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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended March 31, 2018.

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number 001-33528

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**OPKO Health, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**75-2402409**  
(I.R.S. Employer  
Identification No.)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ YES ☐ NO

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

Large accelerated filer ☒

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

Accelerated filer ☐

Smaller reporting company ☐

Emerging growth company ☐

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

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

As of May 1, 2018, the registrant had 559,473,838 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 (the “Securities Act”). Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in “Item 1A-Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2017, and described from time to time in our other reports filed with the Securities and Exchange Commission. We do not undertake an obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

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

- we have a history of losses and may not generate sustained positive cash flow sufficient to fund our operations and research and development programs;
- the risks inherent in developing, obtaining regulatory approvals for and commercializing new, commercially viable and competitive products and treatments;
- our research and development activities may not result in commercially viable products;
- that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results;
- that we may fail to obtain regulatory approval for hGH-CTP or successfully commercialize *Royaldee* and hGH-CTP;
- that we may not generate profits or cash flow from our laboratory operations or substantial revenue from our pharmaceutical and diagnostic products;
- that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied;
- our ability to build a successful pharmaceutical sales and marketing infrastructure;
- our ability and our distribution and marketing partners’ ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates and the operation of our laboratories;
- the performance of our third-party distribution partners, licensees and manufacturers over which we have limited control;
- our success is dependent on the involvement and continued efforts of our Chairman and Chief Executive Officer;
- integration challenges for Transition Therapeutics, BioReference, EirGen and other acquired businesses;
- changes in regulation and policies in the United States and other countries, including increasing downward pressure on healthcare reimbursement;
- our ability to manage our growth and our expanded operations;
- increased competition, including price competition;
- changing relationships with payers, including the various state and multi-state Blues programs, suppliers and strategic partners;
- efforts by third-party payors to reduce utilization and reimbursement for clinical testing services;
- failure to timely or accurately bill and collect for our services;
- failure in our information technology systems, including cybersecurity attacks or other data security or privacy incidents;
- failure to obtain and retain new clients and business partners, or a reduction in tests ordered or specimens submitted by existing clients;
- failure to establish, and perform to, appropriate quality standards to assure that the highest level of quality is observed in the performance of our testing services;
- failure to maintain the security of patient-related information;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to defend our intellectual property rights with respect to our products;
- our ability to operate our business without infringing the intellectual property rights of others;
- our ability to attract and retain key scientific and management personnel;
- our need for, and ability to obtain, additional financing;
- adverse results in material litigation matters or governmental inquiries;

- failure to obtain and maintain regulatory approval outside the U.S.;
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations; and
- our ability to finance and successfully complete construction of a research, development and manufacturing center in Waterford, Ireland.

## PART I. FINANCIAL INFORMATION

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

### Item 1. Financial Statements

**OPKO Health, Inc. and Subsidiaries**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(Unaudited)  
(In thousands, except share and per share data)

	March 31, 2018	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 99,943	\$ 91,499
Accounts receivable, net	158,642	165,516
Inventory, net	49,815	49,333
Other current assets and prepaid expenses	40,946	42,513
Total current assets	349,346	348,861
Property, plant and equipment, net	148,718	146,557
Intangible assets, net	667,637	683,835
In-process research and development	646,386	647,347
Goodwill	719,891	717,099
Investments	41,289	40,642
Other assets	5,627	5,615
Total assets	\$ 2,578,894	\$ 2,589,956
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 64,229	\$ 74,307
Accrued expenses	217,133	230,301
Current portion of 2033 Senior Notes	29,744	—
Current portion of lines of credit and notes payable	6,971	11,926
Total current liabilities	318,077	316,534
2023 Convertible Notes and 2033 Senior Notes	55,199	29,160
Deferred tax liabilities, net	148,732	148,729
Other long-term liabilities, principally contract liabilities, contingent consideration and line of credit	233,622	239,955
Total long-term liabilities	437,553	417,844
Total liabilities	755,630	734,378
Equity:		
Common Stock - \$0.01 par value, 750,000,000 shares authorized; 560,023,745 and 560,023,745 shares issued at March 31, 2018 and December 31, 2017, respectively	5,600	5,600
Treasury Stock - 549,907 and 549,907 shares at March 31, 2018 and December 31, 2017, respectively	(1,791)	(1,791)
Additional paid-in capital	2,895,191	2,889,256
Accumulated other comprehensive loss	(539)	(528)
Accumulated deficit	(1,075,197)	(1,036,959)
Total shareholders' equity	1,823,264	1,855,578
Total liabilities and equity	\$ 2,578,894	\$ 2,589,956

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

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

	For the three months ended March 31,	
	2018	2017
Revenues:		
Revenue from services	\$ 211,315	\$ 228,545
Revenue from products	27,851	22,231
Revenue from transfer of intellectual property and other	15,748	15,606
Total revenues	254,914	266,382
Costs and expenses:		
Cost of service revenue	139,441	139,966
Cost of product revenue	14,648	14,830
Selling, general and administrative	91,519	109,944
Research and development	32,887	26,557
Contingent consideration	1,759	2,371
Amortization of intangible assets	17,271	17,929
Total costs and expenses	297,525	311,597
Operating loss	(42,611)	(45,215)
Other income and (expense), net:		
Interest income	39	249
Interest expense	(2,267)	(1,429)
Fair value changes of derivative instruments, net	1,396	4,037
Other income (expense), net	1,893	3,042
Other income and (expense), net	1,061	5,899
Loss before income taxes and investment losses	(41,550)	(39,316)
Income tax benefit (provision)	892	6,944
Net loss before investment losses	(40,658)	(32,372)
Loss from investments in investees	(2,456)	(2,131)
Net loss	\$ (43,114)	\$ (34,503)
Loss per share, basic and diluted:		
Net loss per share	\$ (0.08)	\$ (0.06)
Weighted average common shares outstanding, basic and diluted	559,473,838	558,434,153

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

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

	For the three months ended March 31,	
	2018	2017
Net loss	\$ (43,114)	\$ (34,503)
Other comprehensive income (loss), net of tax:		
Change in foreign currency translation and other comprehensive income (loss)	4,865	2,592
Investments:		
Change in unrealized loss, net of tax	—	(536)
Reclassification adjustment due to adoption of ASU 2016-01	(4,876)	—
Comprehensive loss	<u>\$ (43,125)</u>	<u>\$ (32,447)</u>

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



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

	For the three months ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (43,114)	\$ (34,503)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	24,757	25,730
Non-cash interest	843	640
Amortization of deferred financing costs	43	56
Losses from investments in investees	2,456	2,131
Equity-based compensation – employees and non-employees	5,936	9,693
Loss (gain) on disposal of fixed assets	(261)	(2,997)
Change in fair value of equity securities and derivative instruments	(3,101)	(4,037)
Change in fair value of contingent consideration	1,759	2,371
Deferred income tax benefit	(2,709)	(9,236)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	6,757	(17,771)
Inventory, net	204	(50)
Other current assets and prepaid expenses	5,445	4,692
Other assets	(131)	(235)
Accounts payable	(10,206)	19,539
Foreign currency measurement	(11)	(69)
Contract liabilities	(15,358)	(13,849)
Accrued expenses and other liabilities	(8,829)	(16,024)
Net cash used in operating activities	(35,520)	(33,919)
Cash flows from investing activities:		
Investments in investees	(1,000)	—
Proceeds from sale of equity securities	1,286	—
Proceeds from the sale of property, plant and equipment	541	3,095
Capital expenditures	(5,973)	(9,537)
Net cash used in investing activities	(5,146)	(6,442)
Cash flows from financing activities:		
Issuance of 2033 Senior Notes, net, including related parties	55,000	—
Proceeds from the exercise of Common Stock options and warrants	—	1,866
Borrowings on lines of credit	6,611	7,825
Repayments of lines of credit	(12,420)	(7,517)
Net cash provided by financing activities	49,191	2,174
Effect of exchange rate changes on cash and cash equivalents	(81)	506
Net increase (decrease) in cash and cash equivalents	8,444	(37,681)
Cash and cash equivalents at beginning of period	91,499	168,733
Cash and cash equivalents at end of period	\$ 99,943	\$ 131,052

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

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

	For the three months ended March 31,	
	2018	2017
<b>SUPPLEMENTAL INFORMATION:</b>		
Interest paid	\$ 641	\$ 550
Income taxes paid, net of refunds	\$ 2,292	\$ 848
Non-cash financing:		
Shares issued upon the conversion of:		
Common Stock options and warrants, surrendered in net exercise	\$ —	\$ 696

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

**OPKO Health, Inc. and Subsidiaries**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)**

**NOTE 1 BUSINESS AND ORGANIZATION**

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories, Inc. (“BioReference”), the nation’s third-largest clinical laboratory with a core genetic testing business and an almost 400-person sales and marketing team to drive growth and leverage new products, including the *4Kscore* prostate cancer test and the *Claros 1* in-office immunoassay platform (in development). Our pharmaceutical business features *Rayaldee*, an FDA-approved treatment for secondary hyperparathyroidism (“SHPT”) in adults with stage 3 or 4 chronic kidney disease (“CKD”) and vitamin D insufficiency (launched in November 2016), OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia, OPK88003, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists (Phase 2b), 88002, a NK-1 antagonist to treat pruritis (itching) in dialysis patients, and OPK88001, a proprietary oligonucleotide to treat Dravet Syndrome. Our pharmaceutical business also features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a once-daily Factor VIIa drug for hemophilia. We are incorporated in Delaware and our principal executive offices are located in leased offices in Miami, Florida.

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

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

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

## NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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

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

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

*Inventories.* Inventories are valued at the lower of cost and net realizable value. Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost and net realizable value. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories. Inventory obsolescence expense for the three months ended March 31, 2017 was \$4.6 million.

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

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

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

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

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

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense was \$17.3 million and \$17.9 million for the three months ended March 31, 2018 and 2017, respectively.

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

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

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

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

*Property, plant and equipment.* Property, plant and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets and includes amortization expense for assets capitalized under capital leases. The estimated useful lives by asset class are as follows: software - 3 years, machinery, medical and other equipment - 5-8 years, furniture and fixtures - 5-12 years, leasehold improvements - the lesser of their useful life or the lease term, buildings and improvements - 10-40 years, automobiles - 3-5 years. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation expense was \$7.5 million and \$7.8 million for the three months ended March 31, 2018 and 2017, respectively. Assets held under capital leases are included within Property, plant and equipment, net in our Condensed Consolidated Balance Sheet and are amortized over the shorter of their useful lives or the expected term of their related leases.

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

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

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the “Tax Act”) was enacted into law and the new legislation contains several key tax provisions, including a reduction of the corporate income tax rate from 35% to 21% effective January 1, 2018, and a one-time mandatory transition tax on accumulated foreign earnings, among others. We are required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring our U.S. deferred tax assets and

liabilities, as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Act (“SAB 118”), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date.

Through March 31, 2018, we did not have any significant adjustments to our provisional amounts. As we continue to perform our analysis of the Tax Act, and interpret any additional accounting guidance issued by the FASB, the U.S. Department of the Treasury and the IRS, we may make adjustments to these provisional amounts.

Effective January 1, 2018, the Tax Act provides for a new global intangible low-taxed income (GILTI) provision. Under the GILTI provision, certain foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary’s tangible assets are included in U.S. taxable income. We are now subject to GILTI but have not triggered an income inclusion as of March 31, 2018. Any future inclusion is expected to be offset by net operating loss carry forwards in the U.S. We are still evaluating, pending further interpretive guidance, whether to make a policy election to treat the GILTI tax as a period expense or to provide U.S. deferred taxes on foreign temporary differences that are expected to generate GILTI income when they reverse in future years.

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

We operate in various countries and tax jurisdictions globally. For interim reporting purposes, we record income taxes based on the expected annual effective income tax rate taking into consideration global forecasted tax results. For the three months ended March 31, 2018, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the valuation allowance against certain U.S. and non-U.S. deferred tax assets, the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

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

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

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

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk since the related healthcare programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. At March 31, 2018 and December 31, 2017, receivable balances (net of contractual adjustments) from Medicare and Medicaid were 15.1% and 15.8%, respectively, of our consolidated Accounts receivable, net.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At March 31, 2018 and December 31, 2017, receivables due from patients represent approximately 2.7% and 3.2%, respectively, of our consolidated Accounts receivable, net.

We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer’s ability to pay. Actual results could differ from those estimates. Our reported



net income (loss) is directly affected by our estimate of the collectability of accounts receivable. The allowance for doubtful accounts was \$1.5 million and \$1.4 million at March 31, 2018 and December 31, 2017, respectively. The provision for bad debts for the three months ended March 31, 2018 and 2017 was \$0.1 million and \$0.9 million, respectively.

*Equity-based compensation.* We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options, as cash flows from operations. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. During the three months ended March 31, 2018 and 2017, we recorded \$5.9 million and \$9.7 million, respectively, of equity-based compensation expense.

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

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

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

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

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

*Variable interest entities.* The consolidation of a variable interest entity (“VIE”) is required when an enterprise has a controlling financial interest. A controlling financial interest in a VIE will have both of the following characteristics: (a) the power to direct the activities of a VIE that most significantly impact the VIE’s economic performance and (b) the obligation to absorb losses of the VIE that could potentially be significant to the VIE. Refer to Note 5.

*Investments.* We have made strategic investments in development stage and emerging companies. We record these investments as equity method investments or as equity securities based on our percentage of ownership and whether we have significant influence over the operations of the investees. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Losses from investments in investees in our Condensed Consolidated Statements of Operations. Refer to Note 5. For investments classified as equity securities, we record changes in their fair value as Other income (expense) in our Condensed Consolidated Statements of Operations based on their closing price per

share at the end of each reporting period unless the equity security does not have a readily determinable fair value. Refer to Note 5.

*Recently adopted accounting pronouncements.*

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

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

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

**Condensed Consolidated Statement of Operations**

	For the three months ended March 31, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Revenue from services	\$ 228,545	\$ 255,286	\$ (26,741)
Revenue from transfer of intellectual property and other	15,606	18,579	(2,973)
Selling, general and administrative	109,944	136,685	(26,741)
Research and development	26,557	26,022	535

**Condensed Consolidated Balance Sheet**

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



## Condensed Consolidated Statement of Cash Flows

	For the three months ended March 31, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Net loss	\$ (34,503)	\$ (30,995)	\$ (3,508)
Contract liabilities	(13,849)	(17,357)	3,508

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

In addition, under Topic 606, the upfront consideration received for a license and contract services combined performance obligation is recognized as revenue to the extent of costs incurred based on the length of the expected performance period and the subjectivity in estimating progress towards satisfaction of the performance obligation. Under previous accounting, we recognized revenue over the expected performance period. The adoption of Topic 606 resulted in a cumulative revenue reduction of \$29.8 million and an increase of our accumulated deficit balance as of December 31, 2017; with a corresponding increase in our contract liabilities. For the three months ended March 31, 2017, Revenue from the transfer of intellectual property and other was reduced by \$3.5 million for the change in accounting. For a further discussion of the adoption of Topic 606, see Note 12, "Revenue Recognition."

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

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

### *Pending accounting pronouncements.*

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," which will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

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

### **NOTE 3 EARNINGS (LOSS) PER SHARE**

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

A total of 16,570,675 and 2,623,001 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for three months ended March 31, 2018 and 2017, respectively, because their inclusion would be antidilutive. A full presentation of diluted earnings per share has not been provided because the required adjustments to the numerator and denominator resulted in diluted earnings per share equivalent to basic earnings per share.

During the three months ended March 31, 2018, no Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised.

During the three months ended March 31, 2017, 1,106,872 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 1,021,890 shares of Common Stock. Of the 1,106,872 Common Stock options and Common Stock warrants exercised, 84,982 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)	March 31, 2018	December 31, 2017
Accounts receivable, net:		
Accounts receivable	\$ 160,169	\$ 166,962
Less: allowance for doubtful accounts	(1,527)	(1,446)
	<u>\$ 158,642</u>	<u>\$ 165,516</u>
Inventories, net:		
Consumable supplies	\$ 22,138	\$ 21,546
Finished products	22,137	21,012
Work in-process	4,505	5,873
Raw materials	6,892	7,467
Less: inventory reserve	(5,857)	(6,565)
	<u>\$ 49,815</u>	<u>\$ 49,333</u>
Other current assets and prepaid expenses:		
Taxes recoverable	17,359	18,138
Other receivables	7,980	8,798
Prepaid supplies	9,058	8,207
Prepaid insurance	2,179	3,532
Other	4,370	3,838
	<u>\$ 40,946</u>	<u>\$ 42,513</u>
Intangible assets, net:		
Customer relationships	\$ 449,474	\$ 448,345
Technologies	341,044	340,921
Trade names	50,582	50,553
Licenses	10,306	10,305
Covenants not to compete	16,381	16,372
Product registrations	10,586	10,475
Other	5,920	5,799
Less: accumulated amortization	(216,656)	(198,935)
	<u>\$ 667,637</u>	<u>\$ 683,835</u>
Accrued expenses:		
Contract liabilities	\$ 61,378	\$ 61,388
Employee benefits	46,708	50,377
Clinical trials	14,130	12,191
Taxes payable	2,592	4,609
Contingent consideration	5,254	11,750
Capital leases short-term	3,366	3,399
Milestone payment	4,918	4,868
Professional fees	2,856	2,355
Other	75,931	79,364
	<u>\$ 217,133</u>	<u>\$ 230,301</u>

(In thousands)	March 31, 2018	December 31, 2017
Other long-term liabilities:		
Contract liabilities	\$ 63,642	\$ 78,990
Line of credit	105,091	104,152
Contingent consideration	37,858	29,603
Mortgages and other debts payable	1,432	1,567
Capital leases long-term	7,342	7,786
Other	18,257	17,857
	<u>\$ 233,622</u>	<u>\$ 239,955</u>

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

The changes in value of the intangible assets and goodwill during the three months ended March 31, 2018 are primarily due to foreign currency fluctuations between the Chilean Peso, the Euro and the Shekel against the U.S. dollar.

The following table summarizes the changes in Goodwill during the three months ended March 31, 2018.

(In thousands)	2018		
	Balance at January 1	Foreign exchange and other	Balance at March 31
<b>Pharmaceuticals</b>			
CURNA	\$ 4,827	\$ —	\$ 4,827
EirGen	89,226	2,564	91,790
FineTech	11,698	—	11,698
OPKO Chile	5,203	98	5,301
OPKO Biologics	139,784	—	139,784
OPKO Health Europe	7,898	227	8,125
OPKO Renal	2,069	—	2,069
Transition Therapeutics	3,608	(97)	3,511
<b>Diagnostics</b>			
BioReference	401,821	—	401,821
OPKO Diagnostics	17,977	—	17,977
OPKO Lab	32,988	—	32,988
	<u>\$ 717,099</u>	<u>\$ 2,792</u>	<u>\$ 719,891</u>

## NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

### Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of March 31, 2018:

(in thousands)

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	\$ 21,753	\$ 23,590
Variable interest entity, equity method	545	—
Equity securities	12,879	
Equity securities with no readily determinable fair value	1,108	
Warrants and options	5,004	
Total carrying value of investments	<u>\$ 41,289</u>	

### Equity method investments

Our equity method investments consist of investments in Pharmsynthez (ownership 9%), Cocrystal Pharma, Inc. (“COCP”) (9%), Non-Invasive Monitoring Systems, Inc. (“NIMS”) (1%), Neovasc (1%), VBI Vaccines Inc. (“VBI”) (10.4%), InCellDx, Inc. (29%), BioCardia, Inc. (“BioCardia”) (5%), and Xenetic Biosciences, Inc. (“Xenetic”) (4%). The total assets, liabilities, and net losses of our equity method investees as of and for the three months ended March 31, 2018 were \$382.2 million, \$(142.7) million, and \$(20.8) million, respectively. We have determined that we and/or our related parties can significantly influence the success of our equity method investments through our board representation and/or voting power. Accordingly, we account for our investment in these entities under the equity method and record our proportionate share of their losses in Loss from investments in investees in our Condensed Consolidated Statements of Operations. The aggregate value of our equity method investments based on the quoted market price of their common stock and the number of shares held by us as of March 31, 2018 is \$43.8 million.

### Equity Securities

Our equity securities consist of investments in RXi Pharmaceuticals Corporation (“RXi”) (ownership 2%), ChromaDex Corporation (0%), MabVax Therapeutics Holdings, Inc. (“MabVax”) (2%), and Eloxx Pharmaceuticals, Inc. (“Eloxx”) (5%). We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of these investments. Accordingly, we account for our investment in these entities as equity securities, and we record changes in the fair value of these investments in Other income (expense) each reporting period when they have readily determinable fair value. Equity securities without a readily determinable fair value are adjusted to fair value when an observable price change can be identified. Net gains and losses on our equity securities for the three months ended March 31, 2018 are as follows:

(in thousands)

Equity Securities	For the three months ended March 31, 2018
Net gains recognized during the period on equity securities	\$ 1,818
Less: Net losses recognized during the period on equity securities sold during the period	(113)
Unrealized net gains and losses recognized during the period on equity securities still held at the reporting date	<u>\$ 1,931</u>

### Sales of investments

Gains (losses) included in earnings from sales of our investments are recorded in Other income (expense), net in our Condensed Consolidated Statements of Operations. We did not have significant sales activity during the three months ended March 31, 2018 and 2017. The cost of securities sold is based on the specific identification method.

### Warrants and options

In addition to our equity method investments and equity securities, we hold options to purchase 0.4 million additional shares of BioCardia, 0.1 million of which are vested as of March 31, 2018, and 1.0 million, 0.7 million, 0.5 million, 0.2 million and 4.9 million of warrants to purchase additional shares of COCP, InCellDx, Inc., Xenetic and RXi and NeoVasc, respectively. We

recorded the changes in the fair value of the options and warrants in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations. We also recorded the fair value of the options and warrants in Investments, net in our Condensed Consolidated Balance Sheets. See further discussion of the Company's options and warrants in Note 8 and Note 9.

*Investments in variable interest entities*

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

We own 1,260,000 shares of Zebra Series A-2 Preferred Stock and 900,000 shares of Zebra restricted common stock (ownership 29% at March 31, 2018). Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Dr. Richard Lerner, M.D., a member of our Board of Directors, is a founder of Zebra and, along with Dr. Frost, serves as a member of Zebra's Board of Directors.

In order to determine the primary beneficiary of Zebra, we evaluated our investment and our related parties' investment, as well as our investment combined with the related party group's investment to identify if we had the power to direct the activities that most significantly impact the economic performance of Zebra. Based on the capital structure, governing documents and overall business operations of Zebra, we determined that, while a VIE, we do not have the power to direct the activities that most significantly impact Zebra's economic performance and have no obligation to fund expected losses. We did determine, however, that we can significantly influence the success of Zebra through our board representation and voting power. Therefore, we have the ability to exercise significant influence over Zebra's operations and account for our investment in Zebra under the equity method.

## NOTE 6 DEBT

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

The issuance of the 2023 Convertible Notes and the issuance of the Shares, if any, upon conversion thereof was not, and will not be, respectively, registered under the Securities Act of 1933, pursuant to the exemption provided by Section 4(a)(2) thereof, and we have not agreed to register the Shares if or when such Shares are issued.

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

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

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

(In thousands)	2033 Senior Notes	Discount	Debt Issuance Cost	Total
Balance at December 31, 2017	\$ 31,850	\$ (2,565)	\$ (125)	\$ 29,160
Amortization of debt discount and debt issuance costs	—	547	37	584
Balance at March 31, 2018	\$ 31,850	\$ (2,018)	\$ (88)	\$ 29,744

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

On or after February 1, 2017 and before February 1, 2019, we may redeem for cash any or all of the 2033 Senior Notes but only if the last reported sale price of our Common Stock exceeds 130% of the applicable conversion price for at least 20 trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date on which we



deliver the redemption notice. The redemption price will equal 100% of the principal amount of the 2033 Senior Notes to be redeemed, plus any accrued and unpaid interest to but not including the redemption date. On or after February 1, 2019, we may redeem for cash any or all of the 2033 Senior Notes at a redemption price of 100% of the principal amount of the 2033 Senior Notes to be redeemed, plus any accrued and unpaid interest up to but not including the redemption date.

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

For accounting and financial reporting purposes, we combined these embedded derivatives and valued them together as one unit of accounting.

The change in derivative income for the three months ended March 31, 2017 related to the embedded derivatives was \$3.2 million and the fair value at that date was \$13.6 million. In 2017, certain terms of the embedded derivatives expired pursuant to the original agreement and the embedded derivatives no longer met the criteria to be separated from the host contract and, as a result, the embedded derivatives are no longer required to be valued separate and apart from the 2033 Senior Notes and were reclassified to additional paid in capital. Accordingly, there was no derivative income (loss) for the three months ended March 31, 2018.

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

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

In November 2015, BioReference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. ("CB"), as lender and administrative agent, as amended (the "Credit Agreement"). The Credit Agreement provides for a \$175.0 million secured revolving credit facility and includes a \$20.0 million sub-facility for swingline loans and a \$20.0 million sub-facility for the issuance of letters of credit. BioReference may increase the credit facility to up to \$275.0 million on a secured basis, subject to the satisfaction of specified conditions. The Credit Agreement matures on November 5, 2020 and is guaranteed by all of BioReference's domestic subsidiaries. The Credit Agreement is also secured by substantially all assets of BioReference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in BioReference. Availability under the Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein. As of March 31, 2018, \$12.7 million was available to be borrowed under the Credit Agreement. Principal under the Credit Agreement is due upon maturity on November 5, 2020.

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

In February 2018, BioReference and certain of its subsidiaries entered into Amendment No. 7 to the Credit Agreement, which amended the Credit Agreement to permit BioReference and its subsidiaries to use cash on hand, up to a maximum amount set forth in the amendment, to meet the availability requirements that otherwise would trigger (i) covenants that would



require BioReference to maintain a minimum fixed charge coverage ratio and provide certain increased reporting under the Credit Agreement and (ii) CB's right, as agent for the lenders under the Credit Agreement, to exercise sole dominion over funds held in certain accounts of BioReference. The other terms of the Credit Agreement remain unchanged.

The Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require BioReference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws and restrictions on the ability of BioReference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the Credit Agreement, notwithstanding the ability of BioReference to meet its debt service obligations. The Credit Agreement also includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Credit Agreement and execution upon the collateral securing obligations under the Credit Agreement. Substantially all the assets of BioReference and its subsidiaries are restricted from sale, transfer, lease, disposal or distributions to the Company, subject to certain exceptions. BioReference and its subsidiaries net assets as of March 31, 2018 were approximately \$0.9 billion, which includes goodwill of \$401.8 million and intangible assets of \$436.0 million.

In addition to the Credit Agreement with CB, we have line of credit agreements with eleven other financial institutions as of March 31, 2018 and December 31, 2017 in the 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 BioReference, Chilean and Spanish lines of credit:

(Dollars in thousands)			Balance Outstanding	
Lender	Interest rate on borrowings at March 31, 2018	Credit line capacity	March 31, 2018	December 31, 2017
JPMorgan Chase	3.27%	\$ 175,000	\$ 105,091	\$ 104,152
Itau Bank	5.50%	1,810	275	446
Bank of Chile	6.60%	3,800	1,090	1,598
BICE Bank	5.50%	2,500	863	1,819
BBVA Bank	5.50%	3,250	500	1,665
Security Bank	5.50%	573	573	501
Estado Bank	5.50%	3,500	930	2,111
Santander Bank	5.50%	4,500	1,243	1,988
Scotiabank	5.00%	1,800	378	384
Corpbanca	5.00%	—	—	—
Banco Bilbao Vizcaya	2.90%	308	—	—
Santander Bank	2.67%	370	—	—
Total		\$ 197,411	\$ 110,943	\$ 114,664

At March 31, 2018 and December 31, 2017, the weighted average interest rate on our lines of credit was approximately 4.1% and 4.2%, respectively.

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

(In thousands)	March 31, 2018	December 31, 2017
Current portion of notes payable	\$ 1,339	\$ 1,632
Other long-term liabilities	2,085	2,011
Total	\$ 3,424	\$ 3,643

The notes and other debt mature at various dates ranging from 2018 through 2024 bearing variable interest rates from 1.8% up to 6.3%. The weighted average interest rate on the notes and other debt at March 31, 2018 and December 31, 2017, was 2.5% and 3.0%, respectively. The notes are secured by our office space in Barcelona.

## NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

For the three months ended March 31, 2018, changes in Accumulated other comprehensive income (loss), net of tax, were as follows:

(In thousands)	Foreign currency	Unrealized gain (loss) in Accumulated OCI	Total
Balance at December 31, 2017	\$ (5,404)	\$ 4,876	\$ (528)
Other comprehensive income (loss) before reclassifications	4,865	—	4,865
Reclassification adjustment due to adoption of ASU 2016-01	—	(4,876)	(4,876)
Net other comprehensive income (loss)	4,865	(4,876)	(11)
Balance at March 31, 2018	\$ (539)	\$ —	\$ (539)

## NOTE 8 FAIR VALUE MEASUREMENTS

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

As of March 31, 2018, we have money market funds that qualify as cash equivalents, equity securities (refer to Note 5), forward foreign currency exchange contracts for inventory purchases (refer to Note 9) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics and OPKO Renal that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with BioCardia, we record the related BioCardia options at fair value as well as the warrants from COCP, InCellDx, Inc., Xenetic, RXi and Neovasc.

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

(In thousands)	Fair value measurements as of March 31, 2018			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Equity securities	12,879	—	—	12,879
Common stock options/warrants	—	5,004	—	5,004
Total assets	\$ 12,879	\$ 5,004	\$ —	\$ 17,883
Liabilities:				
Forward contracts	—	104	—	104
Contingent consideration	—	—	43,112	43,112
Total liabilities	\$ —	\$ 104	\$ 43,112	\$ 43,216

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

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

The following table reconciles the beginning and ending balances of our Level 3 assets and liabilities as of March 31, 2018:

(In thousands)	March 31, 2018
Balance at December 31, 2017	\$ 41,353
Change in fair value:	
Included in results of operations	1,759
Balance at March 31, 2018	<u>\$ 43,112</u>

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

*Contingent consideration* – We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to OPKO Diagnostics, CURNA and OPKO Renal transactions. If estimated future sales were to decrease by 10%, the contingent consideration related to OPKO Renal, which represents the majority of our contingent consideration liability, would decrease by \$2.5 million. As of March 31, 2018, of the \$43.1 million of contingent consideration, \$5.3 million is recorded in Accrued expenses and \$37.9 million is recorded in Other long-term liabilities. As of December 31, 2017, of the \$41.4 million of contingent consideration, \$11.8 million is recorded in Accrued expenses and \$29.6 million is recorded in Other long-term liabilities.

## NOTE 9 DERIVATIVE CONTRACTS

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

(In thousands)	Balance Sheet Component	March 31, 2018	December 31, 2017
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	\$ 5,004	\$ 3,333
Forward contracts	Unrealized gains on forward contracts are recorded in Other current assets and prepaid expenses. Unrealized (losses) on forward contracts are recorded in Accrued expenses.	\$ (104)	\$ (317)

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

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

(In thousands)	Three months ended March 31,	
	2018	2017
Derivative gain (loss):		
Common Stock options/warrants	\$ 1,671	\$ (955)
2033 Senior Notes	—	4,945
Forward contracts	(275)	47
Total	<u>\$ 1,396</u>	<u>\$ 4,037</u>

## NOTE 10 RELATED PARTY TRANSACTIONS

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

We hold investments in Zebra (ownership 29%), Neovasc (1%), ChromaDex Corporation (0%), MabVax (2%), COCP (9%), NIMS (1%) and BioCardia (5%). These investments were considered related party transactions as a result of our executive management's ownership interests and/or board representation in these entities. See further discussion of our investments in Note 5.

In February 2018, we invested an additional \$1.0 million in COCP for a convertible note, which is convertible into 123,456 shares of its common stock. In April 2017, we invested an additional \$1.0 million in COCP for 138,889 shares of its common stock, and in August 2016, we had invested an additional \$2.0 million in COCP for 162,602 shares of its common stock.

In November 2017, we invested an additional \$3.0 million in Neovasc for 2,054,794 shares of its common stock, 2,054,794 Series A warrants, 2,054,794 Series B warrants and 822,192 Series C warrants.

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

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

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

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

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost for out-of-pocket operating costs for the use of the airplane by Dr. Frost or Company executives for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive. For the three months ended March 31, 2018 and 2017, we recognized approximately \$79 thousand and \$20 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

## NOTE 11 COMMITMENTS AND CONTINGENCIES

In connection with our acquisitions of CURNA, OPKO Diagnostics and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of March 31, 2018, we have recorded \$43.1 million as contingent consideration, with \$5.3 million recorded within Accrued expenses and \$37.9 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

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

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

We currently anticipate that a decision by the VHA with respect to the RFP will occur during 2018, although there can be no assurance that a decision will be made by such time or that, if favorable, such decision will not be challenged by participants in the RFP process or otherwise.

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review established accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For the matters referenced in the paragraph below, the amount of liability is not probable or the amount cannot be reasonably estimated; and, therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for matters which the likelihood of material loss is at least reasonably possible, we provide disclosure of the possible loss or range of loss; however, if a reasonable estimate cannot be made, we will provide disclosure to that effect.

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

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

In April 2017, the Civil Division of the United States Attorney’s Office for the Southern District of New York (the “SDNY”) informed BioReference that it believes that, from 2006 to the present, BioReference had, in violation of the False Claims Act, improperly billed Medicare and TRICARE (both are federal government healthcare programs) for clinical laboratory services provided to hospital inpatient beneficiaries at certain hospitals. BioReference is reviewing and assessing

the allegations made by the SDNY, and, at this point, BioReference has not determined whether there is any merit to the SDNY's claims nor can it determine the extent of any potential liability. While management cannot predict the outcome of these matters at this time, the ultimate outcome could be material to our business, financial condition, results of operations, and cash flows.

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

At March 31, 2018, we were committed to make future purchases for inventory and other items in 2018 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating \$82.5 million.

## **NOTE 12 REVENUE RECOGNITION**

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

### *Revenue from services*

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

The following are descriptions of our payors for laboratory services:

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

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

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

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

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, require us to estimate the potential for retroactive adjustments as an element of variable



consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known.

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

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

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

The composition of Revenue from services by payor for the three months ended March 31, 2018 and 2017 is as follow:

(In thousands)	Three months ended March 31,	
	2018	2017
Healthcare insurers	\$ 100,953	\$ 112,696
Government payers	67,136	77,053
Client payers	37,529	33,939
Patients	5,697	4,857
Total	<u>\$ 211,315</u>	<u>\$ 228,545</u>

#### *Revenue from products*

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

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



We recognize revenue for shipments of *Royaldee* at the time of delivery to customers after estimating Sales Deductions and product returns as elements of variable consideration utilizing historical information and market research projections. For the three months ended March 31, 2018, we recognized \$3.7 million in net product revenue from sales of *Royaldee*. Amounts shipped prior to March 31, 2017 were insignificant.

The following table presents an analysis of product sales allowances and accruals as contract liabilities for the three months ended March 31, 2018:

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2017	\$ 233	\$ 348	\$ 437	\$ 1,018
Provision related to current period sales	961	1,339	(70)	2,230
Credits or payments made	(805)	(955)	(185)	(1,945)
Balance at March 31, 2018	<u>\$ 389</u>	<u>\$ 732</u>	<u>\$ 182</u>	<u>\$ 1,303</u>
Total gross <i>Royaldee</i> sales				\$ 5,922
Provision for <i>Royaldee</i> sales allowances and accruals as a percentage of gross <i>Royaldee</i> sales				38%

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

#### *Revenue from intellectual property*

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

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

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

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

until we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We re-evaluate the probability of achievement of such development milestones and any related constraint each reporting period. We adjust our estimate of the overall transaction price, including the amount of revenue recorded, if necessary.

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

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

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

For the three months ended March 31, 2018 and 2017, revenue from transfer of intellectual property principally reflects \$14.7 million and \$14.1 million of revenue, respectively related to the Pfizer Transaction. Refer to Note 13. Total contract liabilities included in Accrued expenses and Other long-term liabilities was \$125.0 million and \$140.4 million at March 31, 2018 and December 31, 2017, respectively. The contract liability balance at March 31, 2018 relates primarily to the Pfizer Transaction.

## **NOTE 13 STRATEGIC ALLIANCES**

### *Japan Tobacco Inc.*

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

In connection with the license, OPKO received an initial upfront payment of \$6 million ("JT Upfront Payment"). OPKO will receive another \$6 million upon the initiation of OPKO's planned phase 2 study for *Royaldee* in dialysis patients in the U.S. OPKO is also eligible to receive up to an additional aggregate amount of \$31 million upon the achievement of certain regulatory and development milestones by JT for *Royaldee* in the JT Territory, and \$75 million upon the achievement of certain sales based milestones by JT in the JT Territory. OPKO will also receive tiered, double digit royalty payments at rates ranging from low double digits to mid-teens on net sales of *Royaldee* within the JT Territory. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for *Royaldee* in Japan and for all commercial activities pertaining to *Royaldee* in Japan, except for certain preclinical expenses which OPKO has agreed to reimburse JT up to a capped amount ("Preclinical Expenses").

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

The initial consideration primarily includes the non-refundable \$6 million upfront payment and \$6 million of probable variable consideration we will receive upon the initiation of our planned phase 2 study for *Royaldee* in dialysis patients in the

U.S. The initial consideration will be recognized over the performance period through 2021, when we anticipate completing the transfer of license materials specified in the JT Agreement and our performance obligation is complete.

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

*Vifor Fresenius Medical Care Renal Pharma Ltd*

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

Under the terms of the VFMCRP Agreement, EirGen granted to VFMCRP an exclusive license in the VFMCRP Territory in the VFMCRP Field to use certain EirGen patents and technology to make, have made, use, sell, offer for sale, and import Products and to develop, commercialize, have commercialized, and otherwise exploit the Product. EirGen received a non-refundable and non-creditable initial payment of \$50 million, which was recognized in Revenue from the transfer of intellectual property and other in our Condensed Consolidated Statement of Operations in 2016. EirGen is also eligible to receive up to an additional \$37 million in regulatory milestones (“Regulatory Milestones”) and \$195 million in launch and sales-based milestones (“Sales Milestones”), and will receive tiered royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon the commencement of sales of the Product within the VFMCRP Territory and in the VFMCRP Field.

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

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 of sales-based milestones upon the achievement of certain milestones and would be obligated to pay royalties at percentage rates that range from the mid-teens to the mid-twenties on sales of the Product in the United States for the Dialysis Indication. To date, VFMCRP has not exercised its option.

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 the period in which the associated milestone is achieved or sales occur, assuming all other revenue recognition criteria are met. To date, no revenue has been recognized related to the milestones or royalties.

*Pfizer Inc.*

In December 2014, we entered into an exclusive worldwide agreement with Pfizer Inc. (“Pfizer”) for the development and commercialization of our long-acting hGH-CTP for the treatment of growth hormone deficiency (“GHD”) in adults and

children, as well as for the treatment of growth failure in children born small for gestational age (“SGA”) (the “Pfizer Transaction”).

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

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

We are recognizing the non-refundable \$295.0 million upfront payments as the research and development services are completed. We recognized \$14.7 million and \$14.1 million of revenue related to the Pfizer Transaction in Revenue from transfer of intellectual property in our Condensed Consolidated Statements of Operations during the three months ended March 31, 2018 and 2017, respectively, and had contract liabilities related to the Pfizer Transaction of \$116.4 million at March 31, 2018. As of March 31, 2018, \$58.8 million of contract liabilities related to the Pfizer Transaction was classified in Accrued expenses and \$57.6 million was classified in Other long-term liabilities in our Condensed Consolidated Balance Sheets.

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

#### *TESARO*

In November 2009, we entered into an asset purchase agreement (the “NK-1 Agreement”) under which we acquired VARUBI™ (rolapitant) and other neurokinin-1 (“NK-1”) assets from Merck. In December 2010, we entered into an exclusive license agreement with TESARO, in which we out-licensed the development, manufacture, commercialization and distribution of our lead NK-1 candidate, VARUBI™ (the “TESARO License”). Under the terms of the license, we received a \$6.0 million upfront payment from TESARO and we received \$30 million of milestone payments from TESARO upon achievement of certain regulatory and commercial sale milestones and we are eligible to receive additional commercial milestone payments of up to \$85 million if specified levels of annual net sales are achieved. The sales based milestone payments will be recognized as revenue in full in the period in which the associated sales occur. During the three months ended March 31, 2018 and 2017, no revenue was recognized related to the achievement of the milestones under the TESARO License.

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

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

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

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

### *Pharmsynthez*

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

### *RXi Pharmaceuticals Corporation*

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

### *Other*

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

## **NOTE 14**

### **SEGMENTS**

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 acquisition of BioReference and our point-of-care operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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

(In thousands)	For the three months ended March 31,	
	2018	2017
Revenue from services:		
Pharmaceutical	\$ —	\$ —
Diagnostics	211,315	228,545
Corporate	—	—
	<u>\$ 211,315</u>	<u>\$ 228,545</u>
Revenue from products:		
Pharmaceutical	\$ 27,851	\$ 22,231
Diagnostics	—	—
Corporate	—	—
	<u>\$ 27,851</u>	<u>\$ 22,231</u>
Revenue from transfer of intellectual property and other:		
Pharmaceutical	\$ 15,748	\$ 15,606
Diagnostics	—	—
Corporate	—	—
	<u>\$ 15,748</u>	<u>\$ 15,606</u>
Operating loss:		
Pharmaceutical	\$ (22,948)	\$ (26,145)
Diagnostics	(8,018)	(3,100)
Corporate	(11,645)	(15,970)
	<u>\$ (42,611)</u>	<u>\$ (45,215)</u>
Depreciation and amortization:		
Pharmaceutical	\$ 6,740	\$ 6,775
Diagnostics	17,987	18,925
Corporate	30	30
	<u>\$ 24,757</u>	<u>\$ 25,730</u>
Loss from investment in investees:		
Pharmaceutical	\$ (2,172)	\$ (1,814)
Diagnostics	(284)	(317)
Corporate	—	—
	<u>\$ (2,456)</u>	<u>\$ (2,131)</u>
Revenues:		
United States	\$ 215,311	\$ 229,436
Ireland	17,282	17,209
Chile	11,733	10,121
Spain	5,532	4,505
Israel	3,614	4,217
Mexico	1,420	865
Other	22	29
	<u>\$ 254,914</u>	<u>\$ 266,382</u>



(In thousands)	March 31, 2018	December 31, 2017
Assets:		
Pharmaceutical	\$ 1,294,067	\$ 1,287,964
Diagnostics	1,226,077	1,241,388
Corporate	58,750	60,604
	<u>\$ 2,578,894</u>	<u>\$ 2,589,956</u>
Goodwill:		
Pharmaceutical	\$ 267,104	\$ 264,313
Diagnostics	452,787	452,786
Corporate	—	—
	<u>\$ 719,891</u>	<u>\$ 717,099</u>

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

#### NOTE 15 SUBSEQUENT EVENTS

We have reviewed all subsequent events and transactions that occurred after the date of our March 31, 2018 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, 2017 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part II, Item 1A of our Form 10-K for the year ended December 31, 2017, and described from time to time in our other reports filed with the Securities and Exchange Commission. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.*

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories ("BioReference"), the nation's third-largest clinical laboratory with a core genetic testing business and an almost 400-person sales and marketing team to drive growth and leverage new products, including the *4Kscore* prostate cancer test and the *Claros 1* in-office immunoassay platform (in development). Our pharmaceutical business features *Royaldee*, an FDA-approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency (launched in November 2016), OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia, OPK88003, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists (Phase 2b), OPK88002, an NK-1 antagonist to treat pruritis (itching) in dialysis patients, and OPK88001, a proprietary oligonucleotide to treat Dravet Syndrome. Our pharmaceutical business also features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a once-daily Factor VIIa drug for hemophilia.

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

### RECENT DEVELOPMENTS

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

The issuance of the 2023 Convertible Notes and the issuance of the Shares, if any, upon conversion thereof was not, and will not be, respectively, registered under the Securities Act of 1933, pursuant to the exemption provided by Section 4(a)(2) thereof, and we have not agreed to register the Shares if or when such Shares are issued.

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



## RESULTS OF OPERATIONS

### FOR THE THREE MONTHS ENDED MARCH 31, 2018 AND 2017

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

#### Revenues

(In thousands)	For the three months ended March 31,		
	2018	2017	Change
Revenue from services	\$ 211,315	\$ 228,545	\$ (17,230)
Revenue from products	27,851	22,231	5,620
Revenue from transfer of intellectual property and other	15,748	15,606	142
Total revenues	<u>\$ 254,914</u>	<u>\$ 266,382</u>	<u>\$ (11,468)</u>

The decrease in Revenue from services is attributable to decreased volume and overall reimbursement at BioReference, which was partially offset by increased volume and reimbursement at BioReference's GeneDx division. The increase in Revenue from products is attributable to an increase in revenue from OPKO Chile and Spain and to \$3.7 million of revenue from sales of *Rayaldee*. Revenue from transfer of intellectual property for the three months ended March 31, 2018 and 2017 principally reflects \$14.7 million and \$14.1 million, respectively, of revenue related to the Pfizer Transaction. The composition of Revenue from services by payor for the three months ended March 31, 2018 and 2017 is as follow:

(In thousands)	Three months ended March 31,	
	2018	2017
Healthcare insurers	\$ 100,953	\$ 112,696
Government payers	67,136	77,053
Client payers	37,529	33,939
Patients	5,697	4,857
Total	<u>\$ 211,315</u>	<u>\$ 228,545</u>

*Cost of revenue.* Cost of revenue for the three months ended March 31, 2018 was consistent with the comparative period in 2017. Cost of service revenue as a percent of revenue increased in the first quarter of 2018 compared to 2017 due to a change in the mix of accessions performed and a decrease in reimbursement at BioReference. Cost of revenue for the three months ended March 31, 2018 and 2017 were as follows:

#### Cost of Revenue

(In thousands)	For the three months ended March 31,		
	2018	2017	Change
Cost of service revenue	\$ 139,441	\$ 139,966	\$ (525)
Cost of product revenue	14,648	14,830	(182)
Total cost of revenue	<u>\$ 154,089</u>	<u>\$ 154,796</u>	<u>\$ (707)</u>

*Selling, general and administrative expenses.* Selling, general and administrative expenses for the three months ended March 31, 2018 and 2017, were \$91.5 million and \$109.9 million, respectively. The decrease in selling, general and administrative expenses was primarily due to decreased selling, general and administrative expenses at BioReference due to planned cost reduction initiatives. Selling, general and administrative expenses during the three months ended March 31, 2018 and 2017, include equity-based compensation expense of \$4.1 million and \$7.9 million, respectively.

*Research and development expenses.* Research and development expenses for the three months ended March 31, 2018 and 2017, were \$32.9 million and \$26.6 million, respectively. Research and development costs include external and internal expenses. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and pre-market approvals

(“PMAs”) for diagnostics tests, if any. Internal expenses include employee-related expenses including salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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

Research and Development Expenses	For the three months ended March 31,	
	2018	2017
External expenses:		
Phase 3 clinical trials	\$ 3,778	\$ 4,614
Manufacturing expense for biological products	11,294	6,394
PMA studies	59	—
Earlier-stage programs	3,166	1,994
Research and development employee-related expenses	8,651	6,666
Other internal research and development expenses	5,939	6,889
Total research and development expenses	<u>\$ 32,887</u>	<u>\$ 26,557</u>

The increase in research and development expenses is primarily due to an increase in research and development expenses related to hGH-CTP, a long acting human growth hormone which was outlicensed to Pfizer in 2015. Research and development expenses for the three months ended March 31, 2018 and 2017 include equity-based compensation expense of \$1.1 million and \$1.4 million, respectively. We expect our research and development expenses to increase as we continue to expand our research and development of potential future products.

*Contingent consideration.* Contingent consideration expense for the three months ended March 31, 2018 and 2017, were \$1.8 million and \$2.4 million, respectively. The contingent consideration expense for the three months ended March 31, 2018 and 2017, was primarily attributable to an increase in the fair value of our contingent obligations for OPKO Renal due to the time value of money. The contingent consideration liabilities at March 31, 2018 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011 and March 2013, respectively.

*Amortization of intangible assets.* Amortization of intangible assets was \$17.3 million and \$17.9 million, respectively, for the three months ended March 31, 2018 and 2017. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Our indefinite lived IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, the IPR&D assets will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

*Interest income.* Interest income for the three months ended March 31, 2018 and 2017 was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

*Interest expense.* Interest expense for the three months ended March 31, 2018 and 2017 was \$2.3 million and \$1.4 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes including amortization of related deferred financing costs, to interest incurred on BioReference’s outstanding debt under its credit facility and to interest incurred on the 2023 Convertible Notes issued in February 2018. The increase in interest expense for the three months ended March 31, 2018 is primarily due to higher outstanding debt under BioReference’s credit facility in 2018 compared to 2017.

*Fair value changes of derivative instruments, net.* Fair value changes of derivative instruments, net for the three months ended March 31, 2018 and 2017, was \$1.4 million and \$4.0 million of income, respectively. Derivative income for the three months ended March 31, 2018 principally related to the change in fair value of warrants to purchase additional shares of Neovasc, Inc. Derivative income for the three months ended March 31, 2017 principally related to the change in the fair value of the embedded derivatives in the 2033 Senior Notes.

*Other income (expense), net.* Other income (expense), net for the three months ended March 31, 2018 and 2017, were \$1.9 million and \$3.0 million of income, respectively. Other income for the three months ended March 31, 2018 primarily consists of net gains recognized during the period on equity securities. Other income for the three months ended March 31, 2017 primarily consists of a \$3.0 million gain on the sale of non-strategic assets at a wholly-owned BioReference subsidiary.

*Income tax benefit (provision).* Our income tax benefit (provision) for the three months ended March 31, 2018 and 2017 was \$0.9 million and \$6.9 million, respectively, and reflects quarterly results using our expected effective tax rate for the full year. For the three months ended March 31, 2018, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the valuation allowance against certain U.S. and non-U.S. deferred tax assets, the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

*Loss from investments in investees.* We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report a net loss. Loss from investments in investees was \$2.5 million and \$2.1 million for the three months ended March 31, 2018 and 2017, respectively.

## LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2018, we had cash and cash equivalents of approximately \$99.9 million. Cash used in operations of \$35.5 million during 2018 principally reflects expenses related to general and administrative activities of our corporate operations, research and development activities and commercialization activities related to *Royaldee*. Cash used in investing activities primarily reflects capital expenditures of \$6.0 million. Cash provided by financing activities primarily reflects the issuance of \$55.0 million of 2023 Convertible Notes in February 2018. We have not generated sustained positive cash flow sufficient to offset our operating and other expenses and our primary source of cash has been from the public and private placement of stock, the issuance of the 2033 Senior Notes and 2023 Convertible Notes and credit facilities available to us.

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

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

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

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

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

We currently anticipate that a decision by the VHA with respect to the RFP will occur during 2018, although there can be no assurance that a decision will be made by such time or that, if favorable, such decision will not be challenged by participants in the RFP process or otherwise.

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

In May 2016, EirGen, our wholly-owned subsidiary, partnered with VFMCRP through a Development and License Agreement for the development and commercialization of *Royaldee* in Europe, Canada, Mexico, Australia, South Korea and certain other international markets. The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the product in human patients, provided that initially the license is for the use of the product for the treatment or prevention of SHPT related to patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency/deficiency (“VFMCRP Initial Indication”). We received a non-refundable and non-creditable upfront payment of \$50 million and are eligible to receive up to an additional \$232 million upon the achievement of certain regulatory and sales-based milestones. In addition, we are eligible to receive tiered royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon commencement of sales of the product.

As part of the arrangement, the companies will share responsibility for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. For the initial development plan, the companies have agreed to certain cost sharing arrangements. VFMCRP will be responsible for all other development costs that VFMCRP considers necessary to develop the product for the VFMCRP Initial Indication in the VFMCRP Territory except as otherwise provided in the VFMCRP Agreement. EirGen also granted to VFMCRP an option to acquire an exclusive license to use, import, offer for sale, sell, distribute and commercialize the product in the United States for treatment of SHPT in dialysis patients with stage 5 CKD and vitamin D insufficiency (the “Dialysis Indication”). Upon exercise of the Option, VFMCRP will reimburse EirGen for all of the development costs incurred by EirGen with respect to the product for the Dialysis Indication in the United States. VFMCRP would also pay EirGen up to an additional aggregate amount of \$555 million upon the achievement of certain milestones and would be obligated to pay royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon commencement of sales of the product.

In January 2015, we partnered with Pfizer through a worldwide agreement for the development and commercialization of our long-acting hGH-CTP for the treatment of GHD in adults and children, as well as for the treatment of growth failure in children born SGA. Under the terms of the agreements with Pfizer, we received non-refundable and non-creditable upfront payments of \$295 million in 2015 and are eligible to receive up to an additional \$275 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both hGH-CTP and Pfizer’s Genotropin®.

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

We have completed post-hoc sensitivity analyses to evaluate the influence of outliers on the primary endpoint results using multiple statistical approaches. Analyses that excluded outliers showed a statistically significant difference between hGH-CTP and placebo on the change in trunk fat mass. Additional analyses that did not exclude outliers showed mixed results. Following completion of the analyses, OPKO and Pfizer agreed that OPKO may proceed to discuss a possible BLA submission with the FDA.

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



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 March 31, 2018, \$31.9 million principal amount of 2033 Senior Notes was outstanding.

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

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

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

As of March 31, 2018, the total availability under our Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain was \$127.5 million, of which \$110.9 million was used and outstanding as of March 31, 2018. The weighted average interest rate on these lines of credit is approximately 4.1%. 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 three months ended March 31, 2018, was \$114.9 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

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

We believe that the cash and cash equivalents on hand at March 31, 2018, the amounts available to be borrowed under our lines of credit and the proceeds from the 2023 Convertible Promissory Notes which we issued in the first quarter of 2018 are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements will depend on a number of factors, including our relationship with Pfizer, the commercial success of *Rayaldee*, BioReference's financial performance, possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, our success in developing markets for our product candidates and results of government investigations, payor claims, and legal proceedings that may arise. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions.

The following table provides information as of March 31, 2018, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining nine months ending December 31, 2018	2019	2020	2021	2022	Thereafter	Total
Open purchase orders	\$ 82,058	\$ 416	\$ 57	\$ —	\$ —	\$ —	\$ 82,531
Operating leases	18,139	15,145	9,023	5,948	2,642	3,115	54,012
Capital leases	2,492	2,890	2,473	1,739	643	470	10,707
2033 Senior Notes and 2023 Convertible Notes	—	31,850	—	—	—	55,000	86,850
Deferred payments	5,000	5,000	—	—	—	—	10,000
Mortgages and other debts payable	1,264	474	525	487	379	379	3,508
Lines of credit	5,852	—	105,091	—	—	—	110,943
Severance payments	3,568	—	—	—	—	—	3,568
Interest commitments	768	214	40	30	16	13,713	14,781
Total	<u>\$ 119,141</u>	<u>\$ 55,989</u>	<u>\$ 117,209</u>	<u>\$ 8,204</u>	<u>\$ 3,680</u>	<u>\$ 72,677</u>	<u>\$ 376,900</u>

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

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



## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

*Accounting estimates.* The preparation of financial statements in conformity with 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 and other intangible assets, including IPR&D, acquired in business combinations, licensing and other transactions at both March 31, 2018 and December 31, 2017 was \$2.0 billion, representing approximately 79% of total assets at March 31, 2018.

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

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

Goodwill was \$719.9 million and \$717.1 million, respectively, at March 31, 2018 and December 31, 2017. Goodwill is tested at least annually for impairment or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value. Examples of qualitative factors include our share price, our

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

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

Intangible assets, net were \$1.3 billion, including IPR&D of \$646.4 million and \$647.3 million, respectively, at March 31, 2018 and December 31, 2017. Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the project is completed or abandoned. Upon obtaining regulatory approval, the IPR&D asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the IPR&D asset is charged to expense.

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

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

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

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense was \$17.3 million and \$17.9 million for the three months ended March 31, 2018 and 2017, respectively.

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

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

The following are descriptions of our payors for laboratory services:

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

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

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

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

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, require us to estimate the potential for retroactive adjustments as an element of variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known.

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

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

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

The composition of Revenue from services by payor for the three months ended March 31, 2018 and 2017 is as follow:

(In thousands)	Three months ended March 31,	
	2018	2017
Healthcare insurers	\$ 100,953	\$ 112,696
Government payers	67,136	77,053
Client payers	37,529	33,939
Patients	5,697	4,857
Total	<u>\$ 211,315</u>	<u>\$ 228,545</u>

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

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

We recognize revenue for shipments of *Royaldee* at the time of delivery to customers after estimating Sales Deductions and product returns as elements of variable consideration utilizing historical information and market research projections. For the three months ended March 31, 2018, we recognized \$3.7 million in net product revenue from sales of *Royaldee*. Amounts shipped prior to March 31, 2017 were insignificant.

The following table presents an analysis of product sales allowances and accruals as contract liabilities for the three months ended March 31, 2018:

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2017	\$ 233	\$ 348	\$ 437	\$ 1,018
Provision related to current period sales	961	1,339	(70)	2,230
Credits or payments made	(805)	(955)	(185)	(1,945)
Balance at March 31, 2018	<u>\$ 389</u>	<u>\$ 732</u>	<u>\$ 182</u>	<u>\$ 1,303</u>
Total gross <i>Royaldee</i> sales				\$ 5,922
Provision for <i>Royaldee</i> sales allowances and accruals as a percentage of gross <i>Royaldee</i> sales				38%

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

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

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

**Upfront License Fees:** If a license to our intellectual property is determined to be functional intellectual property distinct from the other performance obligations identified in the arrangement, we recognize revenue from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is

recognized when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we apply an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

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

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

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

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

For the three months ended March 31, 2018 and 2017, revenue from transfer of intellectual property principally reflects \$14.7 million and \$14.1 million of revenue, respectively related to the Pfizer Transaction. Refer to Note 13. Total contract liabilities included in Accrued expenses and Other long-term liabilities was \$125.0 million and \$140.4 million at March 31, 2018 and December 31, 2017, respectively. The contract liability balance at March 31, 2018 relates primarily to the Pfizer Transaction.

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

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk since the related healthcare programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. At March 31, 2018 and December 31, 2017, receivable balances (net of contractual adjustments) from Medicare and Medicaid were 15.1% and 15.8%, respectively, of our consolidated Accounts receivable, net.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At March 31, 2018 and December 31, 2017, receivables due from patients represent approximately 2.7% and 3.2%, respectively, of our consolidated Accounts receivable, net.



We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer's ability to pay. Actual results could differ from those estimates. Our reported net income (loss) is directly affected by our estimate of the collectability of accounts receivable. The allowance for doubtful accounts was \$1.5 million and \$1.4 million at March 31, 2018 and December 31, 2017, respectively.

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

On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the "Tax Act") was enacted into law and the new legislation contains several key tax provisions, including a reduction of the corporate income tax rate from 35% to 21% effective January 1, 2018, and a one-time mandatory transition tax on accumulated foreign earnings, among others. We are required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring our U.S. deferred tax assets and liabilities, as well as reassessing the net realizability of our deferred tax assets and liabilities. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Act ("SAB 118"), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Through March 31, 2018, we did not have any significant adjustments to our provisional amounts. As we continue to perform our analysis of the Tax Act, and interpret any additional accounting guidance issued by the FASB, the U.S. Department of the Treasury and the IRS, we may make adjustments to these provisional amounts.

Effective January 1, 2018, the Tax Act provides for a new global intangible low-taxed income (GILTI) provision. Under the GILTI provision, certain foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets are included in U.S. taxable income. We are now subject to GILTI but have not triggered an income inclusion as of March 31, 2018. Any future inclusion is expected to be offset by net operating loss carry forwards in the U.S. We are still evaluating, pending further interpretive guidance, whether to make a policy election to treat the GILTI tax as a period expense or to provide U.S. deferred taxes on foreign temporary differences that are expected to generate GILTI income when they reverse in future years.

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

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

*Inventories.* Inventories are valued at the lower of cost and net realizable value. Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost and net realizable value. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories. Inventory obsolescence expense for the three months ended March 31, 2017 was \$4.6 million.

*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

### *Recently adopted accounting pronouncements.*

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

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

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

### Condensed Consolidated Statement of Operations

	For the three months ended March 31, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Revenue from services	\$ 228,545	\$ 255,286	\$ (26,741)
Revenue from transfer of intellectual property and other	15,606	18,579	(2,973)
Selling, general and administrative	109,944	136,685	(26,741)
Research and development	26,557	26,022	535

### Condensed Consolidated Balance Sheet



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

### Condensed Consolidated Statement of Cash Flows

	For the three months ended March 31, 2017 (in thousands)		
	As adjusted under Topic 606	As originally reported	Effect of change
Net loss	\$ (34,503)	\$ (30,995)	\$ (3,508)
Contract liabilities	(13,849)	(17,357)	3,508

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

In addition, under Topic 606, the upfront consideration received for a license and contract services combined performance obligation is recognized as revenue to the extent of costs incurred based on the length of the expected performance period and the subjectivity in estimating progress towards satisfaction of the performance obligation. Under previous accounting, we recognized revenue over the expected performance period. The adoption of Topic 606 resulted in a cumulative revenue reduction of \$29.8 million and an increase of our accumulated deficit balance as of December 31, 2017; with a corresponding increase in our contract liabilities. For the three months ended March 31, 2017, Revenue from the transfer of intellectual property and other was reduced by \$3.5 million for the change in accounting. For a further discussion of the adoption of Topic 606, see Note 12, “Revenue Recognition.”

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

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

#### *Pending accounting pronouncements.*

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” which will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed

Consolidated Financial Statements.

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

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

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

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

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

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

**Interest Rate Risk** – Our exposure to interest rate risk relates to our cash and investments and to our borrowings. We 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 March 31, 2018, we had cash and cash equivalents of \$99.9 million. The weighted average interest rate related to our cash and cash equivalents for the three months ended March 31, 2018 was less than 1%. As of March 31, 2018, the principal outstanding balance under our Credit Agreement with JPMorgan Chase Bank, N.A. and our Chilean and Spanish lines of credit was \$110.9 million in the aggregate at a weighted average interest rate of approximately 4.1%.

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

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

#### **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 March 31, 2018.

##### ***Changes to the Company's Internal Control Over Financial Reporting***

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

These changes to the Company's internal control over financial reporting that occurred during the most recent quarter ended March 31, 2018 have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

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

### **Item 1A. Risk Factors**

Our operations and financial results are subject to various risks and uncertainties, including those described in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2017, 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, 2017.

### **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**

<a href="#">Exhibit 3.1(1)</a>	<a href="#">Amended and Restated Certificate of Incorporation.</a>
<a href="#">Exhibit 3.2(2)</a>	<a href="#">Amended and Restated By-Laws.</a>
<a href="#">Exhibit 3.3(3)</a>	<a href="#">Certificate of Designation of Series D Preferred Stock.</a>
<a href="#">Exhibit 4.3(4)</a>	<a href="#">Indenture, dated as of January 30, 2013, between OPKO Health, Inc. and Wells Fargo Bank, National Association.</a>
<a href="#">Exhibit 10.29(5)</a>	<a href="#">Form of 5% Convertible Promissory Note dated February 27, 2018.</a>
<a href="#">Exhibit 31.1</a>	<a href="#">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 March 31, 2018.</a>
<a href="#">Exhibit 31.2</a>	<a href="#">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 March 31, 2018.</a>
<a href="#">Exhibit 32.1</a>	<a href="#">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 March 31, 2018.</a>
<a href="#">Exhibit 32.2</a>	<a href="#">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 March 31, 2018.</a>
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

- (1) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2013 for the Company's three month period ended September 30, 2013, and incorporated herein by reference.
- (2) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008, and incorporated herein by reference.
- (3) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2009, and incorporated herein by reference.
- (4) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2013, and incorporated herein by reference.
- (5) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2018, 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: May 8, 2018

**OPKO Health, Inc.**

/s/ Adam Logal

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Adam Logal

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



**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: May 8, 2018

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.

Chief Executive Officer

**CERTIFICATIONS**

I, Adam Logal, certify that:

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

Date: May 8, 2018

/s/ Adam Logal

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Adam Logal

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

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

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

The Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018 (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: May 8, 2018

/s/ Phillip Frost, M.D.

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Phillip Frost, M.D.

Chief Executive Officer

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

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

The Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018 (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: May 8, 2018

/s/ Adam Logal

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Adam Logal

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