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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016.

OR

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

For the transition period from _____ to _____.

Commission file number 001-33528

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

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

(305) 575-4100
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" (in Rule 12b-2 of the Exchange Act) (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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 July 27, 2016, the registrant had 550,380,939 shares of Common Stock outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended, 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, 2015, 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 funding, developing and obtaining regulatory approvals of 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 the launch of commercial sales for *Rayaldee* may not be successful;
- that we may fail to obtain regulatory approval for or successfully commercialize our product candidates;

- 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 develop a 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 Bio-Reference, EirGen and other acquired businesses;
- changes in regulation and policies in the United States and other countries, including increasing downward pressure on health care 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 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.; and
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations.

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)

	June 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 156,015	$ 193,598
Marketable securities	15,634	—
Accounts receivable, net	213,372	193,875
Inventory, net	42,046	39,681
Other current assets and prepaid expenses	78,506	26,904
Total current assets	505,573	454,058
Property, plant and equipment, net	128,274	131,798
Intangible assets, net	804,445	638,152
In-process research and development	606,035	792,275
Goodwill	691,060	743,348
Investments, net	34,249	34,716
Other assets	4,385	4,841
Total assets	$ 2,774,021	$ 2,799,188
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 61,062	$ 72,535
Accrued expenses	209,848	167,899
Current portion of lines of credit and notes payable	10,327	11,468
Total current liabilities	281,237	251,902
2033 Senior Notes and estimated fair value of embedded derivatives, net of discount	45,233	48,986
Deferred tax liabilities, net	207,595	226,036
Other long-term liabilities, principally deferred revenue and line of credit	224,316	292,470
Total long-term liabilities	477,144	567,492
Total liabilities	758,381	819,394
Equity:		
Common Stock - $0.01 par value, 750,000,000 shares authorized; 548,301,575 and 546,188,516 shares issued at June 30, 2016 and December 31, 2015, respectively	5,483	5,462
Treasury Stock - 586,760 and 1,120,367 shares at June 30, 2016 and December 31, 2015, respectively	(1,911)	(3,645)
Additional paid-in capital	2,736,816	2,705,385
Accumulated other comprehensive loss	(23,431)	(22,537)
Accumulated deficit	(701,317)	(704,871)
Total shareholders' equity	2,015,640	1,979,794
Total liabilities and equity	$ 2,774,021	$ 2,799,188

The accompanying 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 June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Revenues:				
Revenue from services	$ 266,012	$ 1,908	$ 518,534	$ 3,977
Revenue from products	22,807	22,848	42,706	38,334
Revenue from transfer of intellectual property and other	68,281	17,673	86,898	30,202
Total revenues	357,100	42,429	648,138	72,513
Costs and expenses:				
Cost of service revenue	140,971	2,505	278,568	4,764
Cost of product revenue	12,468	11,929	22,407	19,991
Selling, general and administrative	117,511	20,937	245,513	38,382
Research and development	31,348	29,570	59,170	55,072
Contingent consideration	10,758	(339)	12,511	4,836
Amortization of intangible assets	15,778	3,236	29,221	5,901
Grant repayment	—	—	—	25,889
Total costs and expenses	328,834	67,838	647,390	154,835
Operating income (loss)	28,266	(25,409)	748	(82,322)
Other income and (expense), net:				
Interest income	135	5	178	12
Interest expense	(2,217)	(986)	(4,004)	(3,551)
Fair value changes of derivative instruments, net	1,235	(16,556)	(188)	(66,344)
Other income (expense), net	5,970	760	6,515	(748)
Other income and (expense), net	5,123	(16,777)	2,501	(70,631)
Income (loss) before income taxes and investment losses	33,389	(42,186)	3,249	(152,953)
Income tax (provision) benefit	(15,868)	(251)	4,638	(5,760)
Income (loss) before investment losses	17,521	(42,437)	7,887	(158,713)
Loss from investments in investees	(1,988)	(804)	(4,333)	(2,565)
Net income (loss)	15,533	(43,241)	3,554	(161,278)
Less: Net loss attributable to noncontrolling interests	—	(475)	—	(1,400)
Net income (loss) attributable to common shareholders	$ 15,533	$ (42,766)	$ 3,554	$ (159,878)
Earnings (loss) per share:				
Earnings (loss) per share, basic	$ 0.03	$ (0.09)	$ 0.01	$ (0.35)
Earnings (loss) per share, diluted	$ 0.02	$ (0.09)	$ 0.00	$ (0.35)
Weighted average common shares outstanding, basic	547,558,800	462,253,161	546,691,117	454,361,137
Weighted average common shares outstanding, diluted	557,040,435	462,253,161	556,735,862	454,361,137

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

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

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2015	2016	2015
Net income (loss)	$ 15,533	$ (43,241)	$ 3,554	$ (161,278)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss)	(4,432)	(694)	2,510	(4,547)
Available for sale investments:				
Change in unrealized loss, net of tax	(1,889)	(682)	(3,404)	(1,941)
Comprehensive income (loss)	9,212	(44,617)	2,660	(167,766)
Less: Comprehensive loss attributable to noncontrolling interest	—	(475)	—	(1,400)
Comprehensive income (loss) attributable to common shareholders	$ 9,212	$ (44,142)	$ 2,660	$ (166,366)

The accompanying 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 six months ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	$ 3,554	$ (161,278)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	46,780	7,685
Non-cash interest	1,408	1,681
Amortization of deferred financing costs	74	895
Losses from investments in investees	4,333	2,565
Equity-based compensation – employees and non-employees	26,105	14,090
Revenue from receipt of equity	—	(120)
Realized gain on equity securities	(2,494)	(216)
Loss on conversion of 3.00% convertible senior notes	—	291
Change in fair value of derivative instruments	188	66,344
Change in fair value of contingent consideration	12,511	4,836
Deferred income tax benefit	(8,999)	—
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	(18,388)	(4,186)
Inventory, net	(1,763)	(2,547)
Other current assets and prepaid expenses	(14,309)	1,142
Other assets	732	(512)
Accounts payable	(13,205)	7,101
Foreign currency measurement	(405)	300
Deferred revenue	(35,938)	263,926
Accrued expenses and other liabilities	33,452	2,741
Net cash provided by operating activities	33,636	204,738
Cash flows from investing activities:		
Investments in investees	(5,921)	(2,345)
Acquisition of businesses, net of cash	—	(94,674)
Purchase of marketable securities	(15,630)	—
Proceeds from the sale of property, plant and equipment	708	—
Capital expenditures	(12,866)	(1,439)
Net cash used in investing activities	(33,709)	(98,458)
Cash flows from financing activities:		
Proceeds from the exercise of Common Stock options and warrants	1,912	17,366
Cash from non-controlling interest	—	100
Borrowings on lines of credit	9,496	11,038
Repayments of lines of credit	(49,341)	(10,022)
Net cash (used in) provided by financing activities	(37,933)	18,482
Effect of exchange rate changes on cash and cash equivalents	423	(452)
Net (decrease) increase in cash and cash equivalents	(37,583)	124,310
Cash and cash equivalents at beginning of period	193,598	96,907
Cash and cash equivalents at end of period	$ 156,015	$ 221,217
SUPPLEMENTAL INFORMATION:		
Interest paid	$ 900	$ 1,724
Income taxes paid, net	$ 7,172	$ 757
Non-cash financing:		
Shares issued upon the conversion of:		
2033 Senior Notes	$ —	$ 92,172
Common Stock options and warrants, surrendered in net exercise	$ 325	$ 14,239
Issuance of capital stock to acquire or contingent consideration settlement:		
EirGen Pharma Limited	$ —	$ 33,569
OPKO Health Europe	$ 313	$ 1,813

The accompanying 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 Bio-Reference Laboratories, Inc. ("Bio-Reference"), the nation's third-largest clinical laboratory with a core genetic testing business and a 420-person sales and marketing department 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 patients 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 PDUFA date for IV formulation is January 2017). Our pharmaceutical business includes OPKO Biologics, which features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), a once-daily Factor VIIa drug for hemophilia (Phase 2a), and long-acting oxyntomodulin ("OXM") for diabetes and obesity (Phase 1). We are incorporated in Delaware and our principal executive offices are located in leased offices in Miami, Florida.

In June 2016, we entered into a definitive agreement under which we agreed to acquire Transition Therapeutics, Inc. ("Transition Therapeutics"), a clinical stage biotechnology company. Under the terms of the agreement, holders of Transition Therapeutics common stock will receive approximately 6.4 million shares of OPKO common stock. Assuming a closing price of $9.34 per share of OPKO common stock, the transaction is valued at approximately $60.1 million. We expect the transaction to be completed during the second half of 2016. Closing of the transaction is subject to approval of Transition Therapeutics' shareholders and other customary conditions.

In August 2015, we completed the acquisition of Bio-Reference, the third largest full service clinical laboratory in the United States, known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately $950.1 million, based on a closing price per share of our Common Stock of $12.38 as reported by the New York Stock Exchange on the closing date, or $34.05 per share of Bio-Reference common stock. Included in the transaction value is $2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

Through our acquisition of Bio-Reference, 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 perform cancer cytogenetic testing at our leased facilities in Elmwood Park, NJ, Clarksburg, MD, Milford, MA, and genetic testing at our leased facility in Gaithersburg, MD, as well as at our Elmwood Park facility. We perform cytology testing at our leased facilities in Frederick, MD, Milford, MA, Melbourne Fl, Houston, TX and at our Elmwood Park facility. We market our laboratory testing services directly to physicians, geneticists, hospitals, clinics, correctional and other health facilities.

In May 2015, we acquired all of the issued and outstanding shares of EirGen Pharma Limited ("EirGen"), a specialty pharmaceutical company incorporated in Ireland focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products, for $133.8 million. We acquired the outstanding shares of EirGen for approximately $100.2 million in cash and delivered 2,420,487 shares of our Common Stock valued at approximately $33.6 million based on the closing price per share of our Common Stock as reported by the New York Stock Exchange on the closing date of the acquisition, $13.88 per share.

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 leased facilities in Miramar, Florida, Woburn, Massachusetts, Waterford, Ireland, Nes Ziona, 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 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 accounting principles generally accepted in the United States 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 six months ended June 30, 2016, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2016 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, 2015.

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 accounting principles generally accepted in the United States 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 or market (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 or market. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories. The provision for inventory obsolescence for the six months ended June 30, 2016 and 2015 was $0.2 million and $0.6 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. At June 30, 2016 and December 31, 2015, there were no pre-launch inventories.

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 June 30, 2016 and December 31, 2015 was $2.1 billion and $2.2 billion, respectively.

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

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

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

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense was $29.2 million and $5.9 million for the six months ended June 30, 2016 and 2015, respectively.

We reclassified $187.6 million of IPR&D related to *Rayaldee* from In-process research and development to Intangible assets, net in our Condensed Consolidated Balance Sheet upon the FDA's approval of *Rayaldee* in June 2016. The assets will be amortized on a straight-line basis over their estimated useful life of approximately 12 years.

Fair value measurements. The carrying amounts of our cash and cash equivalents, marketable securities, 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 June 30, 2016 and December 31, 2015 are carried at fair value. Our debt under the credit agreement with JPMorgan Chase Bank, N.A. approximates fair value due to the variable rate of interest.

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

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

Derivative financial instruments. We record derivative financial instruments on our Condensed Consolidated Balance Sheet at their fair value and recognize the changes in the fair value in our Condensed Consolidated Statement of Operations when they occur, the only exception being derivatives that qualify as hedges. For the derivative instrument to qualify as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At June 30, 2016 and December 31, 2015, our forward contracts for inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in the fair values of our derivatives instruments, net, in our Condensed Consolidated Statement of Operations. Refer to Note 9.

Property, plant and equipment. Property, plant and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets and includes amortization expense for assets capitalized under capital leases. The estimated useful lives by asset class are as follows: software - 3 years, machinery, medical and other equipment - 5-8 years, furniture and fixtures - 5-10 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 $17.6 million and $1.8 million for the six months ended June 30, 2016 and 2015, respectively. Assets held under capital leases are included within Property, plant and equipment, net in our Condensed Consolidated Balance Sheet and are amortized over the shorter of their useful lives or the expected term of their related leases.

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

Income taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and 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 interim periods presented herein, 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 losses incurred in tax jurisdictions which do not result in a tax benefit.

During the three months ended June 30, 2016, we received approval from the Internal Revenue Service on an application for a change in accounting method. As a result of the change, we recognized an additional $51.2 million of income tax benefits, of which $39.4 million was recognized as a receivable in Other current assets and prepaid expenses and $11.8 million was recognized as a reduction of Deferred tax liabilities, net.

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 January 5, 2016, the Israeli Parliament officially published the *Law for the Amendment of the Israeli Tax Ordinance* (Amendment 216), that reduces the standard corporate income tax rate from 26.5% to 25%. The amendment was entered into force on January 1, 2016 and the 25% corporate tax rate will apply to income that was generated from that day onwards. The new rate has been used in determining Income tax (provision) benefit in 2016.

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 six months ended June 30, 2016 and 2015, approximately 10% and 4%, respectively, of our revenues from services were derived directly from the Medicare and Medicaid programs. The increase in revenues from laboratory services, including revenue from Medicare and Medicaid programs, is due to the acquisition of Bio-Reference in August 2015.

Generally, we recognize revenue from product sales 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 management's evaluation of specific factors that may increase or decrease the risk of product returns.

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 quarterly basis. For the three and six months ended June 30, 2016, revenue from transfer of intellectual property includes $17.7 million and $35.3 million, respectively, of revenue related to the Pfizer Transaction. For the three and six months ended June 30, 2015, revenue from transfer of intellectual property includes $17.7 million and $30.2 million, respectively, of revenue 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 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 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 $198.5 million and $232.9 million at June 30, 2016 and December 31, 2015, respectively. The deferred revenue balance at June 30, 2016 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 health care 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 health care programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. Accounts receivable balances (net of contractual adjustments) from Medicare and Medicaid were $30.4 million and $26.1 million at June 30, 2016 and December 31, 2015, respectively.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At June 30, 2016 and December 31, 2015, receivables due from patients represent approximately 6.6% and 7.5%, respectively, of our consolidated accounts receivable (prior to allowance for doubtful accounts).

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 $48.8 million and $25.2 million at June 30, 2016 and December 31, 2015, respectively. The provision for bad debts for the six months ended June 30, 2016 and 2015 was $40.5 million and $0.6 million, respectively.

Equity-based compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow and as a reduction of taxes paid in cash flow 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 six months ended June 30, 2016 and 2015, we recorded $26.1 million and $14.1 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 as 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 acquisitions of Bio-Reference 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.

Variable interest entities. The consolidation of variable interest entities ("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 Statement 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 No. 2014-09 clarifies the principles for recognizing revenue and develops a common revenue standard for GAAP and International Financial Reporting Standards 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 No. 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 are currently evaluating both methods of adoption and the impact that the adoption of this ASU will have on our Condensed Consolidated Financial Statements.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force)." ASU No. 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU No. 2014-12 was effective for the Company beginning after January 1, 2016. Our adoption of ASU 2014-12 in the first quarter of 2016 using the prospective application did not have a material impact on our Condensed Consolidated Financial Statements.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 with early adoption permitted. We do not believe the impact of our pending adoption of ASU 2014-15 on our Condensed Consolidated Financial Statements will be material.

In February 2015, the FASB issued ASU No. 2015-02, "Consolidation (Topic 810): Amendments to the Consolidation Analysis," which amends current consolidation guidance including changes to both the variable and voting interest models used by companies to evaluate whether an entity should be consolidated. The requirements from ASU 2015-02 were effective for the Company beginning January 1, 2016. Our adoption of ASU 2015-02 in the first quarter of 2016 did not have a material impact on our Condensed Consolidated Financial Statements.

In April 2015, the FASB issued ASU No. 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs," which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 was effective for the Company beginning January 1, 2016. Our adoption of ASU 2015-03 in the first quarter of 2016 did not have a material impact on our Condensed Consolidated Financial Statements.

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. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In September 2015, the FASB issued ASU No. 2015-16, “Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments,” which replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 requires that the acquirer record, in the same period’s financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. Our early adoption of ASU 2015-16 in 2015 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. 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 this ASU simplifies the presentation of deferred income taxes and reduces complexity without decreasing the usefulness of information provided to users of financial statements. 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 No. 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 No. 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 No. 2016-09 will be effective for fiscal years beginning after December 15, 2016, 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.

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 bifurcated 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. The following table sets forth the computation of basic and diluted earnings (loss) per share:

(Shares in thousands)	For the three months ended June 30, 2016	2015	For the six months ended June 30, 2016	2015
Numerator				
Net income (loss) attributable to common shareholders, basic	$ 15,533	$ (42,766)	$ 3,554	$ (159,878)
Add: Interest on 2033 Senior Notes	604	—	1,196	—
Change in FV of embedded derivative income	(4,872)	—	(4,734)	—
Net income (loss) attributable to common shareholders, diluted	$ 11,265	$ (42,766)	$ 16	$ (159,878)
Denominator				
(Shares in thousands)				
Weighted average common shares outstanding, basic	547,559	462,253	546,691	454,361
Effect of dilutive securities:				
Stock options	4,264	—	4,222	—
Warrants	661	—	1,267	—
2033 Senior Notes	4,556	—	4,556	—
Dilutive potential shares	9,481	—	10,045	—
Weighted average common shares outstanding, diluted	557,040	462,253	556,736	454,361
Earnings (loss) per share, basic	$ 0.03	$ (0.09)	$ 0.01	$ (0.35)
Earnings (loss) per share, diluted	$ 0.02	$ (0.09)	$ —	$ (0.35)

A total of 11,261,582 and 14,375,502 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for the three and six months ended June 30, 2015, respectively, because their inclusion would be antidilutive.

During the three months ended June 30, 2016, 439,238 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 318,082 shares of Common Stock. Of the 439,238 Common Stock options and Common Stock warrants exercised, 121,156 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the six months ended June 30, 2016, 2,238,537 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 2,113,157 shares of Common Stock. Of the 2,238,537 Common Stock options and Common Stock warrants exercised, 125,380 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 June 30, 2015, 2,106,679 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 2,106,634 shares of Common Stock. Of the 2,106,679 Common Stock options and Common Stock warrants exercised, 45 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the six months ended June 30, 2015, 24,168,461 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 22,635,661 shares of Common Stock. Of the 24,168,461 Common Stock options and Common Stock warrants exercised, 1,206,654 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)	June 30, 2016	December 31, 2015
Accounts receivable, net		
Accounts receivable	$ 262,145	$ 219,043
Less: allowance for doubtful accounts	(48,773)	(25,168)
	$ 213,372	$ 193,875
Inventories, net		
Consumable supplies	$ 22,825	$ 22,265
Finished products	13,944	13,404
Work in-process	1,137	1,215
Raw materials	5,453	3,848
Less: inventory reserve	(1,313)	(1,051)
	$ 42,046	$ 39,681
Other current assets and prepaid expenses		
Taxes recoverable	52,588	3,076
Other receivables	13,464	11,946
Prepaid supplies	9,534	8,773
Prepaid insurance	2,144	2,206
Other	776	903
	$ 78,506	$ 26,904
Intangible assets, net:		
Customer relationships	$ 450,792	$ 449,972
Technologies	339,307	151,709
Trade names	50,469	50,416
Licenses	23,509	23,432
Covenants not to compete	16,362	8,612
Product registrations	7,836	7,512
Other	4,394	5,600
Less: accumulated amortization	(88,224)	(59,101)
	$ 804,445	$ 638,152
Accrued expenses:		
Deferred revenue	$ 73,112	$ 70,246
Employee benefits	37,121	29,751
Contingent consideration	30,294	22,164
Taxes payable	10,954	7,605
Capital leases short-term	5,069	5,373
Clinical trials	10,051	2,505
Milestone payment	4,966	5,000
Professional fees	1,967	1,506
Other	36,314	23,749
	$ 209,848	$ 167,899

(In thousands)	June 30, 2016	December 31, 2015
Other long-term liabilities:		
Deferred revenue	$ 125,348	$ 162,634
Line of credit	38,135	72,107
Contingent consideration	36,340	32,258
Mortgages and other debts payable	1,807	2,523
Capital leases long-term	8,500	9,285
Other	14,186	13,663
	$ 224,316	$ 292,470

All of the intangible assets and goodwill acquired relate to our acquisitions of principally OPKO Renal, OPKO Biologics, EirGen and Bio-Reference. 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.

We reclassified $187.6 million of IPR&D related to *Rayaldee* from In-process research and development to Intangible assets, net in our Condensed Consolidated Balance Sheet upon the FDA's approval of *Rayaldee* in June 2016. In addition, we made certain purchase price allocation adjustments related to the Bio-Reference acquisition during the six months ended June 30, 2016. Refer to Note 5. Other changes in value of the intangible assets and goodwill are primarily due to foreign currency fluctuations between the Chilean and Mexican pesos, the Euro and the Shekel against the U.S. dollar.

The following table reflects the changes in Goodwill during the six months ended June 30, 2016.

	2016			
(In thousands)	Balance at January 1st	Purchase accounting adjustments	Foreign exchange	Balance at June 30th
Pharmaceuticals				
CURNA	$ 4,827	$ —	$ —	$ 4,827
EirGen	81,139	—	1,573	82,712
FineTech	11,698	—	—	11,698
OPKO Chile	4,517	—	309	4,826
OPKO Biologics	139,784	—	—	139,784
OPKO Health Europe	7,191	—	130	7,321
OPKO Renal	2,069	—	—	2,069
Diagnostics				
Bio-Reference	441,158	(54,300)	—	386,858
OPKO Diagnostics	17,977	—	—	17,977
OPKO Lab	32,988	—	—	32,988
	$ 743,348	$ (54,300)	$ 2,012	$ 691,060

NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

Bio-Reference acquisition

In August 2015, we completed the acquisition of Bio-Reference, the third largest full service clinical laboratory in the United States, known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately $950.1 million, based on a closing price per share of our Common Stock of $12.38 as reported by the New York Stock Exchange, or $34.05 per share of Bio-Reference common stock. Included in the transaction value is $2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

The following table summarizes the preliminary purchase price allocation and the estimated fair value of the net assets acquired and liabilities assumed at the date of acquisition. The purchase price allocation for Bio-Reference is preliminary pending completion of the fair value analysis of acquired assets and liabilities:

(In thousands)		Bio-Reference
Purchase price:		
Value of OPKO Common Stock issued to Bio-Reference shareholders	$	947,889
Value of replacement stock options awards to holders of Bio-Reference stock options		2,259
Total purchase price	$	950,148
Preliminary value of assets acquired and liabilities assumed:		
Current assets		
Cash and cash equivalents	$	15,800
Accounts receivable		168,164
Inventory		19,674
Other current assets, principally deferred tax assets		99,116
Total current assets		302,754
Property, plant and equipment		112,457
Intangible assets:		
Trade name		47,100
Customer relationships		395,200
Technology		100,600
Other intangible assets		7,750
Total intangible assets		550,650
Goodwill		386,858
Investments		5,326
Other assets		13,265
Total assets		1,371,310
Accounts payable and accrued expenses		(108,217)
Income taxes payable		(1,014)
Lines of credit and notes payable		(65,701)
Capital lease obligations		(18,293)
Deferred tax liability (non-current)		(227,937)
Total purchase price	$	950,148

During 2016, we continued to finalize our purchase price allocation during the measurement period and obtained new fair value information related to certain assets acquired and liabilities assumed of Bio-Reference. As a result, for the six months ended June 30, 2016 we adjusted the purchase price allocation by increasing Other current assets by $38.0 million, increasing Other intangible assets by $7.8 million, decreasing Goodwill by $54.3 million, decreasing Accrued expenses by $0.5 million,

increasing Income taxes payable by $0.6 million and decreasing Deferred tax liability (non-current) by $8.6 million. As a result of these adjustments, Amortization of intangible assets in our Condensed Consolidated Statement of Operations for the six months ended June 30, 2016 increased $2.2 million.

The purchase price allocation adjustments are largely due to an approval we received from the Internal Revenue Service during 2016 on an application for a change in accounting method. As a result of the change, we recognized an additional $51.2 million of income tax benefits, of which $39.4 million was recognized as a receivable in Other current assets and $11.8 million was recognized as a reduction of our Deferred tax liability (non-current). In addition, Goodwill was reduced by $51.2 million.

Goodwill from the acquisition of Bio-Reference principally relates to intangible assets that do not qualify for separate recognition (for instance, Bio-Reference's assembled workforce), our expectation to develop and market new products, 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 diagnostics reporting segment.

The weighted average amortization periods for intangible assets recognized in the Bio-Reference acquisition are 5 years for trade name, 19.3 years for customer relationships, 10.2 years for technology and 13.7 years in total.

Pro forma disclosure for Bio-Reference acquisition

The pro forma information has been prepared utilizing period ends that differ by less than 93 days, as permitted by Regulation S-X. We are a registrant with a fiscal year that ends on December 31 and Bio-Reference was a registrant with a fiscal year that ended on October 31. The pro forma results for the three and six months ended June 30, 2015 combines the results of operations of OPKO and Bio-Reference, giving effect to the merger as if it occurred on January 1, 2014, and are based on the individual condensed consolidated statements of operations of OPKO as of June 30, 2015 and Bio-Reference as of April 30, 2015.

(In thousands)	Three months ended June 30, 2015	Six months ended June 30, 2015
Revenues	$266,415	$505,333
Net loss	(40,252)	(157,880)
Net loss attributable to common shareholders	(39,777)	(156,480)

The unaudited pro forma financial information is presented for information purposes only. The unaudited pro forma financial information may not necessarily reflect our future results of operations or what the results of operations would have been had we owned and operated Bio-Reference as of the beginning of the period presented.

EirGen Pharma Limited acquisition

In May 2015, we acquired all of the issued and outstanding shares of EirGen, a specialty pharmaceutical company incorporated in Ireland focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products, for $133.8 million. We acquired the outstanding shares of EirGen for approximately $100.2 million in cash and delivered 2,420,487 shares of our Common Stock valued at approximately $33.6 million based on the closing price per share of our Common Stock as reported by the New York Stock Exchange on the closing date of the acquisition, $13.88 per share.

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

(In thousands)	EirGen
Current assets [1]	$ 11,795
Intangible assets:	
IPR&D assets	560
Customer relationships	34,155
Currently marketed products	3,919
Total intangible assets	38,634
Goodwill	83,373
Property, plant and equipment	8,117
Other assets	1,232
Accounts payable and other liabilities	(6,254)
Deferred tax liability	(3,131)
Total purchase price	$ 133,766

(1) Current assets include cash, accounts receivable, inventory and other assets of $5.5 million, $2.7 million, $2.2 million and $1.4 million, respectively, related to the EirGen acquisition. The fair value of the accounts receivable equals the gross contractual amount at the date of acquisition.

Goodwill from the acquisition of EirGen principally relates to intangible assets that do not qualify for separate recognition (for instance, EirGen's assembled workforce), our expectation to develop and market new products, and the deferred tax liability generated as a result of this being a partial stock transaction. Goodwill is not tax deductible for income tax purposes and was assigned to the pharmaceutical reporting segment.

Revenue and Net income (loss) in the Condensed Consolidated Statement of Operations for the six months ended June 30, 2015 includes revenue and net loss of EirGen from the date of acquisition to June 30, 2015 of $2.3 million and $0.8 million, respectively.

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. The weighted average amortization periods for amortizing intangible assets recognized in the EirGen acquisition are 15.8 years for customer relationships, 10.0 years for currently marketed product and 15.0 years in total.

Pro forma disclosure for EirGen acquisition

The following table includes the pro forma results for the three and six months ended June 30, 2015 and combines the results of operations of OPKO and EirGen as though the acquisition of EirGen had occurred on January 1, 2014.

(In thousands)	Three months ended June 30, 2015	Six months ended June 30, 2015
Revenues	$43,848	$76,769
Net loss	(43,420)	(162,331)
Net loss attributable to common shareholders	(42,945)	(160,931)

The unaudited pro forma financial information is presented for information purposes only. The unaudited pro forma financial information may not necessarily reflect our future results of operations or what the results of operations would have been had we owned and operated EirGen as of the beginning of the period presented.

Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of June 30, 2016:

(in thousands)

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	$ 27,429	$ 16,254
Variable interest entity, equity method	620	—
Available for sale investments	5,312	
Warrants and options	888	
Total carrying value of investments	$ 34,249	

Equity Method Investments

Our equity method investments consist of investments in Pharmsynthez (ownership 17%), Cocrystal Pharma, Inc. ("COCP") (8%), Sevion Therapeutics, Inc. ("Sevion") (3%), Non-Invasive Monitoring Systems, Inc. (1%), Neovasc (4%), VBI (17%) and InCellDx, Inc. (27%). The total assets, liabilities, and net losses of our equity method investees as of and for the six months ended June 30, 2016 were $421.4 million, $(167.8) million, and $(125.7) 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. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Loss from investments in investees in our Condensed Consolidated Statement of Operations. The aggregate value of our equity method investments based on the quoted market price of their common stock and the number of shares held by us as of June 30, 2016 is $57.7 million.

Available for Sale Investments

Our available for sale investments consist of investments in RXi Pharmaceuticals Corporation ("RXi") (ownership 3%), ChromaDex Corporation (2%), MabVax Therapeutics Holdings, Inc. ("MabVax") (1%), ARNO Therapeutics, Inc. ("ARNO") (4%) and Xenetic Biosciences, Inc. ("Xenetic") (6%). 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.

Sales of Investments

Gains (losses) included in earnings from sales of our investments are recorded in Other income (expense), net in our Condensed Consolidated Statement of Operations. We did not have any such activity in the six months ended June 30, 2016 and 2015. The cost of securities sold is based on the specific identification method. Refer to *Investment in SciVac* below.

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 December 31, 2015, and 1.0 million, 0.8 million, 0.5 million, 1.8 million and 0.7 million of warrants to purchase additional shares of COCP, ARNO, Sevion, MabVax and InCellDx, Inc., 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 record 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 June 30, 2016). 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. We determined that we do not have the power to direct the activities that most significantly impact Zebra's economic performance. 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. 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.

Investment in SciVac

In June 2012, we acquired a 50% stock ownership in SciVac from FDS Pharma LLP ("FDS"). SciVac was a privately-held Israeli company that produced a third-generation hepatitis B-vaccine. From November 2012 through June 30, 2015, we loaned to SciVac a combined $7.9 million for working capital purposes. We determined that we held variable interests in SciVac based on our assessment that SciVac did not have sufficient resources to carry out its principal activities without financial support. We had also determined we were the primary beneficiary of SciVac through our representation on SciVac's board of directors. As a result of this conclusion, we consolidated the results of operations and financial position of SciVac through June 2015 and recorded a reduction of equity for the portion of SciVac we do not own.

On July 9, 2015, SciVac Therapeutics Inc., formerly Levon Resources Ltd. ("STI") completed a reverse takeover transaction (the "Arrangement") pursuant to which STI acquired all of the issued and outstanding securities of SciVac. As a result of this transaction, OPKO's ownership in STI decreased to 24.5%.

Upon completion of the Arrangement, we determined that STI was not a VIE. We also determined that we do not have the power to direct the activities that most significantly impact the economic performance of STI that would require us to consolidate STI. We recorded a $15.9 million gain on the deconsolidation of SciVac in Other income (expense), net in our Condensed Consolidated Statement of Operations for the year ended December 31, 2015. The recognized gain was primarily due to the fair value of the retained interest in STI based on Levon's cash contribution of approximately $21.2 million under the Arrangement.

Following the deconsolidation, we account for our investment in STI under the equity method as we have determined that we and/or our related parties can significantly influence STI through our voting power and board representation. STI is considered a related party as a result of our board representation in STI and executive management's ownership interests in STI.

In May, 2016, STI completed a merger transaction pursuant to which a wholly-owned subsidiary of STI merged with and into VBI Vaccines Inc. with VBI Vaccines Inc. surviving the merger as a wholly-owned subsidiary of STI, and STI changed its name to VBI Vaccines Inc. ("VBI") . We recorded a $2.5 million gain in connection with the merger transaction in Other income (expense), net in our Condensed Consolidated Statement of Operations for the six months ended June 30, 2016. In June 2016, we invested an additional $5.7 million in VBI for 1,362,370 shares of its common stock. As a result of these two transactions, OPKO's ownership in VBI changed to 17%.

We account for our investment in VBI under the equity method as we have determined that we can significantly influence VBI through our board representation.

Other

On January 5, 2016, we completed a stock exchange agreement (the "Exchange Agreement") with Relative Core Cyprus Limited ("Relative Core") pursuant to which Relative Core agreed to transfer and sell to us that certain number shares of Xenetic having a fair market value of $5.0 million in exchange for that number of shares of our common stock having a fair market value of $5.0 million. We issued 494,462 shares of our common stock to Relative Core and received 10,204,082 shares of Xenetic common stock from Relative Core. The number of shares exchanged in the transaction was calculated based on the average closing sale price for our common stock on the NYSE for the ten (10) consecutive trading day period ending on the second day prior to the closing and the average closing sale price for Xenetic's common stock on the OTC "Pink Sheet" for the ten (10) consecutive trading day period ending on the second day prior to the closing. We account for investment in Xenetic as an available for sale investment.

In March 2016, we entered into an agreement with Relative Core pursuant to which we delivered $5.0 million to Relative Core in exchange for a $5.0 million promissory note ("Relative Note") which bears interest at 10% and is due in March 2017. The Relative Note is secured by 4,000,000 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 Sheet.

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 (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 June 30, 2016:

(In thousands)	Embedded conversion option	2033 Senior Notes	Discount	Debt Issuance Cost	Total
Balance at December 31, 2015	$ 23,737	$ 32,200	$ (6,525)	$ (426)	$ 48,986
Amortization of debt discount and debt issuance costs	—	—	907	74	981
Change in fair value of embedded derivative	(4,734)	—	—	—	(4,734)
Balance at June 30, 2016	$ 19,003	$ 32,200	$ (5,618)	$ (352)	$ 45,233

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.

We may not redeem the 2033 Senior Notes prior to February 1, 2017. 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 have determined that these specific terms are

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 have concluded that the embedded derivatives within the 2033 Senior Notes meet these criteria and, as such, must be valued separate and apart from the 2033 Senior Notes and recorded at fair value each reporting period.

For accounting and financial reporting purposes, we combine these embedded derivatives and value them together as one unit of accounting. At each reporting period, we record these embedded derivatives at fair value which is included as a component of the 2033 Senior Notes on our Condensed Consolidated Balance Sheets.

In August 2013, one of the conversion rights in the 2033 Senior Notes was triggered. Holders of the 2033 Senior Notes converted $16.9 million principal amount into 2,396,145 shares of the Company's Common Stock. In June 2014, we entered into an exchange agreement with a holder of the Company's 2033 Senior Notes pursuant to which such holder exchanged $70.4 million in aggregate principal amount of 2033 Senior Notes for 10,974,431 shares of the Company's Common Stock and approximately $0.8 million in cash representing accrued interest through the date of completion of the exchange. During 2015, pursuant to a conversion right or through exchange agreements we entered with certain holders of our 2033 Senior Notes, holders of our 2033 Senior Notes converted or exchanged $55.4 million in aggregate principal amount of 2033 Senior Notes for 8,118,062 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 and the first nine months of 2016, 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. See further discussion in Note 14.

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 holder 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 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 estimates 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:

	June 30, 2016
Stock price	$9.34
Conversion Rate	141.4827
Conversion Price	$7.07
Maturity date	February 1, 2033
Risk-free interest rate	0.66%
Estimated stock volatility	49%
Estimated credit spread	1,018 basis points

The following table sets forth the fair value of the 2033 Senior Notes with and without the embedded derivatives, and the fair value of the embedded derivatives at June 30, 2016. At June 30, 2016 the principal amount of the 2033 Senior Notes was $32.2 million:

(In thousands)	June 30, 2016
Fair value of 2033 Senior Notes:	
With the embedded derivatives	$ 45,821
Without the embedded derivatives	$ 26,818
Estimated fair value of the embedded derivatives	$ 19,003

Changes in certain inputs into the lattice model can have a significant impact on changes in the estimated fair value of the embedded derivatives. For example, a decrease in our estimated credit spread results in an increase in the estimated value of the embedded derivatives. Conversely, a decrease in the price of our Common Stock results in a decrease in the estimated fair value of the embedded derivatives. For the six months ended June 30, 2016, we observed an decrease in the market price of our Common Stock which primarily resulted in a $4.7 million decrease in the estimated fair value of our embedded derivatives recorded in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations.

On November 5, 2015, Bio-Reference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. (“CB”), as lender and administrative agent (the “Credit Agreement”), which replaced Bio-Reference’s existing credit facility with PNC Bank, National Association (“PNC”). 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. Bio-Reference 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 Bio-Reference’s domestic subsidiaries. The Credit Agreement is also secured by substantially all assets of Bio-Reference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in Bio-Reference. Availability under the Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of Bio-Reference and certain of its subsidiaries, as specified therein. The proceeds of the new credit facility were used to refinance existing indebtedness, including amounts outstanding under the previous credit facility with PNC which was terminated in 2015 in accordance with its terms, to finance working capital needs and for general corporate purposes of Bio-Reference and its subsidiaries. Principal under the Credit Agreement is due upon maturity on November 5, 2020.

At Bio-Reference’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 0.25% of the lending commitments.

The Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require Bio-Reference 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 Bio-Reference 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 Bio-Reference 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 Bio-Reference and its subsidiaries are restricted from sale, transfer, lease, disposal or distributions to the Company, subject to certain exceptions. Bio-Reference and its subsidiaries net assets as of June 30, 2016 was approximately $1.0 billion, which includes goodwill of $386.9 million and intangible assets of $513.9 million.

In addition to the Credit Agreement with CB, we have line of credit agreements with nine other financial institutions as of June 30, 2016 and ten other financial institutions as of December 31, 2015 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 June 30, 2016	Credit line capacity	June 30, 2016	December 31, 2015
JPMorgan Chase	3.85%	$ 175,000	$ 38,135	$ 72,107
Itau Bank	5.50%	1,450	1,000	282
Bank of Chile	6.60%	2,500	2,493	2,313
BICE Bank	5.50%	2,000	314	1,502
BBVA Bank	5.50%	2,300	1,436	1,825
Security Bank	N/A	N/A	—	145
Estado Bank	5.50%	2,400	1,353	2,210
Santander Bank	5.50%	3,000	1,325	1,345
Scotiabank	5.00%	1,300	1,287	939
Corpbanca	5.00%	500	318	—
Banco Bilbao Vizcaya	2.90%	278	—	—
Total		$ 190,728	$ 47,661	$ 82,668

At June 30, 2016 and December 31, 2015, the weighted average interest rate on our lines of credit was approximately 4.6% and 4.3%, respectively.

At June 30, 2016 and December 31, 2015, 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)	June 30, 2016	December 31, 2015
Current portion of notes payable	$ 1,007	$ 1,054
Other long-term liabilities	1,849	1,963
Total	$ 2,856	$ 3,017

The notes and other debt mature at various dates ranging from 2015 through 2024 bearing variable interest rates from 2.7% up to 6.3%. The weighted average interest rate on the notes and other debt at June 30, 2016 and December 31, 2015, was 3.4% and 4.3%, respectively. The notes payable are secured by our office space in Barcelona.

NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

For the six months ended June 30, 2016, 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, 2015	$ (21,791)	$ (746)	$ (22,537)
Other comprehensive income (loss) before reclassifications	2,510	(3,404)	(894)
Balance at June 30, 2016	$ (19,281)	$ (4,150)	$ (23,431)

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 that should be 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:

	As of June 30, 2016			
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Fair value
Common stock investments, available for sale	$ 8,084	$ 1,210	$ (3,982)	$ 5,312
Total assets	$ 8,084	$ 1,210	$ (3,982)	$ 5,312

	As of December 31, 2015			
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Fair value
Common stock investments, available for sale	$ 2,978	$ 904	$ (267)	$ 3,615
Total assets	$ 2,978	$ 904	$ (267)	$ 3,615

Any future fluctuation in fair value related to our available for sale investments that is judged to be temporary, and any recoveries of previous 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 June 30, 2016, we have money market funds that qualify as cash equivalents, marketable securities, forward foreign currency exchange contracts for inventory purchases (Refer to Note 9) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe, and OPKO Renal that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with Neovasc, we record the related Neovasc options at fair value as well as the warrants from COCP, ARNO, Sevion and MabVax.

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

	Fair value measurements as of June 30, 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	$ 34,680	$ —	$ —	$ 34,680
Marketable securities	15,634	—	—	15,634
Common stock investments, available for sale	5,312	—	—	5,312
Common stock options/warrants	—	888	—	888
Total assets	$ 55,626	$ 888	$ —	$ 56,514
Liabilities:				
Embedded conversion option	$ —	$ —	$ 19,003	$ 19,003
Forward contracts	—	206	—	206
Contingent consideration	—	—	66,634	66,634
Total liabilities	$ —	$ 206	$ 85,637	$ 85,843

	Fair value measurements as of December 31, 2015			
(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	$ 84,421	$ —	$ —	$ 84,421
Common stock investments, available for sale	3,615	—	—	3,615
Common stock options/warrants	—	5,338	—	5,338
Forward contracts	—	9	—	9
Total assets	$ 88,036	$ 5,347	$ —	$ 93,383
Liabilities:				
Embedded conversion option	$ —	$ —	$ 23,737	$ 23,737
Contingent consideration	—	—	54,422	54,422
Total liabilities	$ —	$ —	$ 78,159	$ 78,159

The carrying amount and estimated fair value of our 2033 Senior Notes without 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.

	June 30, 2016				
(In thousands)	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2033 Senior Notes	$ 26,582	$ 26,818	$ —	$ —	$ 26,818

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 June 30, 2016 and December 31, 2015, the carrying value of our other 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 June 30, 2016:

(In thousands)	June 30, 2016 Contingent consideration	Embedded conversion option
Balance at December 31, 2015	$ 54,422	$ 23,737
Total losses for the period:		
Included in results of operations	12,511	(4,734)
Foreign currency impact	14	—
Payments	(313)	—
Balance at June 30, 2016	$ 66,634	$ 19,003

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, OPKO Health Europe 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 $2.2 million. As of June 30, 2016, of the $66.6 million of contingent consideration, $30.3 million is recorded in Accrued expenses and $36.3 million is recorded in Other long-term liabilities. As of December 31, 2015, of the $54.4 million of contingent consideration, $22.2 million is recorded in Accrued expenses and $32.3 million is recorded in Other long-term liabilities.

Embedded conversion option – We estimate the fair value of the embedded conversion option related to the 2033 Senior Notes using a binomial lattice model. Refer to Note 6 for detail description of the binomial lattice model and the fair value assumptions used.

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	June 30, 2016	December 31, 2015
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 888	$ 5,338
Embedded conversion option	2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	$ 19,003	$ 23,737
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.	$ (206)	$ 9

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 June 30, 2016 and December 31, 2015, 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 six months ended June 30, 2016 and 2015:

	Three months ended June 30,		Six months ended June 30,	
(In thousands)	2016	2015	2016	2015
Derivative gain (loss):				
Common Stock options/warrants	$ (3,730)	$ (2,446)	$ (4,716)	$ 1,425
2033 Senior Notes	4,872	(14,220)	4,734	(67,950)
Forward contracts	93	110	(206)	181
Total	$ 1,235	$ (16,556)	$ (188)	$ (66,344)

NOTE 10 RELATED PARTY TRANSACTIONS

We hold investments in Zebra (ownership 29%), Sevion (3%), Neovasc (4%), ChromaDex Corporation (2%), MabVax (1%), COCP (8%) and ARNO (4%). 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 July 2015, we made an additional $0.5 million investment in a private placement transaction with Sevion pursuant to which we acquired 66,667 shares of Series C Convertible Preferred Stock convertible into 666,667 shares of common stock and warrants to purchase 333,333 shares of common stock. In October 2015, we made an additional $0.4 million investment in MabVax pursuant to which we acquired 340,909 shares of common stock at $1.10 and 170,454 warrants to purchase shares of common stock. In November 2015, we made an additional $1.0 million investment in Zebra pursuant to which we acquired 420,000 shares of Series A-2 Preferred Stock. In January 2016, we invested an additional $0.3 million in ARNO for 714,285 shares of its common stock.

We lease office space from Frost Real Estate Holdings, LLC ("Frost Holdings") in Miami, Florida, where our principal executive offices are located. Effective May 28, 2015, we entered into an amendment to our lease agreement with Frost Holdings. The lease, as amended, is for approximately 25,000 square feet of space. The lease provides for payments of approximately $66 thousand per month in the first year increasing annually to $75 thousand per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking. The rent was reduced by $0.2 million for the cost of tenant improvements.

Our wholly-owned subsidiary, Bio-Reference purchases and uses certain products acquired from InCellDx, Inc., a company in which we hold a 27% 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 six months ended June 30, 2016, we recognized approximately $62 thousand and $119 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and six months ended June 30, 2015, we recognized approximately $167 thousand and $293 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, OPKO Health Europe, and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of June 30, 2016, we recorded $66.6 million as contingent consideration, with $30.3 million recorded within Accrued expenses and $36.3 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

On or around October 21, 2014, we received a Civil Investigative Demand ("Demand") from the U.S. Attorney's Office for the Middle District of Tennessee ("Attorney's Office"). The Demand concerns an investigation of allegations that the Company or one of its affiliated entities or other parties submitted false claims for payment related to services provided to government healthcare program beneficiaries in violation of the False Claims Act, 31 U.S.C. Section 3729. We entered into a settlement agreement resolving the matter in May 2016, and it did not have a financial impact on the Company.

Following the announcement of entry into an agreement and plan of merger with Bio-Reference, four putative class action complaints challenging the merger were filed in the Superior Court of New Jersey in Bergen County (the "Court"). In September 2015, the parties executed a stipulation and agreement of compromise, settlement and release resolving all matters between them. In January 2016, the Court entered an order finally approving the settlement. The settlement did not have a material impact on our business, financial condition, results of operations or cash flows.

Under a license agreement one of our subsidiaries has with Washington University in St. Louis, we are obligated to pay Washington University a single digit percentage of any sublicensing payment we receive in connection with a sublicense of our rights to Washington University patents subject to certain exceptions. In connection with the Pfizer Transaction, we sublicensed to Pfizer the sole remaining patent licensed to us by Washington University and paid to Washington University the sublicensing payment we believe is due under the license agreement. Washington University disagreed with the computation of the sublicense payment and notified us that it would like to review additional information relating to the sublicense and the Pfizer Transaction to determine whether additional amounts are owed to it. In May 2016, the parties entered into a settlement agreement resolving the matter. The settlement did not have a material impact on our business, financial condition, results of operations or cash flows.

On December 18, 2013, Bio-Reference filed an action in the Superior Court of New Jersey against Horizon, captioned Bio-Reference Laboratories, Inc. v. Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey, Docket No. BER L-009748-13 (N.J. Super. Ct. Bergen County). Bio-Reference has been an in-network provider with Horizon's PPO network for more than 20 years and filed the lawsuit after attempts to resolve its dispute with Horizon were unsuccessful. The parties have agreed to a full and final settlement of the matter with an effective date of March 31, 2016, based on an execution date of May 11, 2016. Among other consideration, under the terms of the settlement, Horizon paid Bio-Reference a negotiated settlement for the disputed claims and Bio-Reference's current PPO contract will remain in effect through December 31, 2018. The settlement was not material to Revenue from services in our Condensed Consolidated Statements of Operations for the three or six months ended June 30, 2016.

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 paragraphs 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. In addition, we are subject to other claims and lawsuits arising in the ordinary course of our business. 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.

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 we prepare for the launch of *Rayaldee*. We do not anticipate that we will generate substantial revenue from the sale of proprietary pharmaceutical products or certain of our diagnostic products for some time and we have generated only limited revenue from our pharmaceutical operations in Chile, Mexico, Israel, Spain, and Ireland, and from sale of the *4Kscore* test. If we acquire additional assets or companies, 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 Bio-Reference which provide for compensation and certain other benefits and for severance payments under certain circumstances. During the six months ended June 30, 2016, we recognized $17.2 million of severance costs pursuant to these employment agreements as a component of Selling, general and administrative expense.

At June 30, 2016, we were committed to make future purchases for inventory and other items in 2016 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating $54.4 million.

NOTE 12 STRATEGIC ALLIANCES

Vifor Fresenius Medical Care 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 Pharma Ltd ("VFMCRP"), entered into a Development and License Agreement (the "VFMCRP Agreement") for the development and marketing of Rayaldee (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 "Territory"). The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the Product in humans (the "Field"), provided that initially the license is for the use of the Product for the treatment or prevention of secondary hyperparathyroidism related to patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency/deficiency (the "Initial Indication").

Under the terms of the VFMCRP Agreement, EirGen granted to VFMCRP an exclusive license in the Territory in the 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, double digit royalty payments or a minimum royalty, whichever is greater, upon the commencement of sales of the Product within the Territory and in the 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 Territory and the commercialization activities outside the Territory and outside the Field in the Territory and VFMCRP will lead the commercialization activities in the Territory and the Field. For the initial development plan agreed to by the companies, 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 Initial Indication in the Territory in the 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 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 (c) ten (10) years after the Product first commercial sale in such country. In addition to termination rights for material breach and bankruptcy, VFMCRP is permitted to terminate the VFMCRP Agreement in its entirety, or with respect to one or more countries in the Territory, after a specified notice period, provided that VFMCRP shall not have the right to terminate the VFMCRP Agreement with respect to certain major countries without terminating the entire VFMCRP Agreement. If the VFMCRP Agreement is terminated by EirGen or VFMCRP, provision has been made for transition of product and product responsibilities to EirGen.

In connection with the VFMCRP Agreement, the parties entered into a letter agreement (the "Letter Agreement") pursuant to which EirGen granted to VFMCRP an exclusive option (the "Option") to acquire an exclusive license under certain EirGen patents and technology to use, import, offer for sale, sell, distribute and commercialize the Product in the 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, 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 certain double digit royalties on VFMCRP's sales 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) VFMCRP 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 VFMCRP Agreement and the Letter Agreement.

For revenue recognition purposes, we evaluated the various agreements with Vifor to determine whether there were multiple deliverables in the arrangement. The VFMCRP Agreement provides for the following: (1) an exclusive license in the Territory in the 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 VFMCRP in the Territory (the "Manufacturing Services"); (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 was a contingent deliverable dependent on the future regulatory and commercial action by VFMCRP 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 for the three and six months ended June 30, 2016. Revenues related to the Manufacturing Services will be recognized as Product is sold to VFMCRP. No revenue related to the Option will be recognized unless and until VFMCRP 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 VFMCRP 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 VFMCRP obtains approval from certain regulatory authorities and will be recognized as revenue in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. We account for the Sales Milestones as royalties and Sales Milestones payments will be recognized as revenue in 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 2019, 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 are recognizing the non-refundable $295.0 million upfront payments on a straight-line basis over the performance period. We recognized $35.3 million of revenue related to the Pfizer Transaction in Revenue from transfer of intellectual property in our Condensed Consolidated Statement of Operations during the six months ended June 30, 2016, and had deferred revenue related to the Pfizer Transaction of $194.2 million at June 30, 2016. As of June 30, 2016, $70.6 million of deferred revenue related to the Pfizer Transaction was classified in Accrued expenses and $123.6 million was classified in Other long-term liabilities in our Condensed Consolidated Balance Sheet.

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.

In the first quarter of 2015, we made a payment of $25.9 million to the Office of the Chief Scientist of the Israeli Ministry of Economy ("OCS") in connection with repayment obligations resulting from grants previously made by the OCS to OPKO Biologics to support development of hGH-CTP and the outlicense of the technology outside of Israel. We recognized the $25.9 million payment in grant repayment expense in our Condensed Consolidated Statement of Operations during the six months ended June 30, 2015.

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 are eligible to receive milestone payments of up to $30 million upon achievement of certain regulatory and commercial sale milestones (of which $20 million has been received to date) and additional commercial milestone payments of up to $85 million if specified levels of annual net sales are achieved. During the six months ended June 30, 2016 and 2015, no revenue has been 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 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. In addition, we will have an option to market the products in Latin America.

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

TESARO's New Drug Application ("NDA") for approval of oral VARUBI™, a neurokinin-1 receptor antagonist in development for the prevention of chemotherapy-induced nausea and vomiting, was approved by the U.S. FDA in September 2015, and in November 2015, TESARO announced the commercial launch of VARUBI™ in the United States. Under the terms of the NK-1 Agreement, upon approval by the FDA of the TESARO's NDA for oral VARUBI™, we were required to pay Merck a $5.0 million milestone payment. In addition, $5.0 million will be due and payable each year thereafter for the next four (4) years on the anniversary date of the NDA approval. We recognized the present value of the milestone payments on FDA approval of $23.0 million as an intangible asset which will be amortized to expense over the expected useful life of the asset, which is approximately 13 years. The present value of the future payments to Merck of $18.6 million at June 30, 2016 is recorded as a liability in our Condensed Consolidated Balance Sheet with $4.9 million in Accrued expenses and $13.7 million in Other long-term liabilities.

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 17%). We also granted rights to certain technologies in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan (the "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 Territories, as well as a percentage of any sublicense income from third parties for the technologies in the 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 is due on or before July 1, 2016, 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 Sheet.

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 UT Southwestern, Washington University, INEOS Healthcare, TSRI, the President and Fellows of Harvard College, and Academia Sinica, among others. 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 Bio-Reference 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:

	For the three months ended June 30,		For the six months ended June 30,	
(In thousands)	2016	2015	2016	2015
Revenue from services:				
Pharmaceutical	$ —	$ —	$ —	$ —
Diagnostics	266,012	1,848	518,534	3,857
Corporate	—	60	—	120
	$ 266,012	$ 1,908	$ 518,534	$ 3,977
Product revenues:				
Pharmaceutical	$ 22,807	$ 22,848	$ 42,706	$ 38,334
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ 22,807	$ 22,848	$ 42,706	$ 38,334
Revenue from transfer of intellectual property:				
Pharmaceutical	$ 68,281	$ 17,673	$ 86,898	$ 30,202
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ 68,281	$ 17,673	$ 86,898	$ 30,202
Operating income (loss):				
Pharmaceutical	$ 35,345	$ (4,660)	$ 34,015	$ (42,584)
Diagnostics	10,374	(7,098)	8,019	(15,575)
Corporate	(17,453)	(12,905)	(41,286)	(22,882)
Less: Operating loss attributable to noncontrolling interests	—	(746)	—	(1,281)
	$ 28,266	$ (25,409)	$ 748	$ (82,322)
Depreciation and amortization:				
Pharmaceutical	$ 2,987	$ 2,371	$ 5,848	$ 4,138
Diagnostics	21,573	1,754	40,893	3,501
Corporate	20	27	39	46
	$ 24,580	$ 4,152	$ 46,780	$ 7,685
Net income (loss) from investment in investees:				
Pharmaceutical	$ 391	$ (804)	$ (4,430)	$ (2,565)
Diagnostics	(2,379)	—	97	—
Corporate	—	—	—	—
	$ (1,988)	$ (804)	$ (4,333)	$ (2,565)
Revenues:				
United States	$ 266,044	$ 2,525	$ 518,482	$ 5,019
Ireland	71,789	19,376	93,932	31,480
Chile	9,597	8,698	16,580	15,150
Spain	4,324	4,920	8,347	8,857
Israel	4,420	5,942	9,162	10,155
Mexico	926	968	1,635	1,852
	$ 357,100	$ 42,429	$ 648,138	$ 72,513

(In thousands)	June 30, 2016	December 31, 2015
Assets:		
Pharmaceutical	$ 1,283,339	$ 1,234,752
Diagnostics	1,408,619	1,421,034
Corporate	82,063	143,402
	$ 2,774,021	$ 2,799,188
Goodwill:		
Pharmaceutical	$ 253,237	$ 251,225
Diagnostics	437,823	492,123
Corporate	—	—
	$ 691,060	$ 743,348

During the three and six months ended June 30, 2015, revenue recognized under the Pfizer Transaction represented 42% of our total revenue. Refer to Note 12. During the three months ended June 30, 2016, revenue recognized under the VFMCRP Agreement represented 14% of our total revenue. No customer represented more than 10% of our consolidated revenue during six months ended June 30, 2016. As of June 30, 2016 , no customer represented more than 10% of our accounts receivable balance. As of December 31, 2015, one customer represented more than 10% of our accounts receivable balance.

NOTE 14 SUBSEQUENT EVENTS

On July 1, 2016, we announced that our 2033 Senior Notes continue to be convertible by holders of such notes. We have elected to satisfy our conversion obligation under the 2033 Senior Notes in shares of our Common Stock. This conversion right has been triggered because the closing price per share of our Common Stock has exceeded $9.19, or 130% of the initial conversion price of $7.07, for at least 20 of 30 consecutive trading days during the period ending on June 30, 2016. The conversion right was previously triggered during the quarters ended March 31, 2015, June 30, 2015, September 30, 2015, December 31, 2015 and March 31, 2016. The 2033 Senior Notes will continue to be convertible until September 30, 2016, 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.

In July 2016, we satisfied a $25.0 million contingent payment to the former owners of OPKO Renal through the issuance of 2,611,648 shares of our common stock.

We have reviewed all subsequent events and transactions that occurred after the date of our June 30, 2016 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, 2015 (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, 2015, 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 Bio-Reference Laboratories, the nation's third-largest clinical laboratory with a core genetic testing business and a 420-person sales and marketing department to drive growth and leverage new products, including the *4Kscore* prostate cancer test and the *Claros* 1 in-office immunoassay platform. Our pharmaceutical operations feature *Rayaldee*, an FDA-approved treatment for secondary hyperparathyroidism ("SHPT") in patients 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 PDUFA Date: January 2017). Our pharmaceutical business includes OPKO Biologics, which features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), a once-daily Factor VIIa drug for hemophilia (Phase 2a), and long-acting oxyntomodulin ("OXM") for diabetes and obesity (Phase 1).

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

In June 2016, we entered into a definitive agreement under which we agreed to acquire Transition Therapeutics (NASDAQ:TTHI, TSX:TTH), a clinical stage biotechnology company. Under the terms of the agreement, holders of Transition Therapeutics common stock will receive approximately 6.4 million shares of OPKO common stock. Assuming a closing price of $9.34 per share of OPKO common stock, the transaction is valued at approximately $60.1 million. We expect the transaction to be completed during the second half of 2016. Closing of the transaction is subject to approval of Transition Therapeutics' shareholders and other customary conditions.

In June 2016, the FDA approved *Rayaldee* for the treatment for SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency. We expect to launch *Rayaldee* in the U.S. through our dedicated renal sales force in the fourth quarter of 2016.

In May 2016, EirGen, our wholly-owned subsidiary, and VFMCRP entered into the Agreement for the development and marketing of *Rayaldee* 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 license to VFMCRP potentially covers all therapeutic and prophylactic uses of *Rayaldee* in humans, provided that initially the license is for the use of the *Rayaldee* for the treatment or prevention of secondary hyperparathyroidism related to patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency/deficiency. In connection with the the license, OPKO also granted VFMCRP an option to acquire rights to the US market for treatment of dialysis patients.

RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED JUNE 30, 2016 AND 2015

Revenues. Revenues for the three months ended June 30, 2016 increased $314.7 million compared to the prior year period. Revenues for the three months ended June 30, 2016 and 2015 were as follows:

Revenues	For the three months ended June 30,		
(In thousands)	2016	2015	Change
Revenue from services	$ 266,012	$ 1,908	$ 264,104
Revenue from products	22,807	22,848	(41)
Revenue from transfer of intellectual property and other	68,281	17,673	50,608
Total revenues	$ 357,100	$ 42,429	$ 314,671

The increase in Revenue from services is attributable to the acquisition of Bio-Reference in August 2015. Revenue from products for the three months ended June 30, 2016 is consistent with the second quarter of 2015. Revenue from transfer of intellectual property principally reflects $50.0 million of revenue from the initial payment in the VFMCRP Agreement for the three months ended June 30, 2016 and $17.7 million of revenue from the transfer of intellectual property related to the Pfizer Transaction for the three months ended June 30, 2016 and 2015, respectively. We are recognizing the non-refundable $295.0 million upfront payments received in the Pfizer Transaction on a straight-line basis over the expected performance period. The performance period is expected to continue through 2019, when we anticipate completing the various research and development services that are specified in the Pfizer Transaction.

Costs of revenue. Cost of revenue for the three months ended June 30, 2016 increased $139.0 million compared to the prior year period. Our acquisition of Bio-Reference in August 2015 accounted for $139.9 million of the quarter-over-quarter cost of revenue growth. Costs of revenue for the three months ended June 30, 2016 and 2015 were as follows:

Cost of Revenue	For the three months ended June 30,		
(In thousands)	2016	2015	Change
Cost of service revenue	$ 140,971	$ 2,505	$ 138,466
Cost of product revenue	12,468	11,929	539
Total cost of revenue	$ 153,439	$ 14,434	$ 139,005

The increase in cost of service revenue is attributable to the acquisition of Bio-Reference in August 2015. The cost of product revenue is consistent with the second quarter of 2015.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended June 30, 2016 and 2015, were $117.5 million and $20.9 million, respectively. The increase in selling, general and administrative expenses for the three months ended June 30, 2016 was primarily due to the acquisition of Bio-Reference in 2015, which recognized $95.2 million of selling, general and administrative expenses in the 2016 period. Selling, general and administrative expenses during the three months ended June 30, 2016 and 2015, include equity-based compensation expense of $6.2 million and $4.2 million, respectively. The increase in equity-based compensation expense is due to stock option grants made in 2015 and 2016.

Research and development expenses. Research and development expenses for the three months ended June 30, 2016 and 2015, were $31.3 million and $29.6 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 PMA (pre-market approval) 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 June 30,	
	2016	2015
External expenses:		
Phase 3 clinical trials	$ 2,946	$ 3,707
Manufacturing expense for biological products	7,903	7,748
Earlier-stage programs	1,843	1,706
Research and development employee-related expenses	7,848	6,984
Other internal research and development expenses	11,475	9,916
Third-party grants and funding from collaboration agreements	(667)	(491)
Total research and development expenses	$ 31,348	$ 29,570

The increase in research and development expenses is primarily due to $2.3 million in research and development expenses during the three months ended June 30, 2016 related to the acquisitions of Bio-Reference and EirGen in August 2015 and May 2015, respectively. This was partially offset by decreased expenses incurred by OPKO Renal related to the development of *Rayaldee*. In addition, during the three months ended June 30, 2016 and 2015, we recorded, as an offset to research and development expenses, $0.7 million and $0.5 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the three months ended June 30, 2016 and 2015 include equity-based compensation expense of $2.2 million and $2.4 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 three months ended June 30, 2016 and 2015, were $10.8 million of expense and $0.3 million of income, respectively. The increase in contingent consideration was attributable to OPKO Renal resulting from an increase in the fair value of our contingent obligations due to changes in assumptions regarding the timing of successful achievement of future milestones driven by the FDA approval of *Rayaldee* in June 2016. The contingent consideration liabilities at June 30, 2016 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $15.8 million and $3.2 million, respectively, for the three months ended June 30, 2016 and 2015. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the three months ended June 30, 2016 includes $12.2 million and $0.6 million from Bio-Reference and EirGen which we acquired in August 2015 and May 2015, respectively. 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. In June 2016 upon the FDA's approval of *Rayaldee*, we reclassified $187.6 million of IPR&D related to *Rayaldee* from In-process research and development to Intangible assets, net in our Condensed Consolidated Balance Sheet.

Interest income. Interest income for the three months ended June 30, 2016 and 2015, 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 June 30, 2016 and 2015, was $2.2 million and $1.0 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 Bio-Reference's outstanding debt under its credit facility. The increase in interest expense for the three months ended June 30, 2016 was due to interest incurred on Bio-Reference's outstanding debt under its credit facility. This was partially offset by a decrease in the principal amount of the 2033 Senior Notes outstanding from $46.2 million at June 30, 2015 to $32.2 million as of June 30, 2016.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended June 30, 2016 and 2015, were $1.2 million of income and $16.6 million of expense, respectively. Fair value changes of derivative instruments, net principally related to non-cash income (expense) related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes of $4.9 million and $(14.2) million for the three months ended June 30, 2016 and 2015, respectively. For the three months ended June 30, 2015, we observed an increase in the market price of our Common Stock which primarily resulted in the increase in the estimated fair value of our embedded derivatives in the 2033 Senior Notes.

Fair value changes of derivative instruments, net for the three months ended June 30, 2016 also reflects $3.2 million of expense related to the change in the fair value of options to purchase additional shares of Neovasc.

Other income (expense), net. Other income (expense), net for the three months ended June 30, 2016 and 2015, were $6.0 million and $0.8 million of income, respectively. The change in other income (expense), net for the three months ended June 30, 2016 compared to the same period in 2015 is due to 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 both in the second quarter of 2016.

Income tax (provision) benefit. Our income tax benefit (provision) for the three months ended June 30, 2016 and 2015 was $(15.9) million and $(0.3) 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 and the acquisition of BioReference in August 2015, which impacted both the geographic mix of results and our ability to benefit from certain operating losses.

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 continue to report a net loss. Loss from investments in investees was $2.0 million and $0.8 million for the three months ended June 30, 2016 and 2015, respectively. The increase in loss from investments in investees is primarily due to our investment in Pharmsynthez.

FOR THE SIX MONTHS ENDED JUNE 30, 2016 AND 2015

Revenues. Revenues for the six months ended June 30, 2016 increased $575.6 million compared to the prior year period. Revenues for the six months ended June 30, 2016 and 2015 were as follows:

Revenues	For the six months ended June 30,		
(In thousands)	2016	2015	Change
Revenue from services	$ 518,534	$ 3,977	$ 514,557
Revenue from products	42,706	38,334	4,372
Revenue from transfer of intellectual property and other	86,898	30,202	56,696
Total revenues	$ 648,138	$ 72,513	$ 575,625

The increase in Revenue from services is attributable to the acquisition of Bio-Reference in August 2015. The increase in Revenue from products principally reflects $7.2 million of revenue from EirGen, which we acquired in May 2015, compared to $2.3 million for the comparable period in 2015. Revenue from transfer of intellectual property principally reflects $50.0 million of revenue from the initial payment in the VFMCRP Agreement for the six months ended June 30, 2016 and $35.3 million and $30.2 million of revenue from the transfer of intellectual property related to the Pfizer Transaction for the six months ended June 30, 2016 and 2015, respectively. We are recognizing the non-refundable $295.0 million upfront payments received in the Pfizer Transaction on a straight-line basis over the expected performance period. The performance period is expected to continue through 2019, when we anticipate completing the various research and development services that are specified in the Pfizer Transaction.

Costs of revenue. Cost of revenue for the six months ended June 30, 2016 increased $276.2 million compared to the prior year period. Our acquisition of Bio-Reference in August 2015 accounted for $274.9 million of the period-over-period cost of revenue growth. Costs of revenue for the six months ended June 30, 2016 and 2015 were as follows:

Cost of Revenue	For the six months ended June 30,		
(In thousands)	2016	2015	Change
Cost of service revenue	$ 278,568	$ 4,764	$ 273,804
Cost of product revenue	22,407	19,991	2,416
Total cost of revenue	$ 300,975	$ 24,755	$ 276,220

The increase in cost of service revenue is attributable to the acquisition of Bio-Reference in August 2015. The increase in cost of product revenue principally reflects cost of revenue of $5.2 million from EirGen for the six months ended June 30,

2016, which we acquired in May 2015, compared to $1.6 million for the comparable period in 2015. This was partially offset by the deconsolidation of STI in July 2015.

Selling, general and administrative expenses. Selling, general and administrative expenses for the six months ended June 30, 2016 and 2015, were $245.5 million and $38.4 million, respectively. The increase in selling, general and administrative expenses for the six months ended June 30, 2016 was primarily due to the acquisition of Bio-Reference in 2015, which recognized $194.9 million of selling, general and administrative expenses in the 2016 period. Included in selling, general and administrative expenses for the six months ended June 30, 2016 are $17.2 million of severance costs for certain Bio-Reference executives.

Selling, general and administrative expenses during the six months ended June 30, 2016 and 2015, include equity-based compensation expense of $21.4 million and $8.1 million, respectively. The increase in equity-based compensation expense is due to stock option grants made in 2015 and 2016 and $8.9 million of expense related to the acceleration of stock option vesting for certain Bio-Reference executives.

Research and development expenses. Research and development expenses for the six months ended June 30, 2016 and 2015, were $59.2 million and $55.1 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 PMA's (pre-market approval) 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 six months ended June 30,	
	2016	2015
External expenses:		
Phase 3 clinical trials	$ 5,789	$ 6,989
Manufacturing expense for biological products	14,939	14,101
Earlier-stage programs	3,039	4,472
Research and development employee-related expenses	14,548	15,191
Other internal research and development expenses	22,322	15,276
Third-party grants and funding from collaboration agreements	(1,467)	(957)
Total research and development expenses	$ 59,170	$ 55,072

The increase in research and development expenses during the six months ended June 30, 2016, is primarily due to a $5.9 million increase in research and development expenses related to hGH-CTP, a long acting human growth hormone which was outlicensed to Pfizer in 2015, including manufacturing expense for biological products. Research and development expenses for the six months ended June 30, 2016 also include $4.2 million from the acquisitions of Bio-Reference and EirGen in August 2015 and May 2015, respectively. This was partially offset by decreased expenses incurred by OPKO Renal related to the development of *Rayaldee*. In addition, during the six months ended June 30, 2016 and 2015, we recorded, as an offset to research and development expenses, $1.5 million and $1.0 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the six months ended June 30, 2016 and 2015 include equity-based compensation expense of $4.0 million and $5.9 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 six months ended June 30, 2016 and 2015, were $12.5 million and $4.8 million of expense, respectively. The increase in contingent consideration was attributable to OPKO Renal resulting from an increase in the fair value of our contingent obligations due to changes in assumptions regarding the timing of successful achievement of future milestones driven by the FDA approval of *Rayaldee* in June 2016. The contingent consideration liabilities at June 30, 2016 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $29.2 million and $5.9 million, respectively, for the six months ended June 30, 2016 and 2015. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the six months ended June 30, 2016 includes $22.2 million and $1.3 million from Bio-Reference and EirGen which we acquired in August 2015 and May 2015, respectively. 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 be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Grant repayment. During the six months ended June 30, 2015, we made a payment of $25.9 million to the Office of the Chief Scientist of the Israeli Ministry of Economy ("OCS") in connection with repayment obligations resulting from grants previously made by the OCS to OPKO Biologics to support development of hGH-CTP and the outlicense of the technology outside of Israel. We did not have any such activity for the six months ended June 30, 2016.

Interest income. Interest income for the six months ended June 30, 2016 and 2015, 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 six months ended June 30, 2016 and 2015, was $4.0 million and $3.6 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 Bio-Reference's outstanding debt under its credit facility. The decrease in interest expense for the six months ended June 30, 2016 is due to a decrease in the principal amount of the 2033 Senior Notes outstanding from $46.2 million at June 30, 2015 to $32.2 million as of June 30, 2016. Interest expense for the six months ended June 30, 2015 also reflects a non-cash write-off of deferred financing costs of $0.7 million as interest expense related to the exchange of $41.4 million principal of 2033 Senior Notes in 2015. This was partially offset by interest incurred on Bio-Reference's outstanding debt under its credit facility for the six months ended June 30, 2016.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the six months ended June 30, 2016 and 2015, were $0.2 million and $66.3 million of expense, respectively. Fair value changes of derivative instruments, net principally related to non-cash expense related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes of $4.7 million of income and $68.0 million of expense for the six months ended June 30, 2016 and 2015, respectively. For the six months ended June 30, 2015, we observed an increase in the market price of our Common Stock which primarily resulted in the increase in the estimated fair value of our embedded derivatives in the 2033 Senior Notes. Fair value changes of derivative instruments, net for the six months ended June 30, 2016 also reflects $3.8 million of expense related to the change in the fair value of options to purchase additional shares of Neovasc.

Other income (expense), net. Other income (expense), net for the six months ended June 30, 2016 and 2015, were $6.5 million of income and $0.7 million of expense, respectively. The change in other income (expense), net for the six months ended June 30, 2016 compared to the same period in 2015 is due to a $2.5 million gain recognized in connection with the merger of STI and VBI Vaccines Inc., a $2.9 million gain recognized in connection with the settlement of a legal matter and foreign currency transaction gains (losses) recognized during the periods.

Income tax (provision) benefit. Our income tax benefit (provision) for the six months ended June 30, 2016 and 2015 was $4.6 million and $(5.8) million, respectively, and reflects six-month 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 and the acquisition of BioReference in August 2015, which impacted both the geographic mix of results and our ability to benefit from certain operating losses. In addition, income taxes in 2016 benefited from a favorable corporate tax rate reduction in Israel.

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 continue to report a net loss. Loss from investments in investees was $4.3 million and $2.6 million for the six months ended June 30, 2016 and 2015, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2016, we had cash, cash equivalents and marketable securities of approximately $171.6 million. Cash provided by operations during 2016 principally reflects a $50.0 million upfront payment received from the VFMCRP Agreement and our operations at Bio-Reference, partially offset by expenses related to selling, general and administrative activities related to our corporate operations, research and development activities and our operations at OPKO Biologics, OPKO Renal and OPKO Diagnostics. Cash used in investing activities primarily reflects capital expenditures of $12.9 million and the purchase of marketable securities of $15.6 million. Cash used in financing activities primarily reflects net repayments on lines of credit of $39.8 million, partially offset by $1.9 million received from Common Stock option and Common Stock warrant exercises. 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.

In June 2016, the FDA approved *Rayaldee* for the treatment for SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency. We expect to launch *Rayaldee* in the U.S. through our dedicated renal sales force in the fourth quarter of 2016.

In June 2016, we entered into a definitive agreement under which we agreed to acquire Transition Therapeutics (NASDAQ:TTHI, TSX:TTH), a clinical stage biotechnology company. Under the terms of the agreement, holders of Transition Therapeutics common stock will receive approximately 6.4 million shares of OPKO common stock. Assuming a closing price of $9.34 per share of OPKO common stock, the transaction is valued at approximately $60.1 million. We expect the transaction to be completed during the second half of 2016. Closing of the transaction is subject to approval of Transition Therapeutics' shareholders and other customary conditions.

In May 2016, EirGen, our wholly-owned subsidiary, partnered with VFMCRP through a Development and License Agreement for the development and marketing of *Rayaldee* in Europe, Canada, Mexico, Australia, South Korea and certain other international markets. The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the Product in humans, provided that initially the license is for the use of the Product for the treatment or prevention of secondary hyperparathyroidism related to patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency/deficiency. 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, double digit royalty payments or a minimum royalty, whichever is greater, upon commencement of sales of the Product within the Territory and in the 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. For the initial development plan agreed to by the companies, 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 Initial Indication in the Territory in the Field except as otherwise provided in the VFMCRP Agreement.

In connection with the VFMCRP Agreement, the parties entered into a Letter Agreement pursuant to which EirGen granted to VFMCRP an 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. 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 certain double digit royalties on VFMCRP's sales in the United States for the Dialysis Indication.

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 the first quarter of 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 August 2015, we completed the acquisition of Bio-Reference, the third largest full service clinical laboratory in the United States, known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately $950.1 million, based on a closing price per share of our Common Stock of $12.38 as reported by the New York Stock Exchange on the closing date, or $34.05 per share of Bio-Reference common stock. Included in the transaction value is $2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

In May 2015, we entered into a series of purchase agreements to acquire all of the issued and outstanding shares of EirGen, a specialty pharmaceutical company incorporated in Ireland focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products, for $133.8 million. We acquired the outstanding shares of EirGen for approximately $100.2 million in cash and delivered 2,420,487 shares of our Common Stock valued at approximately $33.6 million based on the closing price per share of our Common Stock as reported by the New York Stock Exchange on the closing date of the acquisition, $13.88 per share.

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 are eligible to receive milestone payments of up to $30.0 million (of which $20.0 million has been received to date) upon achievement of certain regulatory and commercial sale milestones and additional commercial milestone payments of up to $85.0 million if specified levels of annual net sales are achieved. During the six months ended June 30, 2016 and 2015, no revenue has been 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.

Under the terms of our agreement with Merck, upon approval by the FDA of the TESARO's NDA for oral VARUBI™, which occurred in September 2015, we were required to pay Merck a $5.0 million milestone payment. In addition, $5.0 million will be due and payable each year thereafter for the next four (4) years on the anniversary date of the NDA approval. We recognized the present value of the milestone payments on FDA approval of $23.0 million as an intangible asset which will be amortized to expense over the expected useful life of the asset, which is approximately 13 years. The present value of the future payments to Merck of $18.6 million at June 30, 2016 is recorded as a liability in our Condensed Consolidated Balance Sheet with $4.9 million in Accrued expenses and $13.7 million in Other long-term liabilities.

2033 Senior Notes. 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 June 30, 2016, $32.2 million principal amount of 2033 Senior Notes was outstanding.

On July 1, 2016, we announced that our 2033 Senior Notes continue to be convertible by holders of such notes. We have elected to satisfy our conversion obligation under the 2033 Senior Notes in shares of our Common Stock. This conversion right has been triggered because the closing price per share of our Common Stock has exceeded $9.19, or 130% of the initial conversion price of $7.07, for at least 20 of 30 consecutive trading days during the period ending on June 30, 2016. The 2033 Senior Notes will continue to be convertible until September 30, 2016, 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.

In connection with our acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe 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 $150.0 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, Bio-Reference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. ("CB"), as lender and administrative agent (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. Bio-Reference 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 Bio-Reference's domestic subsidiaries. The Credit Agreement is also secured by substantially all assets of Bio-Reference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in Bio-Reference.

Availability under the Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of Bio-Reference and certain of its subsidiaries, as specified therein. The proceeds of the new credit facility were used to refinance existing indebtedness, to finance working capital needs and for general corporate purposes of Bio-Reference and its subsidiaries.

As of June 30, 2016, the total availability under our Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain was $166.4 million, of which $47.7 million was used and outstanding as of June 30, 2016. The weighted average interest rate on these lines of credit is approximately 4.6%. 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 six months ended June 30, 2016, was $83.5 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, particularly as we prepare for the launch of *Rayaldee* in the fourth quarter of 2016.

We believe that the cash, cash equivalents and marketable securities on hand at June 30, 2016, 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, preparations for the commercial launch of *Rayaldee*, our merger with Bio-Reference, 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 June 30, 2016, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining six months ending December 31, 2016	2017	2018	2019	2020	Thereafter	Total
Open purchase orders	$ 51,954	$ 2,405	$ 5	$ 5	$ 9	$ —	$ 54,377
Operating leases	9,791	12,209	10,021	8,529	4,543	8,322	53,415
Capital leases	2,740	4,182	2,949	1,805	1,045	876	13,597
2033 Senior Notes	—	—	—	32,200	—	—	32,200
Deferred payments	5,000	5,000	5,000	5,000	—	—	20,000
Mortgages and other debts payable	1,778	299	250	242	239	934	3,742
Lines of credit	9,526	—	—	—	38,135	—	47,661
Severance payments	6,327	—	—	—	—	—	6,327
Interest commitments	609	1,026	1,017	204	1,323	55	4,234
Total	$ 87,725	$ 25,121	$ 19,242	$ 47,985	$ 45,295	$ 10,187	$ 235,554

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 7 years and are payable in either shares of our Common Stock or cash, at our option, and that may aggregate up to $189.4 million.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Accounting estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 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. Goodwill and other intangible assets, including IPR&D, acquired in business combinations, licensing and other transactions at June 30, 2016 and December 31, 2015 was $2.1 billion and $2.2 billion, respectively, representing approximately 76% and 78% of total assets, respectively.

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 the valuations are 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. Our recent valuations typically use a U.S. tax rate (and applicable state taxes) after considering the jurisdiction in which the intellectual property is held and location of research and manufacturing infrastructure. We also considered 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 $691.1 million and $743.3 million, respectively, at June 30, 2016 and December 31, 2015. 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 were $1.4 billion, including IPR&D of $606.0 million and $792.3 million, respectively, at June 30, 2016 and December 31, 2015. 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 or 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 $29.2 million and $5.9 million for the six months ended June 30, 2016 and 2015, 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 three months ended June 30, 2016 and 2015, approximately 10% and 4%, respectively, of our revenues were derived directly from the Medicare and Medicaid programs. The increase in revenues from laboratory services, including revenue from Medicare and Medicaid programs, is due to the acquisition of Bio-Reference in August 2015.

Generally, we recognize revenue from product sales 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 management's evaluation of specific factors that may increase or decrease the risk of product returns.

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 quarterly 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 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 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 health care 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 health care programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. Accounts receivable balances (net of contractual adjustments) from Medicare and Medicaid were $30.4 million and $26.1 million at June 30, 2016 and December 31, 2015, respectively.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At June 30, 2016 and December 31, 2015, receivables due from patients represent approximately 6.6% and 7.5% of our consolidated accounts receivable (prior to allowance for doubtful accounts and net of contractual adjustments).

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 $48.8 million and $25.2 million at June 30, 2016 and December 31, 2015, 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 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 Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow and as a reduction of taxes paid in cash flow from operations. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. We estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the "Black-Scholes Model." The Black-Scholes Model requires the use of several variables to estimate the grant-date fair value of stock options including expected term, expected volatility, expected dividends and risk-free interest rate. We perform analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model and to estimate forfeitures of equity-based awards. We are required to adjust our forfeiture estimates on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and

estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates which may have a material impact on our Condensed Consolidated Financial Statements.

Inventories. Inventories are valued at the lower of cost or market (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 or market. 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"), ASU No. 2014-09, "Revenue from Contracts with Customers." ASU No. 2014-09 clarifies the principles for recognizing revenue and develops a common revenue standard for GAAP and International Financial Reporting Standards 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 No. 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 are currently evaluating both methods of adoption and the impact that the adoption of this ASU will have on our Condensed Consolidated Financial Statements.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force)." ASU No. 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU No. 2014-12 was effective for the Company beginning after January 1, 2016. Our adoption of ASU 2014-12 in the first quarter of 2016 using the prospective application did not have a material impact on our Condensed Consolidated Financial Statements.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 with early adoption permitted. We do not believe the impact of our pending adoption of ASU 2014-15 on our Condensed Consolidated Financial Statements will be material.

In February 2015, the FASB issued ASU No. 2015-02, "Consolidation (Topic 810): Amendments to the Consolidation Analysis," which amends current consolidation guidance including changes to both the variable and voting interest models used by companies to evaluate whether an entity should be consolidated. The requirements from ASU 2015-02 were effective for the Company beginning January 1, 2016. Our adoption of ASU 2015-02 in the first quarter of 2016 did not have a material impact on our Condensed Consolidated Financial Statements.

In April 2015, the FASB issued ASU No. 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs," which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU

2015-03 was effective for the Company beginning January 1, 2016. Our adoption of ASU 2015-03 in the first quarter of 2016 did not have a material impact on our Condensed Consolidated Financial Statements.

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. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In September 2015, the FASB issued ASU No. 2015-16, "Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments," which replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 requires that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. Our early adoption of ASU 2015-16 in 2015 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. 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 this ASU simplifies the presentation of deferred income taxes and reduce complexity without decreasing the usefulness of information provided to users of financial statements. The adoption of ASU 2015-17 did not have a significant impact 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 No. 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 No. 2016-09 will be effective for fiscal years beginning after December 15, 2016, 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.

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 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 Statement 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. 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 June 30, 2016, we had cash and cash equivalents and marketable securities of $171.6 million. The weighted average interest rate related to our cash and cash equivalents for the six months ended June 30, 2016 was less than 1%. As of June 30, 2016, the principal outstanding balance under our Credit Agreement with JPMorgan Chase Bank, N.A. and our Chilean and Spanish lines of credit was $47.7 million in the aggregate at a weighted average interest rate of approximately 4.6%.

Our $32.2 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.

Equity Price Risk – We are subject to equity price risk related to the (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. These terms are considered to be embedded derivatives. On a quarterly basis, we are required to record these embedded derivatives at fair value with the changes being recorded in our Condensed Consolidated Statement of Operations. Accordingly, our results of operations are subject to exposure associated with increases or decreases in the estimated fair value of our embedded derivatives.

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 June 30, 2016.

Changes to the Company's Internal Control Over Financial Reporting

In connection with the acquisitions of EirGen in May 2015 and Bio-Reference in August 2015, we began implementing standards and procedures at EirGen and Bio-Reference, 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 EirGen and Bio-Reference. We are continuing to integrate the acquired operations of EirGen and Bio-Reference into our overall internal control over financial reporting process.

These changes to the Company's internal control over financial reporting that occurred during the most recent quarter ended June 30, 2016 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

On December 18, 2013, Bio-Reference filed an action in the Superior Court of New Jersey against Horizon Blue Cross Blue Shield of New Jersey ("Horizon"), captioned Bio-Reference Laboratories, Inc. v. Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey, Docket No. BER L-009748-13 (N.J. Super. Ct. Bergen County). Bio-Reference has been an in-network provider with Horizon's preferred provider organization ("PPO") network for more than 20 years and filed the lawsuit after attempts to resolve its dispute with Horizon were unsuccessful. The parties have agreed to a full and final settlement of the matter with an effective date of March 31, 2016, based on an execution date of May 11, 2016. Among other consideration, under the terms of the settlement, Horizon paid Bio-Reference a negotiated settlement for the disputed claims and Bio-Reference's current PPO contract will remain in effect through December 31, 2018. The settlement was not material to Revenue from services in our Condensed Consolidated Statements of Operations for the three or six months ended June 30, 2016.

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, 2015, 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, 2015.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit 2.1[(1)]	Agreement and Plan of Merger, dated June 3, 2015, by and among, Opko Health, Inc., Bamboo Acquisition, Inc. and Bio-Reference Laboratories, Inc.
Exhibit 2.2[(2)]	Arrangement Agreement, dated June 29, 2016, by and among OPKO Health, Inc., OPKO Global Holdings, Inc. and Transition Therapeutics, Inc.
Exhibit 3.1[(3)]	Amended and Restated Certificate of Incorporation.
Exhibit 3.2[(4)]	Amended and Restated By-Laws.
Exhibit 3.3[(5)]	Certificate of Designation of Series D Preferred Stock.
Exhibit 4.3[(6)]	Indenture, dated as of January 30, 2013, between OPKO Health, Inc. and Wells Fargo Bank, National Association.
Exhibit 10.1[(7)]	OPKO Health, Inc. 2016 Equity Incentive Plan.
Exhibit 10.2[(+)]	Development and License Agreement between OPKO Health, Inc. and Vifor Fresenius Medical Care Renal Pharma Ltd. dated May 8, 2016.
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 June 30, 2016.
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 June 30, 2016.
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 June 30, 2016.
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 June 30, 2016.
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

(+) Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.

(1) Filed as Annex A to the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on July 2, 2015, and incorporated herein.

(2) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 30, 2016, and incorporated herein by reference.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) Filed with the Company's Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on March 25, 2016, 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: August 8, 2016

OPKO Health, Inc.

/s/ Adam Logal

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

Exhibit Index

Exhibit Number	Description
Exhibit 10.2(+)	Development and License Agreement between OPKO Health, Inc. and Vifor Fresenius Medical Care Renal Pharma Ltd. dated May 8, 2016.
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 June 30, 2016.
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(+) Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Exhibit 10.2

DEVELOPMENT AND LICENSE AGREEMENT

BETWEEN

OPKO HEALTH, INC.

AND

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD

May 8, 2016

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Execution Version

DEVELOPMENT AND LICENSE AGREEMENT

This Development and License Agreement (this "Agreement") is entered into and effective as of the 8th day of May, 2016 (the "Effective Date"), by and between EirGen Pharma Limited, an entity formed under the laws of Ireland with registered seat at Westside Business, Old Kilmeaden, Waterford, Ireland ("OPKO"), and Vifor Fresenius Medical Care Renal Pharma Ltd, a corporation formed under the laws of Switzerland with registered seat at Rechenstrasse 37, 9014 St. Gallen, Switzerland ("VF"), for the development and marketing of OPKO's Product in the Territory (as such terms are defined below).

Recitals

A. OPKO is the owner of all right, title and interest in and to the Product.

B. VF, directly or through one of its Affiliates, desires to develop, commercialize, distribute, sell, market and promote the Product in the Field in the Territory, and OPKO is willing to grant VF the right to conduct such activities, all on the terms and subject to the conditions set forth in this Agreement.

C. OPKO and VF desire to work together to develop the Product, promote the Product, and to optimize its sales and commercial success in the Territory.

Agreement

1. Definitions

1.1 "Accounting Standards" means generally accepted accounting standards in the United States and International Financial Reporting Standards as adopted in Switzerland, in each case as applicable and consistently applied by the relevant Person.

1.2 "Additional Indication" shall mean an indication set forth in or proposed to be set forth in the label for the Product for the prevention or treatment of diseases other than or in addition to the Initial Indication, including without limitation the use of the Product in combination with any other active ingredient.

1.3 "Adverse Event(s)" shall mean those events as defined by the FDA and published in the U. S. Code of Federal Regulations, as amended from time to time and published in the Federal Register, or by the EMA or any similar definitions under laws of other jurisdictions within the Territory relating to adverse drug experiences relating to the use of the Product in the Territory.

1.4 "Affiliate" shall mean any Person that directly or indirectly owns, is owned by or is under common ownership with a Party to the extent of at least 50% of the equity or other ownership interest having the power to vote on or direct the affairs of the Person actually controlled by, controlling or under common control with a Party.

1.5 "Agreement Year" shall mean each twelve month period ending on December 31 during the Term.

1.6 "Applicable Law" means any law (including common law), statute, rule, regulation, order, judgment, or ordinance of any Governmental Authority, including those concerning environmental, health, and safety matters.

1.7 **"**Bioequivalent**"** means, inside the United States, "therapeutically equivalent" as evaluated by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the then-current edition of the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations" and, outside the United States, such equivalent determination by the applicable Regulatory Authorities as is necessary to permit pharmacists or other individuals authorized to dispense pharmaceuticals under Applicable Law to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Applicable Law.

1.8 "Business Day" shall mean a day on which commercial banks are open for business in New York City and Zurich, Switzerland. References in this Agreement to "days" other than Business Days shall mean calendar days.

1.9 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.10 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to any objective, those reasonable and good faith efforts and resources to accomplish such objective as a similarly-situated company within the pharmaceutical industry would normally use to accomplish a similar objective under similar circumstances, in each case taking into account all Relevant Factors in effect at the time such efforts are to be expended. With respect to any efforts relating to the development, Regulatory Approval and/or commercialization of a Product, generally in the Territory, such Party will be deemed to have exercised Commercially Reasonable Efforts if such Party has exercised those efforts normally used by a similarly-situated company within the pharmaceutical industry, in the relevant country, with respect to a compound, product or product candidate which is of [***], in each case taking into account all Relevant Factors in effect at the time such efforts are to be expended. [***].

1.11 "Competitive Product" means any product that: (a) is marketed in a country or region in the Territory by one or more Persons that is not VF, an Affiliate of VF, a Sublicensee, Fresenius or any Affiliate of Fresenius; (b) [***].

1.12 "Cover(ed)" means, with respect to any Patent and the subject matter at issue, that, but for a license granted under such Patent, the manufacture, development, use, sale, offer for sale or importation of the subject matter at issue would infringe such Patent, or in the case of a Patent that is a patent application, would infringe such patent application if it were to issue as a patent.

1.13 "Drug Approval Application" shall mean an application for marketing authorization or clearance required to be approved before commercial sale or use of a Product as a drug in a regulatory jurisdiction (i.e. NDA, MAA or equivalent).

1.14 "Effective Date" shall have the meaning set forth in the first paragraph of this Agreement.

1.15 "EMA" shall mean the European Medicines Agency, or any successor agency.

1.16 "Europe" shall mean the countries which are members of the European Union, as such membership may change from time to time.

1.17 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

1.18 "Field" shall mean all therapeutic and prophylactic uses of the Product in humans except for any Additional Indications that are excluded from the Field in accordance with Section 4.1.

1.19 "Fresenius" means Fresenius Medical Care AG & Co KGaA, a partnership organized and existing under the laws of Germany with an interest in VF as of the Effective Date of forty-five percent (45%). For purposes of this Agreement, Fresenius is not an Affiliate of VF.

1.20 "Galenica" shall mean Galenica AG with its registered seat at Untermattweg 8, 3000 Bern, Switzerland. As of the Effective Date, Galenica holds a fifty-five percent (55%) ownership interest in VF.

1.21 "Good Clinical Practices" or "GCP" means all applicable good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other applicable guidelines for good clinical practice for clinical trials on medicinal products; (b) the Declaration of Helsinki (2004), as last amended at the 52nd World Medical Association General Assembly in October 2000, and any further amendments or clarifications thereto; and (c) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and, in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.22 "Governmental Authority" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.23 "Government Official" means (a) any elected or appointed government official (e.g., a member of a ministry of health), (b) any employee or Person acting for or on behalf

of a government official, Governmental Authority, or other enterprise performing a governmental function, (c) any political party, candidate for public office, officer, employee, or Person acting for or on behalf of a political party or candidate for public office, and (d) any employee or Person acting for or on behalf of a public international organization (e.g., the United Nations). For clarity, healthcare providers employed by government-owned hospitals will also be considered Government Officials.

1.24 "HD Trial" shall mean the phase 3 clinical trial contemplated by the Development Plan for treatment of secondary hyperparathyroidism in dialysis (HD) chronic kidney disease (CKD) patients.

1.25 "Initial Indication" shall mean the use of the Product for the treatment or prevention of secondary hyperparathyroidism related to patients with chronic kidney disease and vitamin D insufficiency/deficiency (or if broader, as such may be defined by the wording of the label approved by Regulatory Authorities in the Territory for the Product).

1.26 "Major Country" shall mean any of [***].

1.27 "Marketing Material" shall mean the written, printed, electronic or graphic materials related to strategy, communications and programs associated with the marketing or promotion of the Product, including such strategy, communications, programs and any promotional and marketing materials that (a) specifically identify or describe the Product or (b) otherwise support the Product or raise awareness of the Product.

1.28 "Net Sales" shall mean, on a country-by-country basis, the gross amounts invoiced by VF and its Affiliates and any Sublicensees for sales of Product in a particular country to Third Parties in the Territory during the Royalty Term, in each case, to the extent related to the Product and recognized and allowed in accordance with the Accounting Standards, less the following deductions:

(a) bad debts and uncollectable invoiced amounts relating to sales of the Product that are actually written off in accordance with the Accounting Standards, consistently applied, provided that any such amounts shall be capped at up to [***] of Net Sales for the entire Territory per Agreement Year and any subsequently collected amounts will be included in the current Net Sales calculation,

(b) sales returns and allowances actually paid, granted or accrued, including trade, quantity and cash discounts and other adjustments, including those granted on account of price adjustments, returns, rebates, chargebacks or similar payments granted or given to wholesalers or other institutions,

(c) adjustments arising from consumer discount programs or other similar programs,

(d) clawback taxes, customs or excise duties, valued-added taxes, sales taxes, consumption taxes and other taxes (except income taxes) or duties relating to sales, any payment

in respect of sales to any Governmental Authority, or with respect to any government-subsidized program or managed care organization, each to the extent not already reflected in the amount invoiced, and

(e) freight, insurance and transportation costs for the Product to the extent included in the amount invoiced.

Net Sales shall be determined from books and records maintained in accordance with the Accounting Standards, as consistently applied, with respect to sales of any Product.

The sale of Products to VF's Affiliates and its Sublicensees shall not be deemed as a "sale" within the meaning of this definition.

Net Sales will not include Products transferred for use in connection with clinical trials or other development activity, pre-clinical research and trials, promotional use (including samples), compassionate sales or use, indigent programs, or on a named patient basis.

If a Product is sold in combination (" Combination Product") with another product (as a separate dosage form) or device having an independent or supplementary therapeutic effect, diagnostic utility or device (a "Supplemental Component"), then "Net Sales," for purposes of determining royalty payments on the Combination Product, shall be calculated using one of the methods listed below and then deducting the amounts listed in Sections 1.28(a) through (e) above to the extent not previously deducted.

(i) By multiplying the Net Sales of the Combination Product (calculated before application of this formula) by the fraction A/(A+B), where A is the average gross invoice price, during the applicable Calendar Quarter in the applicable country of the Product when sold separately, and B is the average gross invoice price, during the applicable Calendar Quarter in the applicable country of the Supplemental Component(s) when sold separately.

(ii) If the average gross invoice price of the Product when sold separately during the applicable Calendar Quarter in the applicable country can be determined, but the average gross invoice price of the Supplemental Component during the applicable Calendar Quarter in the applicable country cannot be determined, then by multiplying the Net Sales of the Combination Product (calculated before application of this formula) by the fraction A/C, where A has the meaning set forth in subsection (i) of this Section 1.28 and C is the average gross invoice price of the Combination Product.

(iii) If no separate sales are made of the Product or any of the Supplemental Components in such Combination Product during the applicable Calendar Quarter in the applicable country, Net Sales shall be calculated using the above formula in Section 1.28(i) where A is the reasonably estimated commercial value of the Product when sold separately during the applicable Calendar Quarter in the applicable country, and B is the reasonably estimated commercial value of the Supplemental Components when sold separately during the applicable Calendar Quarter in the applicable country. Any such estimates shall be determined using criteria to be mutually agreed upon by the Parties.

1.29 "New Drug Approval" shall mean an approval by a Governmental Authority of a Drug Approval Application.

1.30 "OPKO Technology" shall mean all present and future information developed solely by OPKO or its Affiliates, or owned or controlled by OPKO or its Affiliates, whether or not in written form, that is not in the public domain and that relates to the Product and shall include, without limitation, all biological, chemical, pharmacological, toxicological, medical or clinical, analytical, quality, manufacturing, research, or sales and marketing information including all processes, methods, procedures, techniques, plans, programs, and data stored or maintained in any form, including electronic, and any other information relating to the Product or useful for the development or commercialization of the Product in the Territory.

1.31 "OPKO Trademark(s)" shall mean Rayaldee™, a trademark owned or controlled by OPKO in the Territory, and any other trademark, service mark or logo developed, applied for, registered, or to be applied for or registered by OPKO or its Affiliates for use in connection with the sale of the Product in the Territory.

1.32 "Party(ies)" shall mean each of OPKO and VF.

1.33 "Patents" shall mean all patents and patent applications in the Territory that are or become owned or controlled by OPKO or its Affiliates, or to which OPKO or its Affiliates otherwise has, now or in the future, the right to grant licenses and license rights or sublicense rights, that Cover the Product or a use or a formulation of the Product. Included within the definition of Patents are all continuations, continuations-in-part, divisionals, patents of addition, reissues, renewals or extensions thereof, and patent term extensions, supplementary protection certificates and pediatric extensions. The current list of patents and patent applications included in the OPKO Patents is set forth in Appendix A attached hereto.

1.34 "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

1.35 "Product" shall mean a modified release product containing calcifediol (25-hydroxyvitamin D_3) and/or calcifediol monohydrate as an active pharmaceutical ingredient.

1.36 "Product First Commercial Sale" shall mean, after all necessary Regulatory Approvals, including pricing and reimbursement approvals, by the appropriate Regulatory Authority(ies), on a country-by-country basis, the first sale of Product Covered by a Valid Claim in a particular country in the Territory by VF, any of its Affiliates, or any permitted Sublicensee to a Third Party for end use or consumption of such Product. A Product First Commercial Sale excludes any sale or other distribution for clinical and pre-clinical research and trials, promotional samples, compassionate sales or use, indigent programs, or on a named patient basis.

1.37 "Quality Agreement" shall mean the quality control and assurance agreement to be mutually agreed upon by the Parties as set forth in Section 10.2.

1.38 "Regulatory Approval" shall mean any approvals, product and/or establishment licenses, registrations, permits, or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity or Regulatory Authority, necessary for the manufacture, distribution, use, storage, importation, export, transport and sale of the Product in a regulatory jurisdiction.

1.39 "Regulatory Authority" shall mean any national, supra-national (e.g., the European Commission, the Council of the European Union, or the EMA), regional, state or local regulatory agency, department, bureau or other governmental entity in the Territory responsible for issuing any technical, medical and scientific licenses, registrations, authorizations and/or approvals of the Product including any marketing authorizations based upon such approvals and pricing, third party reimbursement or labeling approvals that are necessary for the manufacture, distribution, use, storage, importation, export, transport and sale of the Product in a regulatory jurisdiction.

1.40 "Relevant Factors" means all relevant factors that may affect the development, Regulatory Approval or commercialization of a Product, including (as applicable): actual and potential issues of safety, efficacy or stability; product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected development, Regulatory Approval, manufacturing, and commercialization costs; any issues regarding the ability to manufacture or have manufactured any Product; the likelihood of obtaining Regulatory Approvals; the timing of such approvals; the current guidance and requirements for Regulatory Approval for the Product and similar products and the current and projected regulatory status; labeling or anticipated labeling; the then-current competitive environment and the likely competitive environment at the time of projected entry into the market and thereafter; past performance of the Product or similar products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; pricing or reimbursement changes in relevant countries; proprietary position, strength and duration of patent protection and anticipated exclusivity; the commercialization by VF after expiration of the Royalty Term of both the Product that uses the OPKO Trademarks and a generic Product; and other relevant scientific, technical, operational and commercial factors.

1.41 "Sublicensee" means a Third Party who has been granted a sublicense as permitted under Section 2.2 of this Agreement.

1.42 "Term" shall have the meaning set forth in Article 3.

1.43 "Territory" shall mean worldwide, except the Territory shall not include (i) the U.S., (ii) any country in Central America or South America (excluding Mexico), (iii) Russia, (iv) China, (v) Japan, (vi) Ukraine, (vii) Belorussia, (viii) Azerbaijan, (ix) Kazakhstan, and (x) Taiwan.

1.44 "Third Party(ies)" shall mean any Person other than OPKO and VF or their Affiliates.

1.45 "Third Party Payments" shall mean all upfront payments, milestone payments, license fees, royalties or other payments paid or payable to any Third Party under any agreement with a Third Party.

1.46 "U.S." shall mean the United States of America, its territories and possessions, including without limitation the Commonwealth of Puerto Rico.

1.47 "Valid Claim" means a claim of (a) an issued and unexpired patent included in the Patents that has not been (i) held unpatentable or unenforceable by a final decision of a court or other governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and (ii) abandoned or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, or (b) a pending patent application included in the Patents that has been pending for no longer than [***] from the publication date for the particular patent application, that continues to be actively prosecuted in good faith unless and until such claim has been granted. For clarity, any pending claim in an application in any country that has not been granted within [***] from the publication date shall not be included as a Valid Claim until such claim is granted. A claim of a Patent or patent application having a priority date following the Effective Date of this Agreement, to the extent that the claim solely claims an alternate manufacturing process to produce the Bulk Product, including any of its components, shall not be included as a "Valid Claim"; provided that [***].

2. Grant of Rights

2.1 Patents and OPKO Technology.

Subject to the terms and conditions of this Agreement, OPKO hereby grants to VF an exclusive license in the Territory in the Field under the Patents and OPKO Technology to make, have made, use, sell, offer for sale, and import Products and to develop, commercialize, have commercialized, and otherwise exploit the Product. Subject to the terms and conditions of this Agreement, VF hereby grants back to OPKO (i) a non-exclusive right to make, and have made Product in the Territory, and (ii) a non-exclusive right to conduct research and pre-clinical development of the Product in the Territory. For the avoidance of doubt, OPKO retains all of its rights with respect to the Product, the Patents, the OPKO Trademarks, and the OPKO Technology outside the Territory and outside the Field within the Territory. Subject to the terms and conditions of this Agreement and any other agreement(s) OPKO has with respect to the Patents and OPKO Technology and Product outside the Territory, if the JSC reaches consensus on the matter: (a) OPKO will grant VF a limited, non-exclusive license on a project-by-project basis outside the Territory in the Field under the Patents and OPKO Technology to develop (including clinical trials), make and have made Products solely to the extent necessary to support the VF exclusive rights within the Territory and the Field; and (b) VF will grant OPKO a limited, non-exclusive license on a project-by-project basis in the Territory in the Field under the Patents and OPKO Technology to conduct clinical development of Products solely to the extent necessary to support OPKO's exclusive rights outside the Territory and outside the Field within the Territory. If the JSC does not reach consensus with respect to the grant of rights set forth in Sections 2.1(a) or 2.1(b), the matter will be resolved under Section 21.3.

2.2 Subcontracting and Sublicensing.

(a) [***].

(b) VF shall not sublicense its rights and obligations under this Agreement, whether in whole or in part, to any Third Party without the prior written consent of OPKO, which shall not be unreasonably withheld. Notwithstanding the foregoing, without OPKO's consent, and provided that [***].

(c) With respect to each sublicense other than to [***] OPKO shall be notified in writing at least [***] Business Days in advance of the grant (including a description of the rights to be granted, the identity of the Sublicensee and the countries involved) and VF shall obtain the prior written consent of OPKO thereto, which shall not unreasonably be withheld or delayed; (B) VF shall ensure that each such Sublicensees accepts all applicable material terms and conditions of this Agreement and shall use Commercially Reasonable Efforts to ensure that each such Sublicensees complies with all applicable material terms and conditions of this Agreement; and (C) any such Sublicense shall (aa) be subject and subordinate to the terms and conditions of this Agreement including without limitations all restrictive covenants set forth in this Agreement, (bb) be subject to an appropriate written agreement that imposes on any such Sublicensee the confidentiality provisions hereunder, (cc) contain a provision prohibiting such Sublicensee from further sublicensing, (dd) not in any way diminish, reduce or eliminate any of VF's obligations under this Agreement and (ee) be summarized in writing to OPKO with respect to scope, field, countries and incorporation of relevant terms and conditions of this Agreement. If OPKO does not respond to a notice under this Section 2.2(c) within [***] Business Days, OPKO's consent will be deemed to be granted. For the avoidance of doubt, VF will remain directly responsible for all amounts owed to OPKO and performance of all obligations under this Agreement. VF hereby expressly waives any requirement that OPKO exhaust any right, power or remedy, or proceed against a Sublicensee for any obligation or performance hereunder prior to proceeding directly against VF.

2.3 Ex-Territory and Ex-Field Activities.

(a) VF hereby covenants and agrees that, on a country-by-country basis during the Royalty Term, it shall not (and shall cause its Affiliates, Sublicensees and subcontractors not to), either itself or through a Third Party, market, promote or actively offer for sale the Product outside the Field in the Territory in such country or outside of the Territory in or outside of the Field. Without limiting the generality of the foregoing, with respect to countries outside of the Territory, VF shall not (a) engage in any advertising activities relating to the Product directed solely to customers outside the Territory (e.g., participation in conferences, congresses or scientific or medical meetings held throughout the world), or (b) solicit orders from any prospective purchaser located outside the Territory. To the extent permitted by Applicable Law, including applicable antitrust laws, if VF receives any order from a prospective purchaser located in a country outside of the Territory, VF shall immediately refer that order to OPKO and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) any Product under such order. If VF should reasonably know that a customer or distributor is engaged itself or through a Third Party in the sale or distribution of the Product outside of the Territory or outside the Field within the Territory, then VF shall (a) within five (5) Business Days of gaining knowledge of such activities notify OPKO

regarding such activities and provide all information available to VF that OPKO may reasonably request concerning such activities and (b) take Commercially Reasonable Efforts (including cessation of sales to such customer) necessary to limit such sale or distribution outside the Territory or the Field, unless otherwise agreed in writing by the Parties.

(b) OPKO hereby covenants and agrees that during the Term it shall not (and shall cause its Affiliates, sublicensees and subcontractors not to), either itself or through a Third Party, market, promote or actively offer for sale the Product for use in the Field in the Territory. Without limiting the generality of the foregoing, with respect to such countries within the Territory, OPKO shall not (a) engage in any advertising activities relating to the Product for use in the Field directed solely to customers located in such countries, or (b) solicit orders from any prospective purchaser of the Product for use in the Field located in such countries. To the extent permitted by Applicable Law, including applicable antitrust laws, if OPKO receives any order from a prospective purchaser for the Product in the Field located in a country inside of the Territory, OPKO shall immediately refer that order to VF. If OPKO should reasonably know that a customer or distributor is engaged itself or through a Third Party in the sale or distribution of the Product inside the Territory in the Field, then OPKO shall (a) within five (5) Business Days of gaining knowledge of such activities, notify VF regarding such activities and provide all information available to OPKO that VF may reasonably request concerning such activities and (b) take Commercially Reasonable Efforts (including cessation of sales to such customer) necessary to limit such sale or distribution inside the Territory in the Field, unless otherwise agreed in writing by the Parties.

3. Term

3.1 Term.

The term of this Agreement shall commence on the Effective Date and shall continue with respect to the Product in each country of the Territory, on a country by country basis, until the date on which VF shall have no further payment obligations to OPKO under the terms of this Agreement, unless earlier terminated pursuant to Section 16.1 or Article 18 (the "Term").

3.2 Expiration.

Upon the expiration of the Term (and not including any early termination of this Agreement under Article 16) with respect to a Product in a country, the licenses granted to VF under Section 2.1 shall become fully-paid, royalty-free and perpetual and non-exclusive; provided, however, that OPKO and its Affiliates and licensees/sublicensees shall comply with the non-competition obligations under Section 15.2(b). If VF or its Affiliates or permitted Sublicensees use the OPKO Trademarks and Product Trade Dress after the expiry of the Royalty Term in connection with Product in the Field in the Territory, then VF's license to use the OPKO Trademarks and Product Trade Dress shall remain exclusive so long as VF pays OPKO a royalty of [***] of any Net Sales in the applicable country with respect to those Products with which the OPKO Trademarks and Product Trade Dress are used or on which the OPKO Trademarks and Product Trade Dress are displayed, provided VF uses Commercially Reasonable Efforts to promote such Products.

4. Additional Indications

4.1 Additional Indications.

(a) In the event that either Party desires to develop an Additional Indication for the Product for commercialization in the Field (by OPKO on a global basis and VF or any Sublicensee in the Territory), the development of such Additional Indication shall be proposed in writing in sufficient detail to the JSC. [***], which notice is within [***] after such proposal to the JSC, during which time the Parties are discussing the proposal, the [***] shall be determined in accordance with Section 4.1(c). Within [***] after a [***] or within such [***] period during which the Parties are discussing the proposal [***], the non-proposing Party shall elect whether to participate in the development of such Additional Indication ([***]). If the non-proposing Party elects to participate, the Parties are obligated to jointly develop the Additional Indication ([***]) and shall seek to reach a mutual written agreement on the additional terms and conditions for the development of such Additional Indication within next [***]. The terms of the written agreement, if any, would become part of the Development Plan, and all resulting data would be available for use by VF in connection with exercising its rights under this Agreement with respect to the Product in the Field and in the Territory and for use by OPKO outside the Territory in connection with the Product in the Field.

(b) If the Parties do not enter into the written mutual agreement contemplated under Section 4.1(a) with respect to a proposed Additional Indication and the JSC has not [***], the proposing Party may proceed with the development of such Additional Indication and will be [***] responsible for the conduct and costs of such development, in which case, if VF is not a proposing Party, such Additional Indication would be removed from the Field, except not to the extent that VF receives rights pursuant to Section 4.1(d) or 4.1(e). In such case, [***].

(c) If the non-proposing Party believes a proposed Additional Indication [***] for which the Product has been, is planned to be or is being developed in the Territory as to VF, or outside the Territory or the Field as to OPKO, or on the regulatory status of the Product in the Field in such respective territory, based on [***], such non-proposing Party will have the right to refer such matter to the JSC in writing for resolution by consensus [***]. If the JSC does not reach consensus with respect to the Additional Indication, the matter will be resolved (and JSC consensus deemed to have been achieved) as provided under Section 21.3.

(d) If (i) there is JSC consensus of [***], if required pursuant to Section 4.1(c), (ii) VF as the non-proposing Party does not exercise its rights under Section 4.1(a) and (b), (iii) OPKO as the proposing Party does exercise its rights under Section 4.1(a) and (b), and (iv) OPKO or any of its Affiliates desires to enter into a licensing or another arrangement with respect to the Additional Indication with a Third Party, then OPKO must give VF written notice of such desire, including the proposed terms thereof, and [***].

(e) If (i) there is JSC consensus of [***], if required pursuant to Section 4.1(c), (ii) VF as the non-proposing Party does not exercise its rights under Section 4.1(a) and (b), (iii) OPKO as the proposing Party does exercise its rights under Section 4.1(a) and (b), and (iv) OPKO or any of its Affiliates desires to commercialize, market, promote or sell the Product in any country in the Territory for the Additional Indication, then OPKO must give VF written notice of such desire

at the time of filing for Regulatory Approval in such country for such Additional Indication and [***].

(f) After [***], OPKO shall promptly provide [***]. In addition, OPKO shall cause its Affiliates and licensees/sublicensees to comply with this Section 4.1.

(g) For the avoidance of doubt, neither OPKO nor its Affiliates and licensees shall be allowed to license or launch a Product for an Additional Indication in the Territory pursuant to Section 4.1(d) or (e) if the labeling of such Product includes the Initial Indication or any other Additional Indication for which VF has rights in the Territory.

(h) Subject to Section 4.1(g), if OPKO or its Affiliates are allowed to license or launch a Product for an Additional Indication in the Territory pursuant to Section 4.1(d) or (e), then the Parties shall agree in good faith on an effective mechanism to (i) prevent off-label sales in each other's respective field in the Territory of such Product and (ii) provide adequate compensation to the other Party for off-label sales in its respective field in the Territory of such Product. If such an agreement is not reached, the matter will be resolved as provided under Section 21.3.

5. Fees and Payments

5.1 Up-front Payment.

In consideration for the rights under the Patents, OPKO Trademarks, and OPKO Technology granted to VF in this Agreement, VF shall pay a non-refundable and non-creditable payment of $50,000,000 to OPKO within ten (10) Business Days after the Effective Date.

5.2 Milestone Payments.

As additional consideration for the rights under the Patents, OPKO Trademarks, and OPKO Technology granted to VF in this Agreement, VF shall pay non-refundable and non-creditable milestone payments to OPKO in the amounts and upon the occurrence of the events set forth below. Each such payment shall be made within [***] Business Days of the achievement or occurrence of the milestone event. Each milestone payment will be payable only one time. For purposes of clarity, more than one of the Net Sales and regulatory approval milestones may be met during the same Agreement Year and, in that case, each such milestone would be payable. For example, if during one Agreement Year there were Net Sales of the Product in the Territory of [***], and it was the first Agreement Year in which Net Sales of the Product in the Territory exceeded [***], then VF would owe both the [***] and [***] milestone payments and no similar milestone payments would be due in any following Agreement Year if the Net Sales in the Territory exceeded [***] or [***].

Milestone	Milestone Payment
First New Drug Approval in [***] for the treatment of secondary hyperparathyroidism in [***] patients with vitamin D insufficiency	[***]

First New Drug Approval in [***] for the treatment of secondary hyperparathyroidism in [***] patients with vitamin D insufficiency [***]

First New Drug Approval in [***] for the treatment of secondary hyperparathyroidism in [***] patients with vitamin D insufficiency [***]

First New Drug Approval in [***] for the treatment of secondary hyperparathyroidism in [***] patients with vitamin D insufficiency [***]

First New Drug Approval in [***] for the treatment of secondary hyperparathyroidism in [***] patients with vitamin D insufficiency [***]

First New Drug Approval in [***] for the treatment of secondary hyperparathyroidism in [***] patients with vitamin D insufficiency [***]

Product First Commercial Sale in the Territory [***]

First time aggregate Net Sales of the Product in the Territory exceed [***] in an Agreement Year [***]

First time aggregate Net Sales of the Product in the Territory exceed [***] in an Agreement Year [***]

First time aggregate Net Sales of the Product in the Territory exceed [***] in an Agreement Year [***]

5.3 Royalty Payments.

During each Agreement Year, VF shall pay to OPKO royalty payments (the " Royalty Payments") on a [***] basis in an amount equal to the aggregate annual Net Sales of the Product within the Territory multiplied by the Applicable Percentage, as may be adjusted as set forth in this Agreement. The "Applicable Percentage" shall be as follows:

Aggregate Net Sales	Applicable Percentage
Up to but not including [***]	[***]
[***] to [***]	[***]
In excess of [***]	[***]

For the avoidance of doubt, if the aggregate Net Sales exceed [***] in any Agreement Year, the calculation of Royalty Payments shall be as follows: [***] for the first [***] Net Sales; [***] for the Net Sales between [***] and [***]; and [***] for the Net Sales in excess of [***].

5.4 Minimum Royalty.

Beginning on the first day of the first Calendar Quarter after the Product First Commercial Sale, for the periods set forth in the table below, VF shall be obligated to pay OPKO a minimum royalty (the "Minimum Royalty") to the extent the aggregate Royalty Payments due for the applicable period are below the following amounts:

Period	Minimum Royalty
The first [***] consecutive Calendar Quarters beginning on the first day of the first Calendar Quarter after the Product First Commercial Sale	[***]
Each [***] consecutive Calendar Quarters thereafter	[***]

For purposes of clarity, if the total Royalty Payments due under Section 5.3 with respect to each Minimum Royalty period are greater than the applicable Minimum Royalty for the same period, no Minimum Royalty amount shall be payable by VF with respect to such period. To the extent that the total Royalty Payments due under Section 5.3 with respect to a period are less than the Minimum Royalty for the same period, VF shall pay OPKO the difference between the total Royalty Payments and the Minimum Royalty. The calculation for the first period to determine if anything is due under this Section 5.4 is made after [***] Calendar Quarters based on the total Royalty Payments due under Section 5.3 with respect to such [***] Calendar Quarters when compared to the Minimum Royalty of [***]. Thereafter, the calculation for subsequent periods is made for periods of [***] Calendar Quarters each, comparing Royalty Payments due under Section 5.3 with respect to the period to the Minimum Royalty of [***]. The Minimum Royalty obligation under this Section 5.4 shall terminate as of the end of the applicable [***] Calendar Quarter period ending immediately prior to the Calendar Quarter in which: (a) a Competitive Product comes on the market in at least [***] Major Countries and there is a Royalty Payment Reduction in each such country or (b) the Royalty Term expires for a Product in at least [***] Major Countries.

5.5 Royalty Term.

The Royalty Payments due under Section 5.3, will be determined on a country by country basis beginning from the Product First Commercial Sale in a country only until the later of (a) expiration of the last to expire Valid Claim Covering the Product sold in such country, (b) expiration of all regulatory and data exclusivity applicable to the Product in the country of sale, and (c) ten (10) years after the Product First Commercial Sale in such country (with respect to each country in the Territory, the "Royalty Term").

5.6 Competitive Products.

If, in any country or region (e.g., EU) in the Territory, (a) one or more Competitive Products during [***] consecutive Calendar Quarters [***] Competitive Products and Products sold in such country or region or (b) after Regulatory Approval of a Competitive Product in the country or region, [***] for the relevant Product during [***] consecutive Calendar Quarters is more than [***] for the Product in the country or region during the [***] consecutive Calendar Quarters immediately before Regulatory Approval of the Competitive Product in the country or region, then the Royalty Payments with respect to the relevant Product in the country or region shall be reduced by [***] starting with the next Calendar Quarter (a "Royalty Payment Reduction").

5.7 Third Party Payments.

If VF, its Affiliates or permitted Sublicensees are required to pay Third Party Payments (directly to a Third Party) [***], that in the absence of a license thereunder would be infringed by the sale, promotion, manufacturing, use, or import of the Product in the Field in the Territory, VF shall then be entitled to credit [***] of such Third Party Payments against any Royalty Payments due hereunder with respect to the Net Sales of the Product to which the Third Party Payment pertains.

5.8 Late Payments.

Any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest at a rate equal to the [***] day U.S. dollar LIBOR rate effective for the date that payment was first due as reported by The Wall Street Journal plus [***]. Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent.

5.9 Reports and Timing of Payments .

Within [***] calendar days following the end of each Calendar Quarter during an Agreement Year, VF shall provide OPKO with a report of the Net Sales of the Product in each country in the Territory and all calculations used to determine such Net Sales amounts in such detail as OPKO shall reasonably require. Each such quarterly report will include the actual Net Sales of the Product in each country in the Territory and all calculations used to determine such Net Sales for the first [***] months of the applicable Calendar Quarter and a non-binding estimate for the third month of the applicable Calendar Quarter. Within [***] calendar days following the end of each Calendar Quarter, VF shall provide OPKO with a report of the actual Net Sales of the Product in each country in the

Territory and all calculations used to determine such Net Sales for all [***] months during the Calendar Quarter. Not later than [***] calendar days following the end of each Calendar Quarter, VF shall pay to OPKO the Royalty Payment to which OPKO is entitled under Section 5.3. In the event that a Party disputes an invoice or other payment obligation under this Agreement, such Party shall timely pay the undisputed amount of the invoice or other payment obligation, and the Parties shall resolve such dispute in accordance with Article 21.2.

5.10 Taxes.

(a) All payments payable hereunder shall be paid without any reduction, offset, or withholding for taxes. VF shall, in addition to amounts payable pursuant to this Agreement, pay all other taxes levied on amounts payable hereunder; provided that OPKO shall be responsible for any income taxes payable by OPKO on payments made to it under this Agreement. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, taxes payable with respect to this Agreement and that they shall use their Commercially Reasonable Efforts to cooperate and coordinate with each other to achieve such objective as allowed under Applicable Laws. Each Party shall cooperate with the other to the extent reasonably requested for the purpose of filing any tax returns relating sales, use, transfer, stamp, VAT, withholding, or similar taxes, if any, levied on amounts payable hereunder.

(b) For purposes of clarity, all sums payable under this Agreement shall be exclusive of VAT. In the event that any VAT is owing in any jurisdiction in respect of any such payment, VF shall pay such VAT and the payment in respect of which such VAT is owing shall be made by VF without deduction for or on account of such VAT to ensure that OPKO receives a sum equal to the sum which it would have received had such VAT not been due.

5.11 Currency Exchange.

If any Product sold by VF under this Agreement is invoiced in a currency other than U.S. Dollars, all royalty payments by VF to OPKO shall be converted into U.S. Dollars at the average rate of exchange for the Calendar Quarter for which payments are being remitted based on the middle market spot rate therefore published in The Wall Street Journal (U.S. Edition).

6. Development

6.1 Development Responsibilities.

(a) As set forth in the Development Plan, OPKO and VF each agree to cooperate in the development of the Product for the Field in the Territory.

(b) VF shall be responsible for performing, or causing to be performed, all development activities for the Product in the Field in the Territory allocated to VF in the Development Plan in order to obtain Regulatory Approvals for the Product in the Field in the Territory. As set forth in the Development Plan, VF agrees to use Commercially Reasonable Efforts to (i) develop and bring the Product to market in the Field in each Major Country for the Initial Indication and

each Additional Indication included in the Development Plan, and (ii) execute and perform in all material respects the obligations assumed by it under the Development Plan.

(c) OPKO shall be responsible for performing, or causing to be performed, all development activities for the Product in the Field outside the Territory allocated to OPKO in the Development Plan in order to obtain Regulatory Approvals for the Product in the Field in the Territory. As set forth in the Development Plan, OPKO agrees to use Commercially Reasonable Efforts to (i) develop and bring the Product to market in the Field in the U.S. for the Initial Indication and each Additional Indication included in the Development Plan, and (ii) execute and perform in all material respects the obligations assumed by it under the Development Plan.

6.2 Funding of Product Development .

Each Party shall be responsible for [***] of the costs of conducting the HD Trial and those additional studies and trials designated in the Development Plan as being co-funded. VF shall be solely responsible for all other development costs which VF considers necessary in its sole discretion relating to the Product for the Initial Indication in the Territory except as otherwise provided by Section 6.4.

6.3 Publications.

Subject to Applicable Law, the JSC shall develop a strategy for reviewing, coordinating and releasing publications, including results of studies conducted for the Product, presenting Product-related information and materials at conferences, congresses, or scientific or medical meetings held both inside and outside the Territory. The JSC may not prohibit any publication or presentation contemplated by this Section 6.3 without consensus. If the JSC does not reach consensus regarding a proposed prohibition on publication, the matter will be resolved as provided under Section 21.3.

6.4 Access to Data and Information .

Subject to the provisions of this Agreement, each Party shall have the right to access and use all information generated in all clinical and marketing studies with respect to the Product in the Field for sale in the Territory (VF) or outside the Field or the Territory (OPKO); provided, however, if either Party wishes to access and use new data generated by the other Party, its Affiliates, or its licensees/sublicensees that is not in the public domain, [***]. Notwithstanding the foregoing, each Party acknowledges and agrees that it will share all safety data, information and results required to ensure compliance by each Party with Applicable Law and safety standards at no cost to the other Party and that OPKO will make available to VF any additional information and content developed or acquired by OPKO that is required for the registration process in the Territory.

6.5 Development Plan.

(a) The development of the Product shall be governed by a plan setting forth the proposed overall program of development of the Product and the respective development responsibilities of the Parties with respect to such program (the "Development Plan"), as it may be amended from time to time in accordance with this Agreement. The initial Development Plan is

attached hereto as Exhibit A and shall cover the development plan for the Product for the Initial Indication. To the extent any terms or conditions of the Development Plan expressly conflict with the terms or conditions of this Agreement, the terms and provisions of this Agreement shall control.

(b) During the Term, any changes to the Development Plan, including any country-specific appendices required by Applicable Law and changes made in response to any communications with any Regulatory Authorities that require a submission to a Regulatory Authority, an IRB or other ethics committee, will be prepared by VF and will be subject to the approval of the Committees.

(c) During the Term, either Party can propose that additional development activities that are outside the scope of the Development Plan, including any new trials for Additional Indications, be conducted under the Development Plan. If both Parties agree in writing upon such additional development activities, then the Development Plan shall be amended in writing by the Parties to reflect such agreement of the Parties.

7. Government Approvals

7.1 New Drug Approval Applications.

VF shall be responsible for preparing, filing, and prosecuting Drug Approval Applications and seeking Regulatory Approvals for the Product in the Field in the Major Countries and such additional countries in the Territory in which VF considers it commercially reasonable to do so, including preparing all reports necessary as part of a Drug Approval Application, provided that OPKO shall make available to VF all the content in OPKO's possession that VF indicates to OPKO is required for the registration process for the Product in the Field in the Territory and OPKO will make its personnel with relevant subject matter expertise available to consult with VF regarding such registration process. All such Drug Approval Applications shall be owned by VF and a copy of each such Drug Approval Application shall be promptly provided to OPKO upon OPKO's request. OPKO shall promptly provide VF a copy of each Drug Approval Application filed outside the Territory, which is requested by VF. All regulatory costs incurred by VF in connection with the preparation, filing, and maintenance of Regulatory Approvals for the Product in the Field in the Territory shall be borne solely by VF, [***]. In connection with all Drug Approval Applications being prosecuted and filed by VF, OPKO or their Affiliates or licensees/Sublicensees for the Product in the Field, VF or OPKO, as the case may be, agrees to [***] that it or its Affiliates or licensees/Sublicensees make that are requested by the other Party, or that are clearly relevant to the other Party's Regulatory Approvals in the other Party's respective territory promptly upon submission, but in no event later than [***] days after a written request by the other Party, in each case at [***] to the other Party, provided, that in the event any filing is not in English and the filing Party does not have any English translation thereof, any translation requested by the other Party will be at [***].

7.2 Reference to Regulatory Filings.

For any country of the Territory that accepts, as the basis of such country's Drug Approval Application for the Product, the corresponding Regulatory Approval for such Product from a

jurisdiction outside the Territory, OPKO shall provide VF with the right to reference such Regulatory Approval. Each Party shall have the right of cross-reference to the other Party's regulatory filings.

7.3 Cooperation.

The Parties shall consult and cooperate in the preparation of each submission for Regulatory Approvals for the Product in the Field in the Territory and in obtaining and maintaining Regulatory Approvals within the Territory, provided however, that, VF shall be primarily responsible for interactions with Regulatory Authorities throughout the Territory. VF shall provide OPKO with reasonable advance notice of any scheduled meeting with the EMA or any other Regulatory Authority in a regulatory jurisdiction in the Territory relating to any Regulatory Approval for the Product, and OPKO (to the extent permitted by the Regulatory Authority) shall have the right to participate in any such meeting. VF shall from time to time promptly inform OPKO about any significant Regulatory Approval milestones achieved. In the event that any regulatory agency threatens or initiates any action to remove the Product from the market or there is any recall or equivalent action (whether voluntary or involuntary) in any country of the Territory, VF shall promptly notify OPKO of such communication of receipt of such information by VF.

7.4 No Third Party Rights .

During the Term and except as provided in Sections 2.2 and 18.1, VF shall not assign, license or grant any rights in or to any rights or obligations under this Agreement (including, without limitation, terms relating to confidentiality, intellectual property, non-competition) or to the Drug Approval Applications that are held by VF pursuant to this Agreement to any Third Party that is not an Affiliate or Sublicensee of VF, or Fresenius or an Affiliate of Fresenius identified on Exhibit 2.2(b), without the prior written consent of OPKO, which will not be unreasonably withheld. Any such assignment, license or grant of rights to an Affiliate or Sublicensee of VF, or Fresenius or an Affiliate of Fresenius identified on Exhibit 2.2(b) shall be made only pursuant to a written agreement that is entered into in compliance with all of the material terms of this Agreement and that specifically requires such Person's compliance with all material rights and obligations under this Agreement (including, without limitation, terms relating to confidentiality, intellectual property, non-competition).

7.5 Clinical Trial Registries.

(a) From and after the Effective Date, VF will be responsible, in consultation with the JDC, for registering, maintaining and updating any registries pertaining to any trial for the Product conducted pursuant to this Agreement to the extent required by any Applicable Laws (collectively, the "Clinical Trial Registries") in all countries in the Territory.

(b) For clarity, VF will ensure that the information on all Clinical Trial Registries is correct, consistent and in compliance with Applicable Law.

8. Commercialization

8.1 VF Efforts.

Subject to the terms and conditions of this Agreement, VF agrees to use Commercially Reasonable Efforts to (a) commence the regular commercial distribution, use, and sale of the Product in the Field in each Major Country as soon as commercially practicable, and (b) subject to OPKO's compliance with the terms of the Supply Agreement, continue diligently thereafter to commercialize, market, promote and sell the Product in the Field in the Territory for each indication for with the Product has received Regulatory Approval in the Territory.

8.2 Promotional Activities.

(a) Within [***] days after the Effective Date, OPKO shall deliver to VF, at no charge, a copy of the then existing Marketing Material developed or used by OPKO in connection with promotion or marketing the Product outside the Territory. OPKO makes no representation as to the appropriateness or applicability of the Marketing Material in the Territory. VF shall, subject to Applicable Laws, have the right to use all such Marketing Material in connection with its marketing of the Product in the Territory. VF also shall have the right to create, develop and use other Marketing Material in the Territory at its sole cost and expense. VF shall ensure that any Marketing Material developed or used by VF complies with all Applicable Laws in the Territory. OPKO shall not have any liability with respect to use by or on behalf of VF thereof.

(b) Upon request of OPKO, VF shall provide to OPKO a copy of any Marketing Material developed by VF. Subject to the terms and conditions of this Agreement, OPKO (and any of its Affiliates and licensees) shall have the right to use outside the Territory and modify such Marketing Material created and developed by VF for the Territory [***], provided however that OPKO shall be solely responsible for ensuring that such Marketing Material complies with any Applicable Laws outside the Territory, and VF shall not have any liability with respect to use by or on behalf of OPKO thereof.

(c) VF shall use Commercially Reasonable Efforts to commercialize the Product in the Field in the Territory under an OPKO Trademark and under the trade dress or such other trademark or trade dress as mutually agreed by the Parties, including, if applicable, any alternative trademark and any alternative trade dress (the "Product Trade Dress", respectively). Notwithstanding the foregoing, in the event that VF believes that the use or registration of any OPKO Trademark or the use of the Product Trade Dress in a particular country in the Territory would be inappropriate due to such country's linguistic or cultural particularities or against the Applicable Laws of such country, or is rejected by local Regulatory Authorities, or in conflict with any Third Party's intellectual property rights in that country, based on a review of market research, regulatory research, legal searches, investigation results, and any other relevant information that may have been collected by either Party that is relevant to the clearance for use and registration of a trademark or for use and registration of a trade dress (it being understood that there is no obligation for either Party to perform any such review or research), VF shall present such concern to OPKO, and the Parties shall agree on an alternative trademark and trade dress for use and registration, as

appropriate, in the country in question, which shall be owned by OPKO and shall become an OPKO Trademark under this Agreement.

(d) Global Branding Strategy. Subject to Section 9.2(b)(vi), OPKO shall have the right, from time to time during the Term, to implement (and thereafter modify and update) a global branding strategy, including global messaging, for the Product for use in the Field throughout the world (the "Global Branding Strategy"). The Parties intend to collaborate in developing and updating the Global Branding Strategy. To the extent OPKO determines to utilize such Global Branding Strategy, VF shall adhere to the Global Branding Strategy in its commercialization of the Product, including with respect to any newly designed promotional materials; provided, that, in the event that VF believes that the application of the Global Branding Strategy in a particular country or a region in the Territory would be inappropriate whether because of such country's linguistic or cultural particularities, competitive environment, clinical practices, because it is against the Applicable Laws of such country or because VF reasonably determines it would be inconsistent with VF's obligation to use Commercially Reasonable Efforts to commercialize the Territory, VF shall present such concern to OPKO, and the Parties shall discuss whether appropriate revisions to the Global Branding Strategy may make it appropriate for use in such country. If the the Parties do not reach consensus on the application of the Global Branding Strategy, [***]; provided, however, that the matter may be referred by either Party for resolution as provided under Section 21.3 and both Parties shall abide by such resolution.

Nothing in this Section shall be construed to derogate from VF's ultimate right and responsibility to use all Commercially Reasonable Efforts to commercialize the Product in the Territory in accordance with the terms and conditions of this Agreement.

8.3 Identification of OPKO.

To the extent allowed by Applicable Law and consistent with OPKO's internal trademark guidelines adopted from time to time and provided to VF, all Product labeling, packaging and package inserts and any promotional materials associated with the Products shall carry, in a conspicuous location, the Product Trade Dress with a notice that such Product is sold under license from OPKO. Such Product Trade Dress, where so included, shall be in addition to the Product Trade Dress and trademarks of VF.

8.4 Product Pricing.

As soon as appropriate prior to the Product First Commercial Sale in the Territory, as permitted by Applicable Law, including applicable antitrust laws, [***] shall establish pricing levels for the Product in the Territory with input from the JDC; provided that [***] shall bear final authority and responsibility for determining pricing for the Product.

9. Governance

9.1 Joint Development Committee and Joint Steering Committee .

(a) Within [***] days following the date of this Agreement, the Parties shall form: (a) a joint steering committee (the "JSC") with responsibility for the overall coordination and oversight of activities under this Agreement and the Supply Agreement and (b) a specialized joint committee focusing on development and Regulatory Approval of Products (the "JDC"). The JSC and JDC shall have the responsibilities and authority allocated to it in this Article 9 and elsewhere in this Agreement. The JSC and JDC may be referred to separately as a "Committee" and jointly as the "Committees".

(b) The Committees shall have representatives from each of OPKO and VF. Each Party may replace its Committee representatives at any time upon written notice to the other Party. Each Committee shall have a chairperson. The chairperson of the JDC and JSC shall be designated by VF for the first Agreement Year, shall be designated by OPKO for the second Agreement Year, and shall alternate between the Parties on an annual basis thereafter. The chairperson shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting of such Committee, and preparing and issuing minutes of each meeting within [***] days thereafter. The minutes of each meeting shall, among other things, record all matters acted upon and approved or disapproved by the Committee, actions to be taken, and any matters the Committee failed to resolve. Such minutes will not be finalized until both Alliance Managers review and confirm in writing the accuracy of such minutes.

(c) Each Party's designees on a Committee shall, collectively, have [***] vote (the " Party Vote") on all matters brought before the Committee, which Party Vote shall be determined by consensus of such Party's designees present (in person or otherwise) at the meeting. Except as expressly provided in this Section 9.1(c), each Committee shall operate as to matters within its jurisdiction by [***] Party Vote. Any disagreement between the representatives of the Parties on the JDC as to matters within the JDC's jurisdiction shall be submitted for discussion and resolution by the JSC. Except as otherwise required by this Agreement, any disagreement between the representatives of the Parties on the JSC as to matters within the JSC's jurisdiction shall be submitted for discussion and resolution in accordance with Article 21 and any disagreement with respect to matters set forth in Sections [***] shall be resolved as provided under Section 21.3. Notwithstanding the foregoing, any decisions to amend the [***] (for clarity, if the JSC does not reach consensus, the matter will be resolved as provided under Section 21.3).

(d) Each Party will disclose to the other proposed agenda items along with appropriate information at least [***] Business Days in advance of each meeting of each Committee, as applicable; provided that, under exigent circumstances requiring the Committee's input, a Party may provide its agenda items to the other Party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, and such items shall be included in such agenda if such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such Committee meeting.

(e) Notwithstanding the Committee structure established under Section 9.1(a), each Party shall retain the rights, powers and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly

so agree in writing. Without limiting the generality of the foregoing, no Committee shall have any authority or jurisdiction to amend, modify, or waive compliance with this Agreement, any of which shall require mutual written agreement of the Parties.

9.2 Joint Steering Committee.

(a) Each Party shall appoint an equal number of up to [***] of its senior employees to serve on the JSC. The initial JSC representatives for VF shall be [***] and [***], and the initial JSC representatives for OPKO shall be [***] and [***]. The JSC shall: (i) oversee and coordinate the development of, and the making of regulatory filings for, the Products in the Territory in the Field to obtain Regulatory Approvals of Products in the Territory in the Field; (ii) oversee the supply of Products for the Territory in the Field; and (iii) review material activities to be conducted in connection with commercialization of the Products in the Field in the Territory (and outside the Territory to the extent such activities could reasonably be relevant to the commercialization of the Products in the Field in the Territory).

(b) In connection with its responsibilities described in Section 9.2(a), the JSC shall in particular:

(i) provide general oversight for the activities of the JDC;

(ii) subject to Article 8, provide a forum for the Parties to share information, knowledge and planning on the on-going development and commercialization of the Products in and outside the Territory;

(iii) review the Development Plan updates or amendments, including Additional Indications as contemplated by Section 4.1;

(iv) monitor the development of and process for seeking and obtaining Regulatory Approval with respect to the Products in the Territory in the Field based on the updates provided by the JDC;

(v) support VF's development of a strategy for commercialization of the Products for use in the Field in the Territory and exchange information on best practices for commercialization activities for use in the Field;

(vi) discuss reasonable measures to align on a Global Branding Strategy and master documents (for example, training materials) and coordinate activities with respect to certain key opinion leaders;

(vii) monitor and discuss OPKO's supply of Product for the Territory under the Supply Agreement;

(viii) discuss a reimbursement strategy for the Product in the Territory;

(ix) perform such other activities as are expressly allocated to the JSC in this Agreement; and

(x) provide a forum for discussing and attempting to resolve any issues involving the interpretation or application of this Agreement.

(c) Notwithstanding the foregoing: (i) activities pertaining to: (A) negotiation with pricing and reimbursement authorities and payors of pricing and reimbursement in a given jurisdiction for Products; and (B) commercialization of the Product, will be the sole responsibility of VF in the Territory and the Field and of OPKO outside the Territory and outside the Field in the Territory; and (ii) subject to Article 10, activities pertaining to manufacturing shall be the sole responsibility of OPKO within and outside the Territory. The activities listed in Section 9.2(c)(i) and (ii) above shall not come under the governance authority of the JSC, but information with respect thereto may be discussed by the JSC to the extent relevant to the items set forth in Sections 9.2(a) and 9.2(b).

9.3 Committee Meetings.

(a) Committees shall meet at least quarterly unless no later than thirty (30) days in advance of any meeting there is a determination, by agreement of both Parties, that no new business or other activity has transpired since the previous meeting, and that there is no need for a meeting. In such instance, the next meeting will be scheduled. Committees shall also establish a procedure, agreeable to both Parties, for either (i) calling special interim meetings of a Committee in the event of the need a Committee decision between regularly scheduled meetings or (ii) establishing a process for making such interim decisions. Committees establish subcommittees, provided that such subcomittees are comprised of equal representation from both Parties.

(b) The location of such meetings shall alternate between OPKO's offices area and VF's offices unless otherwise agreed upon between the Parties. Committee meetings may, upon the agreement of both Parties, be via teleconference and/or videoconference.

(c) Each Party shall bear their own expenses in connection with attending meetings of the Committees.

9.4 Responsibilities of JDC.

(a) [***] of up to [***] of its senior employees to serve on the JDC. The initial JDC representatives for VF shall be [***] and [***], and the initial JDC representatives for OPKO shall be [***] and [***]. The JDC shall coordinate communication and operations regarding the development of, and the making of regulatory filings for, the Products in the Territory in the Field in order to obtain Regulatory Approvals of Products in the Territory in the Field. The JDC will also facilitate the flow of information with respect to development activities being conducted for the Product that in or outside the Field that are relevant to the Territory and to facilitate exchange of data arising in Clinical Trials of Products relevant to the Territory, whether conducted in or outside the Territory and in the Field.

(b) The JDC shall have planning, oversight, performance evaluation and decision-making authority and responsibility for all development, regulatory, and registration activities (as well as oversight over commercialization plans) related to the Product in the Field in the Territory, except as otherwise set forth in this Agreement and except that the JDC shall have no direct authority over the employees of either Party.

(c) In connection with its responsibilities described in Section 9.4(a), the JDC shall in particular:

(i) [***] between the parties;

(ii) provide a forum for the Parties to share information, knowledge and planning on the on-going development, regulatory strategy and Regulatory Approval activities for the Products relevant to the Field in and outside the Territory;

(iii) review and discuss the Development Plan updates or amendments;

(iv) review and exchange pharmacovigilance information and reports for Products in and outside the Field and in accordance with the pharmacovigilance agreement;

(v) monitor development activities for Products in the Field in the Territory, including with respect to operational matters such as enrollment strategies, site selection, and clinical trial vendor strategies;

(vi) review and facilitate the exchange of all information (other than any information relating to the process development or manufacturing of Product) relating to or arising from all development, regulatory strategy and Regulatory Approval activities described in subsections (iv) - (vi) above for Products in the Field in and outside the Territory;

(vii) discuss and review a regulatory strategy and plan for obtaining Regulatory Approvals for the Products in the Field in the Territory;

(viii) with input from OPKO with respect to its strategy for clinical trials, support development and implementation of a strategy for clinical trials with respect to Products in the Field in the Territory;

(ix) discuss and coordinate post-approval changes to regulatory filings and documentation, including any changes to the registered detail for Products in the Field in and outside the Territory;

(x) provide on a quarterly basis updates on its activities and achievements to the JSC for review and comment;

(xi) perform such other activities as are expressly allocated to the JDC in this Agreement; and

(xii) review and discuss any Third Party to be retained by either Party to perform material activities (e.g., regulatory, manufacturing, clinical or quality activities) with respect to Products in the Territory.

9.5 Alliance Managers.

(a) Each of the Parties shall appoint a single individual to act as that Party's point of contact for day to day communications between the Parties relating to the activities conducted

under this Agreement (each, an "Alliance Manager"). Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party.

(b) Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JSC and JDC. Each Alliance Manager will also: (i) be the point of first referral in all matters of conflict resolution; (ii) coordinate the relevant functional representatives of the Parties in developing and executing strategies and the Development Plan for the Products in the Field in and outside the Territory and any other Development activities with respect to the Field by the Parties; (iii) provide a single point of communication for seeking consensus both internally within the respective Parties' organizations and between the Parties regarding key strategy and Development Plan issues; (iv) identify and bring disputes to the attention of the JSC and JDC in a timely manner; (v) plan and coordinate cooperative efforts and internal and external communications; and (vi) coordinate governance activities, such as the conduct of JSC and JDC meetings and production of meeting minutes so that they occur as set forth in this Agreement, and take actions necessary to facilitate performance of relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

(c) The Alliance Managers shall attend all Committee meetings and support the chairperson of the JSC and JDC in the discharge of their responsibilities. The Alliance Managers shall be nonvoting participants in Committee meetings, unless they are also appointed members of a Committee; provided, however, that an Alliance Manager may bring any matter to the attention of any Committee if such Alliance Manager reasonably believes that such matter warrants such attention.

10. Manufacturing, Distribution and Supply

10.1 OPKO Manufacturing and Supply Responsibilities.

Subject to Section 10.2, OPKO will supply, directly or through a Third Party, bulk capsules of Product ("Bulk Product") to support the development, sale and commercialization of the Product in the Territory, unless and until VF, VF's Affiliates, or any of its Third Party contract manufacturers is qualified as an additional qualified manufacturer for the Territory. The binding terms and conditions for the commercial manufacture and supply of Bulk Product shall be set forth in a Manufacturing and Supply Agreement to be entered into as set forth in Section 10.2 (the "Supply Agreement").

10.2 Manufacturing and Supply Agreement for Commercial Supply of Products.

The Parties shall agree in good faith to execute a mutually satisfactory Supply Agreement containing the terms set forth on Exhibit 10.2 for OPKO's supply of Bulk Product. The Supply Agreement shall provide that the Parties will discuss and cooperate to [***] of Bulk Product for supply thereof for the Territory within a specified time period following the effective date of the Supply Agreement (which may include OPKO, itself or through a Third Party contractor, or VF or its Affiliates). The Parties shall also enter into a Quality Agreement within [***] days after the Effective Date. The

Supply Agreement shall contain terms and conditions set forth in Exhibit 10.2 and other terms and conditions typically contained in agreements governing the commercial manufacture of similar products for similar purposes at similar volumes.

10.3 Clarification.

For clarity, during the Term, VF may exercise its rights to make and have made Products under the license granted to VF pursuant to Section 2.1 only to the extent that OPKO fails to fulfill its obligations under the Supply Agreement.

11. Safety and Surveillance

11.1 Reporting.

VF shall be responsible for any reporting of matters regarding the safety of the Product, including Adverse Events, to the appropriate Regulatory Authority in the Territory, in accordance with Applicable Laws. VF shall promptly notify OPKO of any such matter and furnish complete copies of such reports to OPKO. In the event VF or OPKO should become aware of information that may require a recall, field alert, Product withdrawal or field correction arising from any defect in the Product, it shall immediately notify the other Party in writing.

11.2 Adverse Events.

Promptly after the Effective Date, in recognition of VF's primary responsibility for reporting Adverse Events associated with the Product in the Territory, the Parties shall agree upon the terms of a pharmacovigilance agreement. The Parties shall implement such agreement and shall provide each other on a regular basis with any appropriate information that enables the other Party to meet its regulatory obligations with respect to the Product or that is relevant to the safe use of the Product, whether inside or outside the Territory. The agreement will be reviewed jointly on a regular basis or when there is a change in regulations governing Adverse Event reporting, whether inside or outside the Territory. OPKO shall maintain the global safety database as set forth in the pharmacovigilance agreement.

11.3 Medical Inquiries.

Following the Effective Date, VF shall be responsible for handling all medical questions or inquiries in each such country in the Territory, including all Product complaints, with regard to any Product sold by or on behalf of VF (or any of its Affiliates or Sublicensees) (including having a call center in connection therewith), in each case in accordance with Applicable Laws and this Agreement. VF shall submit a copy of any standardized responses to medical inquiries prior to use thereof for OPKO's review and comment. OPKO shall immediately forward any and all medical questions or inquiries which it receives with respect to any Product sold by or on behalf of VF (or any of its Affiliates or Sublicensees) in the Territory to VF in accordance with all Applicable Laws and VF shall immediately forward to OPKO any and all medical questions or inquiries that it receives with respect to Product outside of the Territory or outside the Field, in each case in accordance with all Applicable Laws. Notwithstanding the foregoing, OPKO shall be primarily responsible for handling

any Product complaints related to quality of the Product, and VF shall refer all such Product complaints to OPKO.

11.4 Recall, Withdrawal, or Market Notification of Product .

In the event that any Governmental Authority threatens or initiates any action to remove the Product from the market whether inside the Territory or outside the Territory (in whole or in part), the Party receiving notice thereof shall notify the other Party of such communication immediately, but in no event later than one (1) Business Day, after receipt thereof. Notwithstanding the foregoing, in all cases, any recall, withdrawal or market notification of the in the Territory shall be as set forth in the Quality Agreement.

12. Audit Rights

12.1 Audit Rights.

VF shall keep complete and accurate records which are relevant to revenues, costs, expenses, and payments on a country by country basis in the Territory under this Agreement and such records shall be maintained by VF for at least two years following their creation. OPKO shall have the right, at OPKO's expense, through an independent certified public accounting firm that is internationally recognized as one of the four largest accounting firms in the world, or like Person reasonably acceptable to VF to examine such records during regular business hours upon reasonable notice during the life of this Agreement and for two years after its termination; provided, however, that such examination shall not take place more often than [***] per Agreement Year and shall not cover such records for more than the preceding [***]. OPKO shall bear the full cost of the audit unless such audit correctly discloses that the discrepancy differs by more [***] from the amount the accountant determines is correct, in such case VF shall pay the reasonable fees and expenses charged by the accountant.

13. Intellectual Property

13.1 Ownership of Intellectual Property.

(a) OPKO shall have and retain sole and exclusive right, title and interest in and to any and all OPKO Technology and all intangible property rights, including, without limitation, any and all inventions, discoveries, writings, trade secrets, methods, practices, procedures, engineering information, designs, devices, improvements, manufacturing information and other technology, including any derivatives of any of the foregoing, whether or not patentable or copyrightable, and any patent applications, patents, or copyrights based therein, thereon and therefrom ("Inventions") that are made, discovered, conceived, reduced to practice or generated by OPKO (or its employees or representatives), solely or with a Third Party, in connection with any activity carried out pursuant to this Agreement and that is related to the Product ("OPKO Inventions") and all rights, titles and interests with respect to the OPKO Trademarks and Patents.

(b) The Parties shall jointly own the right, title and interest in and to all Inventions made, discovered, conceived, reduced to practice or generated jointly by the Parties, their Affiliates

or Sublicensees (or their respective employees or representatives), with or without a Third Party (" Joint Inventions").

(c) VF shall own the right, title and interest in and to all Inventions made, discovered, conceived, reduced to practice or generated solely by VF, or its Affiliates or Sublicensees (or their respective employees or representatives), with or without a Third Party ("VF Inventions").

(d) The determination of inventorship for Inventions under this Section 13.1 shall be in accordance with U.S. inventorship laws as if such Inventions were conceived or reduced to practice in the US.

13.2 Product Inventions.

(a) Notwithstanding the terms of Section 13.1, any Joint Inventions or VF Inventions in connection with the Product directly relating to (i) [***], (ii) [***], (iii) [***], (iv) [***] (collectively, [***], the "Product Inventions"), each shall be the exclusive property of OPKO and the corresponding intellectual property rights shall be owned by OPKO. For the avoidance of doubt, Product Inventions will be included in the OPKO Technology and any resulting patents or patent applications will be included in the OPKO Patents; provided however, that [***]. VF hereby assigns such Product Inventions to OPKO. The provisions of this Section 13.2 shall not apply to any [***]. Any such Inventions will be considered Joint Inventions under this Agreement. As a result, each Party will be free to commercialize their own products using such Joint Inventions without interference from, accounting to or paying a royalty to the other Party with respect to such Joint Inventions; provided however, that [***] and that nothing in this Section 13.2 shall relieve either Party of its obligations under this Agreement with respect to Products (including VF's royalty obligations hereunder with respect to Products, except as provided in the second sentence of this Section 13.7).

13.3 Patent Prosecution.

(a) OPKO, at its expense, shall have [***] responsibility for [***]. VF, at its expense, shall have sole responsibility for [***]. VF shall pay [***] of the prosecution costs of any Joint Patents filed in the Territory. [***] filed by OPKO or VF in the Territory that relate to the Product. OPKO and VF agree to comply with all requirements of the applicable patent offices to secure the validity and enforceability of the OPKO Patents and any Joint Patents related to Product (e.g., filing working statements) and keep VF and OPKO promptly and fully informed of the course of patent prosecution or other related proceedings and to consider any comments of VF or OPKO in good faith. OPKO shall also have responsibility for filing for any applicable supplementary protection certificates, patent term extensions, pediatric extensions, or their equivalent, if available, in any country or region in the Territory with respect to the OPKO Patents. VF agrees to cooperate with OPKO to secure any such supplementary protection certificates, patent term extensions or their equivalents. If requested by VF, OPKO shall record this Agreement or other evidence of the Patent rights granted under this Agreement in the designated patent offices.

(b) If OPKO wishes to abandon any OPKO Patent in the Territory or Joint Patent in the Territory, then, prior to abandonment, OPKO shall offer to assign its rights in such OPKO

Patent or Joint Patent to VF at least forty-five (45) days in advance of any statutory bar or other deadline that would result in loss of such OPKO Patent or Joint Patent. If VF elects to have such OPKO Patent or Joint Patent assigned to it, OPKO shall assign such OPKO Patent or Joint Patent to VF, and VF will be responsible for any direct, out-of- pocket costs of OPKO relating to the assignment of such OPKO Patent or Joint Patent to VF. VF will be responsible for any costs relating to the maintenance of such OPKO Patent or Joint Patent that VF chooses to pursue after the assignment. If a OPKO Patent has been assigned to VF, it shall no longer be considered a OPKO Patent under this Agreement for the purpose of the Royalty Term or otherwise. OPKO has a non-exclusive, sub-licensable (through multiple tiers), royalty-free license outside the Territory under all OPKO Patents or Joint Patents assigned to VF pursuant to this Section 13.13 even after termination or expiration of this Agreement for any reason.

(c) With regard to any Patent rights which fall under the new European Unified Patent System, OPKO shall elect the opt-out option unless the Parties agree otherwise.

13.4 Notification of Patent Litigation .

(a) In the event of the institution of any suit by a Third Party against either OPKO or VF or otherwise, in respect of patent infringement involving the manufacture, use, sale, license or marketing of the Product anywhere in the Territory, such Party sued or to whom notice or knowledge of such proceeding shall arise, shall promptly notify the other Party in writing.

(b) If an action, claim, demand, suit, or proceeding (a " Claim") alleging infringement involving the manufacture, use, sale, license or marketing of the Product anywhere in the Territory is commenced against either Party or their Affiliates, licensees or Sublicensees, then the Parties [***]. [***] Business Days, and [***] to continue such defense at its own expense, except for the expenses for which [***] is to indemnify [***] pursuant this Agreement or pursuant to OPKO's indemnification obligations set forth in the Supply Agreement related to manufacturing. In that case, OPKO shall cooperate with VF and provide any documentation or other assistance reasonably requested by VF at OPKO's expense.

13.5 Patent Infringement.

(a) In the event that OPKO or VF becomes aware of actual or threatened infringement of a Patent anywhere in the Territory, that Party shall promptly notify the other Party in writing. OPKO shall have the first right, to investigate and/or bring an infringement action against any Third Party. In that case, OPKO shall have full control over the conduct of such investigations and litigation, including the settlement thereof, provided that such settlement does not materially adversely affect VF's rights under this Agreement. The cost of such investigation and litigation shall be borne by [***]. The Parties [***]. VF shall reasonably assist OPKO and cooperate in any such investigation and litigation at OPKO's request, including being joined as a party in such action upon OPKO's written request.

(b) OPKO shall provide information about its preliminary intention within [***] days after it first learns of any actual or alleged infringement. If OPKO fails to notify the allegedly infringing party with respect to the OPKO Patents and its infringement allegation within [***] days

after receiving such information and, thereafter, fails to initiate an enforcement action with respect to such actual infringement within [***] days [***] after [***] of the OPKO Patents by such Third Party(ies) and the [***] this [***] day period,VF shall have the right to enforce the OPKO Patents against such infringers to the extent such infringement relates to the manufacture, use, or sale of products Covered by the OPKO Patents in the Field in the Territory.

(c) In the event that entry of a product to a market segment in which the Product is sold in the Territory appears imminent and [***] in the Territory, OPKO shall take all reasonable actions to determine, within [***] calendar days from the date on which OPKO has legally sufficient basis to believe that such product entry would infringe the OPKO Patents or any longer time period agreed by the Parties, whether OPKO intends to apply promptly and diligently for an interim injunction with regard to such possible product entry and shall promptly inform VF of such determination. If OPKO does not take such action, VF may take such action.

(d) In any case, the Parties shall reasonably assist each other and cooperate in any such investigation and litigation to ensure there is an aligned global litigation and enforcement strategy.

13.6 Title to Trademarks.

The ownership and all goodwill from the use of any trademarks associated with the Product shall vest in and inure to the benefit of OPKO.

13.7 Trademark License.

OPKO grants to VF a fully paid, exclusive license to use the OPKO Trademarks and Product Trade Dress in the Territory for the Term in connection with the marketing and promotion of the Product in the Field as contemplated in this Agreement, without limiting in any way OPKO's rights with respect to the OPKO Trademarks and Product Trade Dress outside the Territory ; provided, however, that after expiration of this Agreement VF's license may be exclusive and royalty-bearing pursuant to Section 3.2. OPKO shall use its Commercially Reasonable Efforts to obtain and secure the corresponding domain names in the Territory that the Parties determine to be appropriate and make such domain names available to VF under the conditions of this Section 13.7.

13.8 Maintenance of Trademarks.

(a) OPKO agrees to use Commercially Reasonable Efforts to register and maintain a registration for the OPKO Trademarks in the Territory for the term of this Agreement for use with the Product (including corresponding domain names). Such expenses incurred in connection with the OPKO Trademarks or domain names shall be paid [***]. In the event that any of the OPKO Trademarks are not available for use and registration in connection with the Product in the Territory due to a rejection of the trademark by a government agency, actual or threatened opposition, cancellation or litigation as to use and/or registration of the OPKO Trademarks by a Third Party, and/or a decision by the JDC that use of the OPKO Trademarks is likely to cause confusion with another's trademark, OPKO shall use Commercially Reasonable Efforts to provide

an alternate trademark and shall develop, search, file, register and maintain such alternate trademark [***].

(b) OPKO shall maintain and monitor the OPKO Trademarks (including the corresponding domain names) and take all reasonable actions to protect the OPKO Trademarks (and the corresponding domain names) from similar Third Party trademarks filed in the Territory.

(c) OPKO shall maintain and defend all the OPKO Trademarks (and corresponding domain names) as necessary to allow VF and to fully exercise its rights under Section 3.2.

13.9 Notification of Trademark Litigation .

In the event of the institution of any suit by a Third Party against OPKO or VF for trademark infringement involving the marketing, promotion or sale of the Product in accordance with the annual marketing plan in the Territory, the Party sued shall promptly notify the other Party in writing. OPKO shall defend such action at [***], and indemnify and hold harmless VF and its Affiliates and their respective directors, officers and employees from any damages, judgment, costs and expenses (including, reasonable attorneys' fees) arising or resulting therefrom. VF shall assist and cooperate with OPKO, [***], to the extent necessary in the defense of such suit. In the event and, as a result of the suit, it becomes necessary to secure or file for a new trademark for the Product, OPKO shall be responsible for searching for and filing for such a mark pursuant to Section 13.8.

13.10 Trademark Infringement.

(a) In the event that OPKO or VF becomes aware of actual or threatened infringement of a OPKO Trademark anywhere in the Territory, that Party shall promptly notify the other Party in writing. OPKO shall have the sole right, but not the obligation, to investigate and/or bring an infringement and/or opposition or cancellation action against any Third Party. OPKO shall have full control over the conduct of such investigations and litigation, including the settlement thereof. The cost of such investigation and litigation [***]. The Parties shall [***]. VF shall reasonably assist OPKO and cooperate in any such investigation and litigation at OPKO's request, including being joined as a party in such action upon OPKO's written request.

(b) OPKO shall provide information about its preliminary intention with respect to any actual or threatened OPKO Trademark within [***] days after it first learns of such actual or alleged infringement. VF shall have the right to enforce such Trademark if OPKO does not initiate an enforcement action within sixty (60) days after it first learns of such infringement. The cost of such litigation brought by VF shall be borne [***].

13.11 Information and Settlements.

OPKO shall keep VF informed of the status of any patent or trademark infringement litigation or settlement thereof concerning the Product or the OPKO Trademarks or Patent in the Territory, provided however that no settlement or consent judgment or other voluntary final disposition of any suit defended or action brought pursuant to this Article 13 shall be entered into without the

consent of VF if such settlement shall require VF to be subject to an injunction or to make a monetary payment or shall otherwise adversely and materially affect VF's rights under this Agreement, such consent not to be unreasonably withheld.

13.12 Employees.

Each Party will require all of its and its Affiliates' employees to assign all Inventions that are developed, made or conceived by such employees according to the ownership principles described in this Article 13 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Each Party will also require any agents, independent contractors or sublicensees performing an activity pursuant to this Agreement to assign all Inventions that are developed, made or conceived by such agents, independent contractors or sublicensees to OPKO according to the ownership principles described in this Article 13 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Each Party will be responsible for any payments required to be made to its employees, agents, independent contractors, or sublicensee in connection with any such assignment.

13.13 Third Party Licenses.

(a) If Third Party patent applications or patents are identified by either Party [***], and the Parties [***] under such identified Third Party patent applications or patents (for patent applications, assuming pending claims therein had issued) for the development, manufacture or commercialization of the Product in the Field in the Territory ("Relevant Patents"), [***] to obtain a license to such Relevant Patents, with the right to sublicense, in order to permit [***] to conduct their obligations and exercise their rights under this Agreement. The Parties will consult with each other with respect to the negotiation and the final form of such terms and conditions and discuss [***] upon which such Parties [***] to obtain the license.

(b) If Third Party Patent Applications or Patents are identified by either Party [***] for the development, manufacture or commercialization of the Product in the Field in the Territory, but the Parties [***] a license to such [***], and shall use Commercially Reasonable Efforts to obtain the right to sublicense such [***]. The JSC shall discuss such [***] license, including [***] to the Third Party licensor. For the avoidance of doubt, any [***] licensed to [***] subject to such license will not be included in the [***] unless the Parties otherwise agree in writing.

14. Confidentiality

14.1 Disclosure of OPKO Technology.

To the extent that OPKO has disclosed or in the future discloses to VF any OPKO Technology, VF shall not acquire any ownership rights in such OPKO Technology by virtue of this Agreement or otherwise.

14.2 Confidential Information.

OPKO and VF shall not use or reveal or disclose to Third Parties any confidential information received from the other Party or otherwise developed by either Party in the performance of activities in furtherance of this Agreement without first obtaining the written consent of the disclosing Party, except as may be otherwise provided in, or required in order for a Party to fulfill its obligations under, this Agreement. During and following the Term of this Agreement, this confidentiality obligation shall not apply to such information that (i) is or becomes a matter of public knowledge (other than by breach of this Agreement by the receiving Party), or (ii) is required by law to be disclosed. Following the Term of this Agreement, this confidentiality obligation shall not apply to such information that (i) the receiving Party can establish was already known to it or was in its possession at the time of disclosure without obligation of confidentiality, or (ii) is disclosed to the receiving Party by a Third Party having the right to do so. The Parties shall take reasonable measures to assure that no unauthorized use or disclosure is made by others to whom access to such information is granted.

Nothing in this Agreement shall be construed as preventing either Party from disclosing any information received from the other to an Affiliate of the receiving Party who is necessary for the purposes of enabling the receiving Party to fulfill its obligations under this Agreement, provided, the receiving Party shall be responsible for breaches of the confidentiality obligations by such Affiliate.

14.3 Public Announcements.

No public announcement or other disclosure to Third Parties concerning the existence of or terms of this Agreement shall be made, either directly or indirectly, by either Party, except as may be legally required or as may be required for financial reporting purposes, without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure.

15. Restrictive Covenants

15.1 Non-solicitation.

Without the prior written consent of the other Party, each of OPKO and VF agrees that during the term of this Agreement and for [***] following termination of this Agreement for any reason, neither it nor any of its Affiliates will directly or indirectly solicit for purposes of hiring any person employed by the other Party or any of their Affiliates or who was employed by the other Party or any of their Affiliates within the then prior [***] months, or in any manner seek to induce any such person to leave his or her employment; provided, however, that this restriction shall not apply to a general advertisement of employment. The foregoing covenant will only apply to persons employed by the other Party or any of their Affiliates who were actively involved in the activities with respect to the Product contemplated by this Agreement.

15.2 Non-competition.

(a) During the [***] in each country in the Territory, neither [***] of rights under this Agreement shall promote, market or sell, or enter into any agreement to promote, market or sell [***] during the Term of this Agreement [***] without the prior written consent of OPKO; provided, however, that, with respect to a Sublicensee, the foregoing shall only apply to those countries in which the Sublicensee has rights under this Agreement. The provisions of this Section 15.2 will not apply to (i) [***] of this Agreement as of the Effective Date, (ii) the Product for an [***] commercialize on its own in the Field and in the Territory in accordance with Section 4.1, (iii) [***] or (iv) products that VF may distribute for incorporation as a [***] in order to have an open selection/offering of these other products (provided, that [***] management). During the Term and for [***] thereafter, neither VF nor any of its Affiliates or Sublicensees of a Product shall promote, market or sell, or enter into any agreement to promote, market or sell, nor shall they enter into any license or sublicense to promote, market or sell, any [***] without the prior written consent of OPKO, provided that the non-compete obligation for VF, its Affiliates or Sub-Licensees shall be waived in the event that VF terminates this Agreement for OPKO's breach of agreement (Section 16.1 (b) (ii) below) or bankruptcy (Section 16.1 (b) (iii) below). The provisions of this Section 15.2 shall have no force or effect in any country of the Territory where, and to the extent, such provisions contravene any applicable antitrust or antimonopoly law.

(b) During the [***] in each country in the Territory, neither OPKO nor any of its Affiliates shall, directly or indirectly, [***] any [***] without the prior written consent of VF. During the Term and for [***] thereafter, neither [***] of a [***]. The provisions of this Section 15.2 shall have no force or effect in any country of the Territory where, and to the extent, such provisions contravene any applicable antitrust or antimonopoly law. The provisions of the first sentence of this Section 15.2 will not apply to (i) [***] or (ii) [***]. It is recognized that the provisions of the second sentence of this Section 15.2 will not apply to an [***] has a right to commercialize on its own or with a Third Party in accordance with Section 4.1.

16. Termination; Rights And Duties Upon Termination

16.1 Early Termination.

(a) VF shall have the right to terminate this Agreement upon [***] days prior written notice to OPKO for any reason (a) in its entirety, or (b) with respect to one or more countries in the Territory, provided that VF shall not have the right to terminate the Agreement with respect to any Major Country without terminating the entire Agreement. For clarity, termination by VF of the last remaining country in the Territory under this Agreement shall be deemed to be a termination of this Agreement in its entirety.

(b) Each Party shall have the right to terminate this Agreement before the end of the Term:

(i) by mutual agreement of the Parties;

(ii) upon a material breach of this Agreement by the other Party where such breach is not cured within [***] days (or [***] days for any

payment breach) following the breaching Party's receipt of written notice of such breach from the non-breaching Party; provided, however, that if any breach is not reasonably curable within [***] days and if the breaching Party is making a bona fide effort to cure such breach, such termination shall be delayed for a time period to be agreed by both Parties (but in no event more than [***] days) in order to permit the breaching Party a reasonable period of time to cure such breach; or

(iii) upon the bankruptcy or insolvency, or the making or seeking to make or arrange an assignment for the benefit of creditors of the other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy, the institution of any reorganization, arrangement or other readjustment of debt plan of the other Party not involving the Bankruptcy Code, the appointment of a receiver or trustee of such Party's property that is not discharged within ninety (90) days, or any corporate action taken by the board of directors (or similar governing body) of the other Party in furtherance of any of the foregoing actions.

(c) If the breaching Party disputes in good faith that it has materially breached one of its obligations under this Agreement, termination shall not take effect pending resolution of such dispute pursuant to Article 21.

16.2 Continuing Obligations.

In addition to those specifically identified in the Agreement, the following provisions shall survive the termination or expiration of this Agreement for any reason: Sections 3.2 (Expiration), 12.1 (Audit Rights), 13.1 (Ownership of Intellectual Property), 13.2 (Product Inventions), 13.3(a) (Patent Prosecution), 13.4 (Notification of Patent Litigation); 13.5(d) (Patent Infringement); 13.6 (Title to Trademarks), 13.9 (Notification of Trademark Litigation), 13.10 (Trademark Infringement), Section 13.11 (Information and Settlement), 16.2 (Continuing Obligations), 16.3 (Remedies), 16.4 (Effects of Termination), 17.5 (Indemnification by OPKO), 17.6 (Indemnification by VF), 17.7 (Limitations on Indemnification), 17.8 (Insurance), 17.9 (Limitation of Liability), and Articles 1 (Definitions), 5 (Fees and Payments), 14 (Confidentiality), 15 (Restrictive Covenants), 19 (Notices), Article 20 (Miscellaneous), 21 (Dispute Resolution). In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement.

16.3 Remedies.

(a) Termination of this Agreement in accordance with its provisions shall not limit the remedies that may be otherwise available to either Party in law or equity.

(b) In the event that OPKO is in breach of this Agreement such that VF has the right to elect to terminate the Agreement under Section 16.1(b)(ii) (and after compliance with all notice and cure periods set forth therein), in [***]; provided, however that [***] by [***] of those otherwise due to OPKO and shall be further [***].

16.4 Effects of Termination.

(a) Following a termination of this Agreement by VF under this Article 16:

(i) (A) All licenses granted to VF under this Agreement shall terminate; (B) all rights in and to the Products in the Territory shall revert to OPKO; (C) VF shall transfer to OPKO [***] cost (unless termination by VF was pursuant to Section [***], in which case [***] shall bear such cost) all relevant and necessary materials, results, analyses, reports, Product data, the URL for Product-specific websites, technology, know-how, regulatory filings, and other information in whatever form developed or generated as of the effective date of such termination by or on behalf of VF or its Affiliates with respect to Products; and (D) VF shall submit to any and all Regulatory Authorities in jurisdictions in which any regulatory filings have been made with respect to the Products, within [***] days after the effective date of such termination, a letter (with a copy to OPKO) notifying such Regulatory Authorities of the transfer of any regulatory filings for a Product in such jurisdictions from VF to OPKO; provided that [***]. VF, its Affiliates or their respective permitted Sublicensees shall be permitted to sell, subject to the payment of applicable royalties due under Article 5 and Section 3.2, any Products in inventory (including completion for sale of any work in progress) over the [***] month period following termination.

(ii) Any sublicense granted to a Sublicensee that is not in breach under the applicable sublicense will continue in effect so long as the Sublicensee makes the payments required under Article 5.

(b) Following a termination by OPKO under this Article 16:

(i) All licenses granted to VF by OPKO shall terminate; provided, however, that, unless, at [***] price VF, its Affiliates or their respective permitted Sublicensees shall be permitted to sell, subject to the payment of applicable royalties due under Article 5 and Section 3.2, any Products in inventory (including completion for sale of any work in progress) over the [***] month period following termination.

(ii) All rights in and to the Products in the Territory shall revert to OPKO;

(iii) VF shall transfer to OPKO [***] all relevant and necessary materials, results, analyses, reports, Product data, technology, know-how, regulatory filings, and other information in whatever form developed, controlled, or generated as of the effective date of such termination by or on behalf of VF or its Affiliates with respect to Products, including Product Inventions. VF shall submit to any and all Regulatory Authorities in jurisdictions in which any regulatory filings have been made with respect to the Products, within [***] days after

the effective date of such termination, a letter (with a copy to OPKO) notifying such Regulatory Authorities of the transfer of any regulatory filings for a Product in such jurisdictions from VF to OPKO.

(iv) Any sublicense granted to a Sublicensee that is not in breach under the applicable sublicense will continue in effect so long as the Sublicensee makes the payments required under Article 5.

(c) Nothing in this Article 16 shall limit the Parties' respective rights to damages or specific performance upon the occurrence of an event that constitutes grounds for termination of this Agreement pursuant to Section 16.1 above, as applicable.

17. Representations, Warranties, Covenants, and Indemnification

17.1 Mutual Representations and Warranties.

Each Party hereby represents and warrants (as applicable) to the other Party as follows, as of the Effective Date:

(a) It is an entity duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is formed, and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

(b) It has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, except as enforcement may be affected by bankruptcy, insolvency or other similar laws and by general principles of equity.

(c) The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound, or violate any Laws of any Governmental Authority having jurisdiction over it.

(d) Except with respect to Regulatory Approvals for the development, manufacturing or commercialization of the Product or as otherwise described in this Agreement, all necessary consents, approvals and authorizations of, and all notices to, and filings by such Party with, all Governmental Authorities and other Persons required to be obtained or provided by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the time of execution of this Agreement.

17.2 Representations and Warranties of OPKO.

Except as disclosed on Schedule 17.2, OPKO represents and warrants to VF that:

(a) it owns as of the Effective Date the entire right, title and interest in the Patents, OPKO Trademarks and OPKO Technology free and clear of any claims, liens, charges or encumbrances;

(b) it has the right to grant VF, its Affiliates and Sublicensees the rights and licenses described in this Agreement;

(c) Appendix A includes a complete and correct list of all existing Patents as of the Effective Date;

(d) there is nothing in any Third Party agreement that OPKO or any of its Affiliates have entered into that in any way limits or will limit OPKO's ability to grant the rights and licenses described in this Agreement and to perform all of the obligations undertaken by OPKO under this Agreement,

(e) it will not transfer or encumber, with liens, mortgages, security interests or otherwise, the Patents, OPKO Trademarks and OPKO Technology in any way that could result in any impairment of VF's rights under this Agreement;

(f) the Patents listed on Appendix A are issued patents that are in full force and effect and all applicable filing, maintenance and other fees have been timely paid;

(g) the Patents listed on Appendix A are not the subject of as of the Effective Date any pending re-examination, opposition, interference, inter partes review, litigation or other proceeding;

(h) it has received no written notice of (i) any claim that a patent or trade secret owned or controlled by a Third Party is or would be infringed or misappropriated by the manufacture, use, sale, offer or sale or import of Products in the Field, or (ii) any threatened claims or litigation seeking to invalidate or challenge the Patents or OPKO's rights thereto;

(i) to OPKO's knowledge, no Third Party is infringing the Patents listed on Appendix A;

(j) to OPKO's knowledge, the making, having made, selling, offering for sale, using or importing of a Product does not and will not infringe the patent or other intellectual property rights of any Third Party;

(k) to OPKO's knowledge, there have been no inventorship or ownership challenges with respect to any of the Patents listed on Appendix A;

(l) to the extent that any of the Patents listed on Appendix A are pending patent applications as of the Effective Date, those applications are being diligently prosecuted at the respective patent offices;

(m) to OPKO's knowledge, the research, development and manufacture of the Product before the Effective Date has been conducted in compliance with Applicable Law; and

(n) to OPKO's knowledge , the Patents and OPKO Technology constitute all of the patents, patent applications and technology that are necessary to develop, make, have made, use, offer for sale, sell, import, export and otherwise commercialize the Product in the Initial Indication in the Territory.

17.3 Representations and Warranties of VF .

VF represents and warrants that (i) it has the right to enter into this Agreement, (ii) there is nothing in any Third Party agreement VF has entered into that in any way will limit VF's ability to perform all of the obligations undertaken by VF under this Agreement, and (iii) as of the Effective Date, it neither has in development nor plans to develop any product which will be marketed during the Term which shall compete with the Product.

17.4 Compliance with Law and Ethical Business Practices .

In addition to the other representations, warranties and covenants made by each Party elsewhere in this Agreement, each Party represents and warrants or covenants and agrees, as applicable, with the other Party that during the Term:

(a) it is licensed, registered, or qualified under all Applicable Laws to do business, and has obtained such licenses, consents, authorizations or completed such registrations or made such notifications as may be necessary or required by Applicable Law to provide any products, goods or services encompassed within this Agreement, and providing such products, goods or services is not inconsistent with any other obligation of such Party;

(b) in conducting its activities and obligations hereunder, such Party will and will cause its Affiliates and, to the extent of its legal right to do so, use reasonable efforts to cause its other representatives to comply in all material respects with all Applicable Laws and accepted pharmaceutical industry business practices, including, to the extent applicable to such Party and each of its Affiliates and other representatives;

(c) to its knowledge with respect to any products, payments or services provided under this Agreement, it has not taken and will not during the Term take any action directly or indirectly to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official or any other person in order to gain an improper advantage, and has not accepted, and will not accept in the future, such payment;

(d) it complies in all material respects with the laws and regulations of the countries where it operates, including anti-bribery and anti-corruption laws, accounting and record keeping laws, and laws relating to interactions with healthcare professionals or healthcare providers and Government Officials;

(e) to its knowledge, it and each of its Affiliates has been and will, for the Term, be in compliance in all material respects with all applicable global trade laws, including those related to import controls, export controls or economic sanctions, and such Party will cause each of its Affiliates to remain in compliance in all material respects with the same during the Term;

(f) to its knowledge, except to the extent permissible under United States law, neither it nor any of its Affiliates has, on its own behalf or acting on behalf of any other Person, directly or indirectly engaged with, and will not for the Term, directly or indirectly engage in any transactions with, or otherwise deal with, any country or Person targeted by United States, European Union, United Kingdom or other relevant economic sanctions laws in connection with any activities related to such Party's interaction with the other Party, including those contemplated under this Agreement; and

(g) it is, as between the Parties, solely responsible for ensuring the adherence by the Parties and its respective Affiliates in all material respects to all Applicable Laws, in each case with respect to the activities to be conducted under this Agreement.

17.5 Indemnification by OPKO.

OPKO shall defend, indemnify and hold harmless VF and its Affiliates and their officers, directors, shareholders, employees, agents, representatives, successors and assigns from and against all claims, complaints, or lawsuits for damages (collectively referred to as "Claims") arising out of (i) any negligent act or omission, or willful wrongdoing by OPKO, its Affiliates or representatives in the performance of this Agreement, (ii) the failure by OPKO, its Affiliates or representatives to comply with any Applicable Law, (iii) the infringement or misappropriation by OPKO of any patent, copyright, trademark, or service mark, as a result of OPKO's marketing or promotion of the Product in the Territory which is not pursuant to the terms of this Agreement or in conformity with the direction of the JDC, (iv) any breach of any representation or warranty or covenant of OPKO, and (v) the sale of the Product outside the Territory by OPKO, its Affiliates or its licensees/sublicensees. OPKO shall not be obligated under this Section to the extent that the Claim was the result of the non-performance, negligence or willful misconduct of any employee or agent of VF or anyone acting on behalf of VF, including its Affiliates and their officers, directors, shareholders, employees, agents, representatives, successors and assigns.

17.6 Indemnification by VF.

VF shall defend, indemnify and hold harmless OPKO and its Affiliates and their officers, directors, shareholders, employees, agents, representatives, successors and assigns from and against all Claims arising out of (i) any negligent act or omission, or willful wrongdoing by VF in the performance of this Agreement, (ii) the failure by VF to comply with any Applicable Law, (iii) the infringement or misappropriation by VF of any patent, copyright, trademark, or trade secret, as a result of VF's

marketing or promotion of the Product which is not pursuant to the terms of this Agreement or in conformity with the direction of the JDC, and (iv) any breach of any representation or warranty or covenant of VF. VF shall not be obligated under this Section to the extent that the Claim was the result of the nonperformance, negligence or willful misconduct of any employee or agent of OPKO or anyone acting on behalf of OPKO, including its Affiliates and their officers, directors, shareholders, employees, agents, representatives, successors and assigns.

17.7 Limitations on Indemnification.

The obligations to indemnify, defend, and hold harmless set forth in Sections 17.5 and 17.6 shall be contingent upon the Party seeking indemnification (the "Indemnitee"): (i) notifying the indemnifying Party of a claim, demand or suit within [***] Business Days of receipt of same; provided, however, that Indemnitee's failure or delay in providing such notice shall not relieve the indemnifying Party of its indemnification obligation except to the extent the indemnifying Party is materially prejudiced thereby; (ii) allowing the indemnifying Party and/or its insurers the right to assume direction and control of the defense of any such claim, demand or suit; (iii) using its Commercially Reasonable Efforts to cooperate with the indemnifying Party and/or its insurers in the defense of such claim, demand or suit; and (iv) agreeing not to settle or compromise any claim, demand or suit without prior written authorization of the indemnifying Party. The Indemnitee shall have the right to participate in the defense of any such claim, demand or suit referred to in this Section utilizing attorneys of its choice, at its own expense, provided, however, that the indemnifying Party shall have full authority and control to handle any such claim, demand or suit.

17.8 Insurance.

During the term of this Agreement and for a period of [***] years after the termination of this Agreement, each Party shall obtain and/or maintain, respectively, at its sole cost and expense, product liability insurance in amounts, respectively, which are reasonable and customary in the pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party. Such product liability insurance shall insure against all liability, including personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Product in the Territory. Each Party shall provide written proof of the existence of such insurance to the other Party upon request.

17.9 Limitation of Liability.

EXCEPT IN THE CASE OF A BREACH OF ARTICLE 14, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

18. Assignment

18.1 Assignment.

Neither Party shall assign or transfer its rights or obligations under this Agreement without the prior written consent of the other Party, except to (a) any of its respective Affiliates or (b) to a Third Party successor or purchaser of all or substantially all of its business or assets to which this Agreement relates, whether in merger, sale of stock, sale of assets or similar transaction. In the event of a Change of Control of VF, OPKO shall have the right to terminate this Agreement [***]; provided, however, that the matter will be resolved as provided under Section 21.3 in the event of dispute. For the avoidance of doubt, OPKO shall have [***] in the event of a [***] so long as such restructuring does not result in the effective sale or transfer, directly or indirectly, of this Agreement to a Third Party. A "Change of Control" shall mean if: (i) any Person acquires directly or indirectly the beneficial ownership of any voting security of a Party and immediately after such acquisition such Person is, directly or indirectly, the beneficial owner of voting securities representing 50% or more of the total voting power of all of the then-outstanding voting securities of such Party; (ii) the stockholders or equity holders of a Party shall approve a merger, consolidation, recapitalization, or reorganization of such Party, a reverse stock split of outstanding voting securities, or consummation of any such transaction if stockholder or equity holder approval is not obtained, other than any such transaction which would result in stockholders of equity holders of such Party immediately prior to such transaction owning at least 80% of the outstanding securities of the surviving entity in such transaction immediately following such transaction, with the voting power of each such continuing holder relative to other such continuing holders not substantially altered in the transaction; or (iii) the stockholders or equity holders of a Party shall approve a plan of complete liquidation of the Party or an agreement for the sale or disposition by the Party of all or a substantial portion of the Party's assets.

19. Notices

19.1 Notices.

Any notice, request, approval or other document required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been given when delivered in person, or sent by overnight courier service, postage prepaid, or sent by certified or registered mail, return receipt requested, or by facsimile transmission, to the following addresses of the Parties and to the attention of the persons identified below (or to such other address, addresses or persons as may be specified from time to time in a written notice). Any notices given pursuant to this Agreement shall be deemed to have been given and delivered upon the earlier of (i) if sent by overnight courier service, on the date when received at the address set forth below as proven by a written receipt from the delivery service verifying delivery, or (ii) if sent by certified or registered mail, three (3) Business Days after mailed by certified or registered mail postage prepaid and properly addressed, with return receipt requested, or (iii) if sent by facsimile transmission, on the day when sent by facsimile as confirmed by automatic transmission report coupled with certified or registered mail or overnight courier service receipt proving delivery, or (iv) if delivered in person, on the date of delivery to the address set forth below as proven by written signature of the recipient.

EirGen Pharma Limited:

EirGen Pharma Limited
Westside Business Park, Old Kilmeaden Road
Waterford, Ireland
Attention: Patsy Carney, CEO

Copy to:

OPKO Health, Inc.
4400 Biscayne Boulevard
Miami, FL 33137
Facsimile:
Attention: Kate Inman, General Counsel

Copy to:

Holland & Knight LLP
701 Brickell Avenue
Suite 3300
Miami, Florida 33131
Facsimile: (305) 789-7799
Attention: Rodney H. Bell, Esq.

VF:

Vifor Fresenius Medical Care Renal Pharma Ltd.
Rechenstrasse 37, 9014 St. Gallen, Switzerland
Facsimile: +41 58 851 80 01
Attention: CEO

Copy to:

Vifor Pharma
Flughofstrasse 61, 8152 Glattbrugg, Switzerland
Facsimile: +41 58 851 80 01
Attention: General Counsel

Notwithstanding the foregoing, notice of any breach of this Agreement delivered by a Party under Section 19.1 shall be provided in accordance with the foregoing provisions to the chief executive officer of the other Party in addition to the persons identified above.

20. Miscellaneous

20.1 Force Majeure.

If the performance of any part of this Agreement by either Party, or of any obligation under this Agreement, is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the Party liable to perform, unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use Commercially Reasonable Efforts to avoid or remove such causes of nonperformance and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall discuss what, if any modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

20.2 No Partnership or Joint Venture.

It is expressly agreed that OPKO and VF shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither OPKO nor VF shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so.

20.3 Execution In Counterparts.

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Counterparts may be signed and delivered by facsimile or .PDF file, with the same effect as if delivered personally.

20.4 Governing Law.

This Agreement shall be deemed to have been made in the State of New York and its form, execution, validity, construction and effect shall be determined in accordance with the substantive laws of the State of New York, without regard to conflict of law principals thereof.

20.5 Waiver Of Breach.

The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

20.6 Severability.

In the event any portion of this Agreement were to be held illegal, void or ineffective, the remaining portions of this Agreement shall remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be

deemed to be modified to conform with such statute or rule of law. In the event that the terms and conditions of this Agreement are materially altered as a result of this Section 20.6, the Parties shall renegotiate the terms and conditions of this Agreement to resolve any inequities.

20.7 Entire Agreement.

This Agreement, together with the exhibits, attachments, schedules hereto, shall constitute the entire agreement between the Parties relating to the subject matter thereof and shall supersede all previous writings and understandings, except that the Parties shall continue to be bound by the confidentiality provisions of that certain Confidentiality Agreement dated September 18, 2015. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

20.8 Currency.

Unless otherwise specified in this Agreement, all amounts set forth in this Agreement are in U.S. Dollars.

20.9 Form of Payments.

All payments under this Agreement shall be in U.S. dollars in immediately available funds, and, unless instructed otherwise by the receiving Party, shall be made via wire transfer to the account designated from time to time by the receiving Party.

20.10 Good Faith.

Each Party agrees to act reasonably in giving effect to the provisions of this Agreement.

21. Dispute Resolution

21.1 Internal Resolution.

Any dispute, controversy or claim arising out of or relating to a breach or alleged breach of this Agreement, excluding termination, (collectively referred to as "Dispute") shall be attempted to be settled by the Parties, in good faith, by submitting each such Dispute to the designated senior management representatives of each Party, who shall meet within [***] Business Days as reasonably requested by either Party to review any Dispute. If the Dispute is not resolved by the designated representatives by mutual agreement within [***] Business Days after a meeting to discuss the Dispute, either Party may at any time thereafter provide the other written notice specifying the terms of such Dispute in reasonable detail. Within [***] Business Days of receipt of such notice, the chief executive officer (or other top executive officer with authority to resolve the dispute) of each Party shall meet at a mutually agreed upon time and location for the purpose of resolving such Dispute. They will discuss the problems and/or negotiate for a period of up to [***] Business Days in an effort to resolve the Dispute or negotiate an acceptable interpretation or revision of the applicable portion of this Agreement mutually agreeable to both Parties, without the necessity of formal procedures relating thereto. Except as set forth in Section 21.3 and Section 9.1(c), any

Dispute involving a disagreement within a Committee's authority (other than disagreements within the JDC or JSC relating to a Party's breach or alleged breach under this Agreement or relating to the termination of this Agreement), shall, after compliance with the foregoing procedures set forth in this Section 21.1, be finally resolved by [***].

21.2 Arbitration.

Any controversy or claim arising out of or relating to a breach or alleged breach of this Agreement (other than disagreements of the JDC or JSC as described in Section 21.1 or Section 9.1(c)) or termination, shall be settled by arbitration in accordance with the Commercial Arbitration Rules and supplementary rules for international commercial arbitrations of the American Arbitration Association (AAA) then in effect. The arbitration shall be conducted in English. The seat of the arbitration shall be in the City of New York, Borough of Manhattan. In any arbitration pursuant to this Agreement (other than as set forth in in Section 21.3), the award or decision shall be rendered by a majority of the member of an arbitration panel consisting of three (3) independent arbitrators. Each Party shall appoint one (1) arbitrator, and the third arbitrator shall be selected jointly by the two arbitrators appointed by the Parties, unless the Parties otherwise agree as to the identity of the third arbitrator. If the two arbitrators appointed by the Parties are unable to agree upon the third arbitrator within [***] days of any request for arbitration, such arbitrator shall be selected by the AAA. Persons selected to serve as an arbitrator need not be a professional arbitrator, and persons such as lawyers, accountants, brokers and bankers shall be acceptable. Before undertaking to resolve the dispute, the arbitrators shall be duly sworn faithfully and fairly to hear and examine the matters in controversy and to make a just award according to the best of his or her understanding. The written decision of the arbitrators shall be final, conclusive and binding on the Parties. Each Party shall bear its own costs and expenses (including legal fees and expenses) relating to the Arbitration proceeding, except that the fees of the arbitrators and other related costs of the arbitration shall be shared equally by the Parties. The arbitrators shall be required, in granting any relief, to comply with any express provisions of this Agreement relating to damages or the limitation thereof. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets. Either Party has the right to apply to the state courts of the State of New York located in the City of New York or the United States District Court for the Southern District of New York for interim relief necessary to preserve the Party's rights, including pre-arbitration attachments or injunctions, until the arbitral tribunal is constituted. After the constitution of the arbitral tribunal, the arbitrators shall have exclusive jurisdiction to consider applications for interim relief.

21.3 Expert Arbitrator if no JSC Consensus on Certain Matters .

(a) If either Party is entitled to submit a disputed matter to arbitration pursuant to this Section 21.3, including, notwithstanding any provision of this Agreement to the contrary, matters requiring JSC consensus, it may do so by providing written notice of the disputed matter to the other Party and its election to submit such matter to arbitration in accordance with this Section 21.3. Within [***] days following such notice, the Parties shall each submit their respective proposals with respect to such matter to each other. The Parties shall within such [***] day period mutually select an [***], and failing such mutual agreement during such time frame, either Party

may ask the American Arbitration Association to promptly appoint the expert on behalf of the Parties) (the " Expert Arbitrator"). Both Parties shall submit their respective proposals with respect to such matter to the Expert Arbitrator within [***] Business Days of learning of such Expert Arbitrator's appointment, either through agreement of the Parties or by the American Arbitration Association. If a Party fails to submit a proposal within such timeframe, then the proposal of the submitting Party shall prevail.

(b) Each Party shall have [***] Business Days from receipt of the other Party's submission to the Expert Arbirator to submit a written response to such proposal. A hearing with the Parties and the Expert Arbitrator shall to take place over no more than [***] Business Days and shall commence no later than [***] days after submission of the written responses to each other and the Expert Arbitrator. Each Party shall have a reasonable period of time, to be determined by the Expert Arbitrator (which period of time shall be sufficient for the Expert Arbitrator to fully understand the proposals, responses and the relative merits thereof), to argue for its proposal at the hearing with the Expert Arbitrator. The Expert Arbitrator shall have the right to meet thereafter with the Parties together, as necessary to make a determination. The Expert Arbitrator shall, within [***] Business Days after completion of the hearing, or such longer period as the Parties may agree, [***]. Such determination shall be deemed to be the [***]. The Parties acknowledge and agree that the rendering of a determination by the Expert Arbitrator [***] of the Expert Arbitrator's opinion with respect to such matter, or the basis of its determination, is released, if at all. At any time prior to the determination, either Party may accept the other Party's position on any unresolved issue. The Parties shall inform the Expert Arbitrator of such accepted position and in such event such position will be deemed part of the final resolution of the matter in dispute and no longer subject to arbitration. The Expert Arbitrator's decision shall take into account customary and commercially reasonable industry practices for the conduct of development and other activities in compliance with Applicable Law. [***].

(c) The Expert Arbitrator shall be required, in granting any relief, to comply with any express provisions of this Agreement relating to damages or the limitation thereof. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets. Either Party has the right to apply to the state courts of the State of New York located in the City of New York or the United States District Court for the Southern District of New York for interim relief necessary to preserve the Party's rights, including pre-arbitration attachments or injunctions, until the Expert Arbitrator is appointed. After the Expert Arbitrator is appointed, the Expert Arbitrator shall have exclusive jurisdiction to consider applications for interim relief.

22. Performance.

22.1 Performance.

To the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its requisite efforts (which may be Commercially Reasonable Efforts) to perform any such affected obligations as required by this Agreement.

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

[Signatures on following page.]

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

NOW THEREFORE, the Parties, through their authorized officers, have executed this Agreement as of the date first written above.

EIRGEN PHARMA LIMITED

By:/s/ Patsy Carney
Name: Patsy Carney
Title: Chief Executive Officer

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD

By:/s/ Chris Springer
Name: Chris Springer
Title: Deputy Chief Executive Officer

By:/s/ Stefan Schulze
Name: Stefan Schulze
Title: Chief Executive Officer

PARENT GUARANTY

As an inducement to Vifor Fresenius Medical Care Renal Pharma Ltd ("VF") to enter the foregoing Agreement (this "Agreement") with EirGen Pharma Limited ("OPKO"), OPKO Health, Inc., a Delaware corporation (" Guarantor"), hereby irrevocably and unconditionally guarantees payment (including amounts that would become due but for the operation of the automatic stay under Section 362(a) of the United States Bankruptcy Code) and performance obligations of OPKO to VF under this Agreement and each of the documents contemplated hereunder, subject to any and all rights and defenses that OPKO has or may have under the terms of this Agreement or such document. Guarantor is a party to this Agreement solely for purposes of this guaranty. Guarantor understands that this guaranty is continuing in nature and extends to future obligations of OPKO to VF related to this Agreement and each of the documents contemplated hereunder.

Guarantor waives all rights to require VF to proceed against OPKO or to exhaust any remedy prior to enforcing this guaranty. Guarantor waives any defense based on the cessation or reduction for any cause whatsoever of the liability of VF. Guarantor waives all demands, presentments and notices of every kind. VF may at any time, and from time to time, alter, amend, modify, renew or extend the time for payment of any obligation or any other rights and obligations of OPKO and may cease dealing with OPKO without the participation of Guarantor as VF may elect, all without notice to Guarantor. Guarantor agrees not to enforce any claim it may have against OPKO, including, but not limited to, any rights acquired by way of subrogation under this guaranty, until all obligations of OPKO to VF have been paid in full.

Guarantor hereby represents and warrants to VF as follows:

(a) Guarantor is a corporation duly organized, validly existing and in good standing under the laws of Delaware and Guarantor has all requisite power and authority to execute, deliver and perform this guaranty.

(b) The execution, delivery and performance by Guarantor of this guaranty have been duly authorized by all necessary corporate action and do not and will not contravene its certificate or organizational documents.

(c) The execution, delivery and performance by Guarantor of this guaranty do not and will not contravene any law or governmental regulation or any contractual restriction binding on or affecting Guarantor or any of its affiliates.

(d) No authorization or approval or other action by, and no notice to or filing with, any governmental authority or other regulatory body or third party is required for the due execution, delivery and performance by Guarantor of this guaranty.

(e) This guaranty is a legal, valid and binding obligation of Guarantor, enforceable against Guarantor in accordance with its terms except as limited by bankruptcy, insolvency or similar laws of general application relating to the enforcement of creditors' rights.

(f) There is no action, suit or proceeding pending or, to the knowledge of Guarantor, threatened against or otherwise affecting Guarantor before any court, arbitrator or governmental department, commission, board, bureau, agency or instrumentality that may materially and adversely affect Guarantor's financial condition or its ability to perform its obligations hereunder.

(g) The direct or indirect value of the consideration received and to be received by Guarantor in connection herewith is reasonably worth at least as much as the liability and obligations of Guarantor hereunder, and the incurrence of such liability and obligations in return for such consideration may reasonably be expected to benefit Guarantor, directly or indirectly.

(h) All of the representations and warranties of OPKO set forth in Section 17 of this Agreement are true and correct.

Guarantor may not assign this guaranty, in whole or in part, without the prior written consent of VF. Any assignee will assume all obligations of its assignor under this guaranty and no assignment will relieve Guarantor of responsibility for the performance of any accrued obligations under this guaranty. Subject to the foregoing, this guaranty binds and inures to the benefit of the parties and their heirs, successors and assigns.

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

No failure or delay by VF in exercising any right under this guaranty shall operate as a waiver thereof, nor shall any single or partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right under this guaranty.

OPKO HEALTH, INC.

By:/s/ Kate Inman
Name: Kate Inman
Title: General Counsel, Secretary

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXHIBIT 10.2
SUPPLY AGREEMENT TERMS

[***]

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

SCHEDULE 15.2

None

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

SCHEDULE 17.2

[***]

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

APPENDIX A
(Patents)

[***]

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXHIBIT 2.2(b)
Proposed Third Party Sublicensees

[***]

[***] Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

EXHIBIT A
(Development Plan)

[***]

Exhibit 31.1

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: August 8, 2016

/s/ Phillip Frost, M.D.
Phillip Frost, M.D.
Chief Executive Officer

Exhibit 31.2

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: August 8, 2016

/s/ Adam Logal

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

Exhibit 32.1

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 June 30, 2016 (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: August 8, 2016

/s/ Phillip Frost, M.D.
Phillip Frost, M.D.
Chief Executive Officer

Exhibit 32.2

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 June 30, 2016 (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: August 8, 2016

/s/ Adam Logal

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