lenders (the "Administrative Agent").

W I T N E S S E T H :

WHEREAS, the Borrowers, the other Loan Parties party thereto, the Lenders party thereto, and the Administrative Agent have executed and delivered that certain Credit Agreement dated as of November 5, 2015, as amended by Amendment No. 1 to Credit Agreement dated as of February 29, 2016, as amended by Amendment No. 2 to Credit Agreement dated as of September 26, 2016, and as amended by Amendment No. 3 to Credit Agreement dated as of March 17, 2017 (as further amended, restated, supplemented, or otherwise modified from time to time prior to the date hereof, the "Credit Agreement"); and

WHEREAS, the Borrowers have requested that the Lenders and the Administrative Agent make certain amendments to the Credit Agreement, and the Lenders party hereto, constituting all Lenders under the Credit Agreement, have agreed to such amendments, subject to the terms and conditions hereof.

NOW, THEREFORE, for and in consideration of the above premises and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, each of the Borrowers, the other Loan Parties, the Lenders and the Administrative Agent hereby covenant and agree as follows:

SECTION 1. Definitions. Unless otherwise specifically defined herein, each term used herein (and in the recitals above) which is defined in the Credit Agreement shall have the meaning assigned to such term in the Credit Agreement. As of the date hereof, each reference in the Credit Agreement to "this Agreement," "hereunder," "hereof," "herein," or words of like import, and each reference in the other Loan Documents to the Credit Agreement (including, without limitation, by means of words like "thereunder," "thereof" and words of like import), shall mean and be a reference to the Credit Agreement, as amended hereby.

SECTION 2. Amendments to Credit Agreement. Effective as of the Amendment No. 4 Effective Date (as defined below), the Credit Agreement is hereby amended as follows:

(a) Amendments to Section 1.01.

(i) Section 1.01 of the Credit Agreement is hereby amended by adding the following definition in appropriate alphabetical order:

"Amendment No. 4 Effective Date" means August 7, 2017.

“Special Intercompany Loans” means (i) a loan made within ten (10) days of the Amendment No. 3 Effective Date by the Company to the Parent in an amount not to exceed \$55,000,000 and (ii) a loan made on the Amendment No. 4 Effective Date by the Company to the Parent in an amount not to exceed \$35,000,000.

(b) Section 6.04(d) of the Credit Agreement is amended so that it reads, in its entirety, as follows:

(d) (i) loans or advances made by any Loan Party to any Subsidiary and made by any Subsidiary to a Loan Party or any other Subsidiary, provided that (A) any such loans and advances made by a Loan Party to a Subsidiary that is not a Loan Party shall be evidenced by a promissory note pledged pursuant to the Security Agreement and (B) the amount of such loans and advances made by Loan Parties to Subsidiaries that are not Loan Parties (together with outstanding investments permitted under clause (B) to the proviso to Section 6.04(c) and outstanding Guarantees permitted under the proviso to Section 6.04(e) and excluding any Special Intercompany Loan) shall not exceed \$5,000,000 at any time outstanding (in each case determined without regard to any writedowns or write-offs) and (ii) the Special Intercompany Loans, provided that the Special Intercompany Loans shall each be evidenced by a promissory note pledged pursuant to the Security Agreement;

SECTION 3. Conditions Precedent. This Amendment shall become effective on the date (such date, the “Amendment No. 4 Effective Date”) the following conditions precedent shall have been satisfied:

(a) receipt by the Administrative Agent of signatures to this Amendment from the parties listed on the signature pages hereto; and

(b) the Administrative Agent shall have received from the Borrowers (or the Administrative Agent shall be satisfied with arrangements made for the payment thereof) all other costs, fees, and expenses owed by the Borrowers to the Administrative Agent in connection with this Amendment, including, without limitation, reasonable attorneys’ fees and expenses, in accordance with Section 9.03 of the Credit Agreement.

SECTION 4. Miscellaneous.

(a) Representations and Warranties. To induce the Administrative Agent and Lenders to enter into this Amendment, the Borrowers hereby represent and warrant to the Administrative Agent and the Lenders that all representations and warranties of the Borrowers contained in Article III of the Credit Agreement or any other Loan Document are true and correct in all material respects with the same effect as though made on and as of the Amendment No. 4 Effective Date (except with respect to representations and warranties made as of an expressed date, which representations and warranties are true and correct in all material respects as of such date).

(b) No Offset. To induce the Administrative Agent and Lenders to enter into this Amendment, the Borrowers hereby acknowledge and agree that, as of the date hereof, and after giving effect to the terms hereof, there exists no right of offset, defense, counterclaim, claim, or

objection in favor of the Borrowers or arising out of or with respect to any of the loans or other obligations of the Borrowers owed by the Borrowers under the Credit Agreement or any other Loan Document.

(c) Loan Document. The parties hereto hereby acknowledge and agree that this Amendment is a Loan Document.

(d) Effect of Amendment. Except as set forth expressly hereinabove, all terms of the Credit Agreement and the other Loan Documents shall be and remain in full force and effect, and shall constitute the legal, valid, binding, and enforceable obligations of the Borrowers, enforceable in accordance with their terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other laws affecting creditors' rights generally and subject to general principles of equity, regardless of whether considered in a proceeding in equity or at law.

(e) No Novation or Mutual Departure. The Borrowers expressly acknowledge and agree that (i) this Amendment does not constitute or establish, a novation with respect to the Credit Agreement or any of the other Loan Documents, or a mutual departure from the strict terms, provisions, and conditions thereof, other than with respect to the amendments set forth in Section 2 above, and (ii) nothing in this Amendment shall affect or limit the Administrative Agent's or any Lender's right to (x) demand payment of the Obligations under, or demand strict performance of the terms, provisions and conditions of, the Credit Agreement and the other Loan Documents (in each case, as amended hereby), as applicable, (y) exercise any and all rights, powers, and remedies under the Credit Agreement or the other Loan Documents (in each case, as amended hereby) or at law or in equity, or (z) do any and all of the foregoing, immediately at any time during the occurrence of an Event of Default and in each case, in accordance with the terms and provisions of the Credit Agreement and the other Loan Documents.

(f) Counterparts. This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed and delivered shall be deemed to be an original and all of which counterparts, taken together, shall constitute but one and the same instrument. This Amendment may be executed by each party on separate copies, which copies, when combined so as to include the signatures of all parties, shall constitute a single counterpart of this Amendment.

(g) Fax or Other Transmission. Delivery by one or more parties hereto of an executed counterpart of this Amendment via facsimile, telecopy, or other electronic method of transmission pursuant to which the signature of such party can be seen (including, without limitation, Adobe Corporation's Portable Document Format) shall have the same force and effect as the delivery of an original executed counterpart of this Amendment. Any party delivering an executed counterpart of this Amendment by facsimile or other electronic method of transmission shall also deliver an original executed counterpart, but the failure to do so shall not affect the validity, enforceability, or binding effect of this Amendment.

(h) Recitals Incorporated Herein. The preamble and the recitals to this Amendment are hereby incorporated herein by this reference.

(i) Section References. Section titles and references used in this Amendment shall be without substantive meaning or content of any kind whatsoever and are not a part of the agreements among the parties hereto evidenced hereby.

(j) Governing Law. This Amendment shall be governed by and construed in accordance with the internal laws (and not the law of conflicts) of the State of New York, but giving effect to federal laws applicable to national banks.

(k) Severability. Any provision of this Amendment which is prohibited or unenforceable shall be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof in that jurisdiction or affecting the validity or enforceability of such provision in any other jurisdiction.

(l) Reaffirmation of Loan Parties. Each Loan Party (i) consents to the execution and delivery of this Amendment, (ii) reaffirms all of its obligations and covenants under the Loan Documents (including, without limitation, the Collateral Documents and the Loan Guaranty) to which it is a party, and (iii) agrees that, except to the extent amended hereby, none of its respective obligations and covenants under the Loan Documents shall be reduced or limited by the execution and delivery of this Amendment.

[SIGNATURES ON FOLLOWING PAGES.]

IN WITNESS WHEREOF, the Borrowers, the other Loan Parties, the Administrative Agent and the Lenders have caused this Amendment to be duly executed by their respective duly authorized officers as of the day and year first above written.

BORROWERS:

BIO-REFERENCE LABORATORIES, INC.
GENEDX, INC.
FLORIDA CLINICAL LABORATORY, INC.
MERIDIAN CLINICAL LABORATORY
CORP.

By: /s/ Adam Logal
Name: Adam Logal
Title: Senior Vice President

OTHER LOAN PARTIES

CAREEVOLVE.COM, INC.
BRLI-GENPATH IAGNOSTICS, INC.
GENEDX MENA LLC

By: /s/ Adam Logal
Name: Adam Logal
Title: Senior Vice President

JPMORGAN CHASE BANK, N.A.
Individually as a Lender and as Administrative
Agent, Issuing Bank and Swingline Lender

By: /s/ Eric A. Anderson

Name: Eric A. Anderson

Title: Authorized Officer



August 15, 2017

Veterans Accountable Care Group, LLC
5665 North Scottsdale Road, Suite 110
Scottsdale, Arizona 85250

Attn: Mr. David R. Nelson, President and Chief Executive Officer

Re: Commitment Letter

Dear Mr. Nelson:

Veterans Accountable Care Group, LLC, an Arizona limited liability company ("VACG" or "you"), has advised OPKO Health, Inc. ("OPKO", "we," or "us") that Veterans Accountable Care Organization, LLC ("VACO") has submitted to the Veterans Health Administration ("VHA") a proposal (the "Proposal") for VACO to be awarded (the "Award") a Prime Contract (the "Contract") under the VHA's Community Care Network Initiative described in the VHA's December 28, 2016 Request for Proposals regarding the Community Care Network ("CCN"), VA 791-16-R-0086 (the "RFP"). All references to "dollars" or "\$" in this letter are references to United States dollars.

You have advised us that it is a condition precedent to the Award that VACO satisfies a financial stability requirement under the RFP (the "Financial Requirement"). VACO intends to use the cash proceeds of a \$50,000,000 capital contribution from VACG to VACO to satisfy the Financial Requirement.

1. Commitment.

(a) Subject to the provisions of paragraph 11(a) below, OPKO is pleased to advise VACG of its commitment to provide (through one or more of its affiliates), or to arrange from a third party lender or such other person approved by VACG (such consent not to be unreasonably withheld or conditioned), a line of credit for VACG in the amount of \$50,000,000 (the "Facility") in accordance with the terms and conditions set forth in this letter (or as otherwise agreed to by VACG and the lender under the Facility (the "Lender"). Under the terms of the Facility, VACG shall not be permitted to draw down on the Facility until the date (the "Award Date") on which the VHA awards a CCN contract to VACO (the "CCN Contract"). The Facility shall mature five (5) years following the Award Date (the "Maturity Date"). During the term of the Facility, VACG shall only be required to pay interest on the Facility, with the outstanding principal and all accrued and unpaid interest to be repaid in full on the Maturity Date. Interest will be payable on the unpaid principal amount under the Facility at a rate equal to six and one-half percent (6.5%) per annum, payable quarterly in arrears. The default interest rate under the Facility shall be 18% per annum commencing upon an event of default as defined in the definitive loan documentation for the Facility

(the “Definitive Agreements”), which shall be due and payable on demand by Lender. The Definitive Agreements shall be customary for transactions of the type described in this letter, shall incorporate the terms and conditions set forth in this letter (or as otherwise agreed to by VACG and Lender) and shall be executed and delivered by VACG and Lender on or prior to the Award Date. The parties hereby agree that, except as provided elsewhere herein, no fees shall be payable by VACG or VACO to OPKO hereunder in respect of the Facility or any borrowings by VACG thereunder, or based on VACO being awarded a CCN Contract by the VHA; provided that, if OPKO or one or more of its affiliates is the Lender, then OPKO shall be entitled to the interest on the Facility as provided herein and customary fees and expenses under the Facility as set forth in the Definitive Agreements. OPKO hereby acknowledges and agrees that due to applicable legal and regulatory requirements, VACO’s accounts receivable under any CCN Contract may not be assigned to Lender or used as collateral or security for the Facility. The Definitive Agreements shall provide that in the event of any uncured material default by VACG under the Facility, Lender shall be authorized to sweep from VACO’s bank account funds sufficient to cure such default; provided, that upon any acceleration of the Facility upon an event of default (after giving effect to any applicable notice, grace or cure periods as provided in the Definitive Agreements), Lender shall be authorized to sweep the account to cure such default; provided further, that, to the extent prohibited by applicable law, regulation or directive or the CCN Contract, Lender shall not be permitted to sweep any funds deposited in the accounts in respect of VACO accounts receivable for clinical services payable to VACO under its CCN Contract. The Facility shall also be secured by a pledge of each of David R. Nelson’s and SSB Solutions, Inc.’s respective ownership interests in VACG; provided, that Lender shall only be permitted to exercise its remedies with respect to such pledges in the event of an event of default under the Facility that cannot be cured by Lender exercising the above-mentioned sweep of VACO’s bank account.

(b) If following final resolution of any and all CCN bid protests (i) the VHA awards a CCN Contract to VACO and (ii) VACG and the Lender have entered into and closed the Definitive Agreements for the Facility, OPKO shall receive a membership interest totaling 15% of the outstanding membership interests in VACO in the aggregate (the “Membership Interest”), by virtue of an assignment and transfer of the membership interests held by VACG in VACO.

2. **Use of Proceeds.** Subject to the provisions of paragraph 11(a) below, the funds drawn under the Facility shall be contributed by VACG to VACO to satisfy the Financial Requirement.

3. **Definitive Agreements between Lender and VACG.** In connection with the Facility, OPKO and VACG will negotiate with Lender and VACG and Lender will execute Definitive Agreements, which shall include terms and conditions consistent with those set forth in this letter and other terms and conditions customary for transactions of such type and otherwise acceptable to VACG and Lender. The rights of OPKO as a member of VACO, and in relation to the Membership Interest it will obtain as stated above, will be as set forth in VACO’s Amended and Restated Operating Agreement, which shall be in form and substance reasonably acceptable to OPKO.

4. **Information.** You hereby represent, warrant and covenant that: (a) all written information (other than the Projections (as defined below), other forward-looking information and information of a general economic or industry specific nature) that has been or will be made available to us by you or your representatives, or on your or their behalf, in connection with the Facility (the “Information”) is and will be complete and correct when taken as a whole, in all material respects, and does not and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements contained therein, in the light of the circumstances under which such statements are made, not misleading, and (b) all financial projections concerning VACO and VACG that have been or are hereafter made available to us by you or any of your representatives, or on your or their behalf (the “Projections”) in connection with the Facility have been or will be prepared in good faith based upon assumptions believed by you to be reasonable at the time furnished (it being understood that projections are inherently uncertain and no assurance can be given that the Projections will be realized). You agree that if, at any time prior to the Award Date, you become aware that any of the representations in the preceding sentence would be incorrect in any material respect if the Information and Projections were being furnished, and such representations were being made, at such time, then you will promptly supplement the Information and Projections so that such representations are corrected in accordance with this paragraph at such time. You agree that, in issuing the commitment hereunder, OPKO will be entitled to rely and use the Information and Projections without independent verification thereof. In addition, you agree to promptly advise OPKO of any developments materially affecting VACO, VACG or the Facility prior to the Award Date.

5. **Costs and Expenses.** You hereby agree to pay or reimburse OPKO for all reasonable and documented out-of-pocket expenses (including due diligence expenses, consultant’s fees and expenses and the reasonable fees, charges and disbursements of counsel) incurred by OPKO on or after June 26, 2017 in connection with the preparation, review, negotiation, execution, and delivery of this letter and the Definitive Agreements, whether or not any such agreements are executed by the parties, and whether or not the Award Date occurs. VACG’s obligations hereunder are in addition to any obligations to reimburse Lender for any costs and expenses in connection with the Facility, which obligations shall be covered by the Definitive Agreements or any other agreement between VACG and Lender.

6. **Indemnity.** You hereby agree to indemnify and hold harmless OPKO, its affiliates and their respective directors, officers, employees, advisors, agents and representatives (each an “Indemnified Person”) from and against any and all losses, costs, expenses, damages and liabilities of any kind or nature whatsoever which may be incurred by any such Indemnified Person as a result of or arising out of any actions, suits, investigations, inquiries, or proceedings in connection with this letter, the Facility or the use of proceeds thereof, or any Definitive Agreement (any of the foregoing, for purposes of this paragraph, a “Proceeding”); provided, however, that no Indemnified Person will be indemnified for any such loss, cost, expense, damages or liability: (a) to the extent determined by a final non-appealable judgment of a court of competent jurisdiction to have resulted from (i) the gross negligence, bad faith, or willful misconduct by such Indemnified Person, or (ii) any settlement entered into by any Indemnified Person without VACG’s consent (such consent not

to be unreasonably withheld, conditioned or delayed); or (b) arising out of or in connection with any claim, litigation, investigation or proceeding that is brought by an Indemnified Person against another Indemnified Person and not involving any act or omission by VACG, its subsidiaries or its affiliates. You further agree that no Indemnified Person shall have any liability (whether indirect, in contract, tort, equity or otherwise) to you or your subsidiaries or affiliates or to your or their respective equity holders or creditors arising out of, related to or in connection with this letter or the Facility, except to the extent of direct (as opposed to special, indirect, consequential or punitive) damages determined in a final non-appealable judgment by a court of competent jurisdiction to have resulted from Indemnified Person's gross negligence, bad faith, or willful misconduct.

7. **Confidentiality.** This letter is delivered to you upon your agreement that this letter (including the existence and contents thereof) shall not be disclosed by you or your affiliates to any other person, directly or indirectly, except (a) to your officers, directors, employees, affiliates, attorneys, agents and accountants and actual or prospective investors and lenders on a confidential and need-to-know basis solely in connection with such transactions (assuming such persons are informed by you of the confidential nature of this letter and agrees to maintain this letter in confidence), (b) as required by law or any governmental authority and in any judicial, legal or administrative proceeding (in which case you agree, to the extent permitted by law, to inform us promptly), (c) to the extent required, to VHA or otherwise in connection with the RFP, the Proposal and/or the Award to VACO, if at all, and (d) in connection with the exercise of remedies or enforcement of rights hereunder. This letter and the terms of the Facility may be disclosed (w) in connection with any public filing requirements, (x) to prospective and actual investors and lenders in connection with the Facility, and (y) as may be required by the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") in connection with any filings made with the SEC in connection with the Facility. If such disclosure is made by you pursuant to the exceptions above, you agree to notify us as promptly as practicable of such disclosure to the extent such disclosure to us is permitted by applicable law.

OPKO agrees to maintain the confidentiality of all non-public information received by it in connection with the transactions described in this letter and to use such information solely for purposes related to such transactions except that such information may be disclosed: (a) to the employees, attorneys, auditors and other agents of OPKO on a "need to know" basis solely in connection with such transactions (assuming such persons are informed by OPKO of the confidential nature of such information and agree to maintain such information in confidence), (b) to OPKO's affiliates and its affiliates' respective managers, administrators, directors, members, officers, employees, agents, advisors, and other representatives on a "need to know" basis solely in connection with the transactions described in this letter (assuming such affiliates are informed by OPKO of the confidential nature of such information and agree to maintain such information in confidence), (c) in connection with OPKO's obligation to arrange the Facility in accordance with this letter, including without limitation, to any prospective lender, (d) as required by any governmental authority, regulatory authority and self-regulatory authority, (e) in connection with the exercise of remedies or enforcement of rights hereunder or in connection with the transactions described in this letter or any action or proceeding related to such transactions, (f) to the extent such information becomes

publicly available (other than as a result of a breach of the confidentiality provisions contained in this letter) or OPKO learns of such information from a source other than you, and (g) to the extent required by applicable laws or regulations or by any subpoena or similar legal process. If such disclosure is made pursuant to the exceptions above, OPKO agrees to notify VACG as promptly as practical of such disclosure to the extent such disclosure to VACG is permitted by applicable law.

Any person required to maintain the confidentiality of information as provided in this paragraph 7 shall be considered to have complied with its obligation to do so if such person has exercised the same degree of care to maintain the confidentiality of such information as such person would accord to its own confidential information.

Notwithstanding anything herein to the contrary, you may disclose the tax treatment and structure of the Facility and tax opinions, analyses and related documents to other persons provided that such disclosure shall be subject to the confidentiality provisions hereof.

8. **No Fiduciary Relationship.** You understand that nothing herein or in any related document creates a fiduciary, advisory or agency relationship or duty between us and VACG or VACO or any of their respective subsidiaries, stockholders, creditors, affiliates or any other person and we and you hereby disclaim any fiduciary responsibility in connection with this letter or the transactions described herein and the discussions leading thereto. It is hereby understood and agreed that no party to this letter intends that a fiduciary relationship be created by this letter or any related documents. Any discussions, views or opinions on the subject are exactly that and shall not be construed as advice or recommendations. If advice or recommendations are desired by any party hereto, such party shall contact a legal or financial of such party's choosing. Each party hereto, on behalf of itself and its subsidiaries, hereby waives and releases, to the fullest extent permitted by law, any claims that such party or any of its subsidiaries may have against the other party hereto with respect to any breach or alleged breach of any fiduciary or similar duty in connection with the transactions described in this letter or in connection with any matters leading up to the execution of this letter or definitive agreements relating to the Facility.

Each party hereto acknowledges and understands that the transactions described herein are arm's length transactions and is responsible for creating its own independent judgment with respect to the transactions described in this letter and the process leading thereto. Each party further acknowledges and agrees that the other party hereto is not providing any advice as to any legal, tax, investment, accounting or regulatory matters in any jurisdiction. Each party hereto shall consult with its own advisors concerning such matters and shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby, and neither party hereto shall have any responsibility or liability to the other party hereto with respect thereto. Any review by either party of the other party, the transactions described herein or other matters relating to such transactions will be performed solely for the benefit of the reviewing party and shall not be on behalf of the other party.

9. **WAIVER OF JURY TRIAL.** EACH OF THE PARTIES HERETO IRREVOCABLY WAIVES ANY RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING, SUIT, CLAIM OR COUNTERCLAIM BROUGHT BY OR ON BEHALF OF ANY PARTY RELATED TO OR ARISING OUT OF THIS LETTER.

10. **Governing Law.** This letter shall be governed by, and construed in accordance with the laws of the State of Florida without regard to principles of conflicts of law to the extent that the application of the laws of another jurisdiction will be required thereby. Each of the parties hereto hereby irrevocably and unconditionally submits to the exclusive jurisdiction of the federal and state courts located in Miami-Dade County, Florida (and appellate courts thereof) in connection with any dispute related to this letter or any matters contemplated hereby and agrees that any service of process, summons, notice or document by registered mail addressed to such party shall be effective service of process for any suit, action or proceeding relating to any such dispute. You and we irrevocably and unconditionally waive any objection to the laying of venue of any such suit, action or proceeding brought in any such court and any claim that any such suit, action or proceeding has been brought in an inconvenient forum. A final judgment in any such suit, action or proceeding may be enforced in any jurisdiction by suit on the judgment or in any other manner provided by law.

11. **Miscellaneous.**

(a) Each of OPKO and VACG agrees that, subject to the last sentence of this subparagraph (a), this letter is intended as and constitutes a binding and enforceable agreement with respect to the subject matter contained herein, it being acknowledged and agreed that the terms of the Facility shall be reflected in the Definitive Agreements between Lender and VACG; provided, that OPKO shall be deemed to satisfy its obligations under paragraph 1 of this letter if it enters into the Definitive Agreements to provide the Facility (through one or more of its affiliates) or arranges the Facility with a third party lender. Notwithstanding anything in this letter to the contrary, in the event VHA does not issue the CCN Contract to VACO, the parties agree that this letter shall be deemed automatically null and void and the parties' respective agreements set forth herein (other than the obligations under paragraphs 5, 6 and 7 of this letter) shall be deemed automatically terminated, in either case without liability, and, thereafter, neither OPKO nor VACG nor their respective affiliates shall have any obligation or liability with respect to the matters set forth in this letter or otherwise relating to the Facility (other than any obligation or liability under paragraphs 5, 6 and 7 of this letter). In the event that, after the Award Date, the Award is irrevocably withdrawn in connection with any bid protest, the parties agree that the Facility shall be automatically rescinded and this letter and the Definitive Agreements relating to the Facility shall be deemed automatically null and void, in each case without liability, and, in such event: (i) VACG shall promptly return to Lender the full amount of the proceeds of the Facility previously paid to VACG, if any, in accordance with the terms of the Definitive Agreements; (ii) OPKO shall immediately forfeit and relinquish the Membership Interest in VACO (including, without limitation, returning to VACO any certificates representing such Membership Interest), and OPKO shall cease to have or to be entitled to benefit from any rights as a Member of VACO; and (iii) the parties shall, at their respective expense, promptly take such other actions as may be necessary in order to unwind the Facility and the

Definitive Agreements, provided that to the extent the Definitive Agreements are executed by VACG with a Lender, OPKO shall have no obligation to take any further action to unwind the Facility.

(b) This letter constitutes the entire agreement and understanding between you and OPKO with respect to the transactions described in this letter and supersedes all prior written or oral agreements and understandings relating to the specific matters hereof. No individual has been authorized by you or OPKO to make any oral or written statements that are inconsistent with this letter.

(c) This letter may not be amended or any provision hereof waived or modified except by an instrument in writing signed by the parties hereto.

(d) This letter shall not be assignable by any party hereto without the prior written consent of each other party hereto (and any purported assignment without such consent shall be null and void), except that OPKO may assign this letter and its obligations hereunder to any affiliate of OPKO, is intended to be solely for the benefit of the parties hereto and is not intended to and does not confer any benefits upon, or create any rights in favor of, any person other than the parties hereto and, to the extent expressly set forth herein, the Indemnified Persons.

(e) Notwithstanding anything to the contrary set forth in this letter, the compensation, expense reimbursement, confidentiality, indemnification, governing law, waiver of jury trial, and forum provisions in this letter shall survive termination or expiration of this letter. The provisions under the heading "Information" above shall survive the execution and delivery of this letter and the definitive agreements relating to the Facility.

(f) Headings are for convenience of reference only and shall not affect the construction of, or be taken into consideration when interpreting, this letter.

(g) Delivery of an executed counterpart of a signature page to this letter by facsimile or electronic .pdf shall be effective as delivery of a manually executed counterpart of this letter. This letter may be executed in any number of counterparts, and by the different parties hereto on separate counterparts, each of which counterpart shall be an original, but all of which shall together constitute one and the same instrument.

Please indicate your acceptance of the terms of this letter by returning to us executed counterparts hereof and thereof by no later than 5:00pm ET on August 16, 2017.

[Remainder of page intentionally left blank]

We are pleased to have been given the opportunity to assist you in connection with this matter.

Very truly yours,

OPKO HEALTH, INC.

By: /s/ Steven D. Rubin

Name: Steven D. Rubin

Title EVP Administration

Approved for Signature

OPKO Legal Department

By: /s/ Camielle Green

Date: 8/10/17

ACCEPTED AND AGREED:

VETERANS ACCOUNTABLE CARE GROUP, LLC.

By: /s/ David R. Nelson

David R. Nelson

President and Chief Executive Officer

CERTIFICATIONS

I, Phillip Frost, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.

Chief Executive Officer

CERTIFICATIONS

I, Adam Logal, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

/s/ Adam Logal

Adam Logal

Senior Vice President, Chief Financial Officer,
Chief Accounting Officer and Treasurer

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002, I, Phillip Frost, Chief Executive Officer of OPKO Health, Inc. (the “Company”), hereby certify that:

The Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017 (the “Form 10-Q”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2017

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.

Chief Executive Officer

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002, I, Adam Logal, Chief Financial Officer of OPKO Health, Inc. (the “Company”), hereby certify that:

The Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017 (the “Form 10-Q”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2017

/s/ Adam Logal

Adam Logal

Senior Vice President, Chief Financial Officer
Chief Accounting Officer and Treasurer