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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 that have an effective date after the date of this filing.

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**PART I. FINANCIAL INFORMATION**

Page

Item 1. Financial Statements

Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016 (unaudited)  
Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017

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- 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.;

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- 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.











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







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In November 2015, the FASB issued ASU No. 2015-1







## NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

### *Transition Therapeutics acquisition*

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

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

(In thousands)	Transition Therapeutics
Cash and cash equivalents	\$ 15,878
IPR&D assets	41,000
Goodwill	3,453
Other assets	634
Accounts payable and other liabilities	(1,035)
Deferred tax liability	(140)

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value of our equity method investments based on the quoted market price



activities that most significantly impact Zebra's economic performance and have no obligation to fund expected losses. We did determine, however, that we can significantly influence the success of Zebra through our board representation and voting power. Therefore, we have the ability to exercise significant influence over Zebra's operations and account for our investment in Zebra under the equity method.

*Other*

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



**NOTE 6 DEBT**

In January 2013, we entered into note purchase agreements (the “2033 Senior Notes”) with qualified institutional buyers and accredited investors (collectively, the “Purchasers”) in a private placement in reliance on exemptions from registration under the Securities Act of 1933, as amended (the “Securities Act”). The 2033 Senior Notes were issued on January 30, 2013. The 2033 Senior Notes, which totaled \$175.0 million in original principal amount, bear interest at the rate of 3.00% per year, payable semiannually on February 1 and August 1 of each year. The 2033 Senior Notes will mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change as defined in the Indenture, dated as of January 30, 2013, by and between the Company and Wells Fargo Bank N.A., as trustee, governing the 2033 Senior Notes (the “Indenture”), subject to certain exceptions, the holders may require us to repurchase all or any portion of their 2033 Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the 2033 Senior Notes being repurchased, plus any accrued and unpaid interest to but not including the related fundamental change repurchase date.

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

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

The 2033 Senior Notes will be convertible at any time on or after November 1, 2032, through the second scheduled trading day immediately preceding the maturity date, at the option of the holders. Additionally, holders may convert their 2033 Senior Notes prior to the close of business on the scheduled trading day immediately preceding November 1, 2032, under the following circumstances: (1) conversion based upon satisfaction of the trading price condition relating to the 2033 Senior Notes; (2) conversion based on the Common Stock price; (3) conversion based upon the occurrence of specified corporate events; or (4) if we call the 2033 Senior Notes for redemption. The 2033 Senior Notes will be convertible into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our election unless we have made an irrevocable election of net share settlement. The initial conversion rate for the 2033 Senior Notes will be 141.48 Common Shares per \$1,000 of principal amount of the 2033 Senior Notes.

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meet these criteria for periods prior to February 1, 2017 and, as such, were valued separate and apart from the 2033 Senior Notes and recorded at fair value each reporting period.

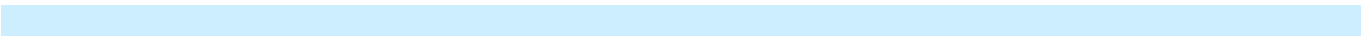
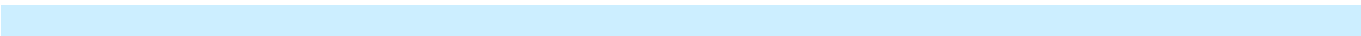
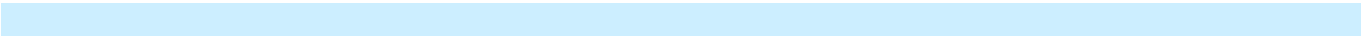
For accounting and financial reporting purpose

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**NOTE 9 DERIVATIVE CONTRACTS**

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

<u>(In thousands)</u>	Balance Sheet Component	September 30, 2017	December 31, 2016
Derivative financial instruments:			
Common Stock option	Common Stock		




**NOTE 10 RELATED PARTY TRANSACTIONS**

We hold investments in Zebra (ownership 29%), Sevion (31%), Neovasc (4%), ChromaDex Corporation (1%), MabVax (4%), COCP (9%) ARNO (5%), ~~NIMS~~(1%), BioCardia (5%) and Eloxx (3%). These investments were considered related party transactions as a result of our executive management's ownership interests and/or board representation in these entities. See further discussion of our investments in Note 5.

In June 2017, we invested \$1.5 million in Eloxx for 99,915 Preferred C Shares and in July 2017, we invested an additional \$1.5 million in Sevion for 10,000,000 shares of Sevion common stock. An entity controlled by Dr. Frost also made an investment in Eloxx and committed to investing additional funds in Sevion by December 31, 2017. Sevion and Eloxx entered into an acquisition agreement on May 31, 2017 under which Eloxx will become a wholly owned subsidiary of Sevion. Upon completion of the transaction, Sevion will change its name to Eloxx Pharmaceuticals, % i 5

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had, in violation of the False Claims Act, improperly billed Medicare and Tricare (both are federal government healthcare programs) for clinical laboratory services provided to hospital inpatient beneficiaries at certain hospitals. BioReference is reviewing and assessing the allegations made by the SDNY, and, at this point, BioReference has not determined whether there is any merit to the SDNY's claims nor can it determine the extent of any potential liability. While management cannot predict the outcome of these matters at this time, the ultimate outcome could be material to our business, financial condition, results of operations, and cash flows.

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

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

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

## **NOTE 12 STRATEGIC ALLIANCES**

### *Vifor Fresenius Medical Care Renal Pharma Ltd*

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

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

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

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





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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. Duringt ~ w

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<u>(In thousands)</u>	September 30, 2017	December 31, 2016
Assets:		
Pharmaceutike		

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**RESULTS OF OPERATIONS****FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016**

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

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

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

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

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

*Research and development expenses.* Research and development expenses for the three months ended September 30, 2017 and 2016, were \$32.3 million and \$24.4 million, respectively. Research and development costs include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and pre-market approvals ("PMAs") for diagnostics tests, if any. Internal expenses include employee-related expenses including salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to w



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

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

*Other income (expense), net.* Other income (expense), net for the nine months ended September 30, 2017 and 2016, were \$3.1 million and \$3.5 million of income, respectively. Other income for the nine months ended September 30, 2017 primarily consists of a \$3.0 million gain on the sale of non-strategic assets at a wholly-owned BioReference subsidiary. Other income for the nine months ended September 30, 2016 primarily consisted of a \$2.5 million gain recognized in connection with the merger of STI and VBI Vaccines Inc. and a \$2.9 million gain recognized in connection with the settlement of a legal matter, which was partially offset by a \$3.9 million other-than-temporary impairment charge to write our investments in Xenetic and RXi down to their respective fair values.

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

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

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**LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2017, we

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The Facility is subject to the negotiation of

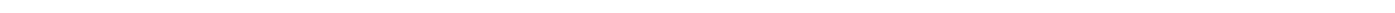




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incur between \$40 million and \$45 million for the construction and validation of the facility. Construction of the facility began in the fourth quarter of 2016 with expected completion in 2019. Currently, we plan to fund the project from cash on hand or from third party funding sources that may be available to us.

Our licensee, TESARO, received approval by the U.S. FDA in September 2015 for oral VARUBI™, a neurokinin-1 receptor antagonist for the prevention of chemotherapy-induced nausea and vomiting. In November 2015, TESARO announced the commercial f ch





## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

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

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

- Unit of account – Most intangible assets are valued as single global assets rather than multiple assets for each jurisdiction or indication after considering the development stage, expected levels of incremental costs to obtain additional approvals, risks associated with further development, amount and timing of benefits expected to be derived in the future, expected patent lives in various jurisdictions and the intention to promote the asset as a global brand.
  - Estimated useful life – The asset life expected to contribute meaningful cash flows is determined after considering all pertinent matters associated with the asset, including expected regulatory approval dates (if unapproved), exclusivity periods and other legal, regulatory or contractual provisions as well as the effects of any obsolescence, demand, competition, and other economic factors, including barriers to entry.
  - Probability of Technical and Regulatory Success (“PTRS”) Rate – PTRS rates are determined based upon industry averages considering the respective program’s development stage and disease indication and adjusted for specific information or data known at the acquisition date. Subsequent clinical results or other internal or external data obtained could alter the PTRS rate and materially impact the estimated fair value of the intangible asset in subsequent ~~the~~ent - n ~ 2
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assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment.

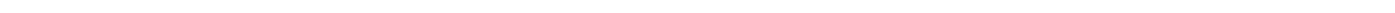
*Equity-based compensation.* We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statements of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options, as cash flows from operations. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. We estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the "Black-Scholes Model." The Black-Scholes Model requires the use of several variables: stock price, exercise price, risk-free interest rate, expected volatility, and expected term.

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

In July 2015, the FASB issued ASU No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory," which requires that inventory be measured at the lower of cost or market. The ASU is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. We are currently evaluating the impact of this ASU on our financial statements.



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

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

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

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

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

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

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

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## **Item 4. Controls and Procedures**

### ***Disclosure Controls and Procedures***

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, management concluded that our disclosure controls and procedures were effective as of September 30, 2017.

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

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

We are in the process of implementing a new comprehensive enterprise resource planning ("ERP") system on a company-wide basis, which is one of the systems used for financial reporting. The implementation of the ERP system in our financial systems

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## **PART II. OTHER INFORMATION**

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

We are, from time to time, party to various legal proceedings arising out of our business. During the reporting period, there have been no material changes to the description of legal proceedings set forth in our Annual Report on Form 10-K for the year ended December 31, 2016 and our Quarterly Report on Form 10-Q for the quarters ended March 31, 2017 and June 30, 2017.

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

Our operations and financial results are subject to various risks and uncertainties, including those described in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common and capital stock. There have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2016.

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

None.

### **Item 3. Defaults Upon Senior Securities**

None.

### **Item 4. Mine Safety Disclosures**

Not Applicable.

### **Item 5. Other Information**

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

**Item 6. Exhibits**

<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 10.1*</a>	<a href="#">Amendment No. 4 to Credit Agreement by and between Bio-Reference Laboratories, Inc. and certain of its subsidiaries and JPMorgan Chase Bank, N.A. dated August 7, 2017</a>
<a href="#">Exhibit 10.2*</a>	<a href="#">Commitment Letter by and between OPKO Health, Inc. and Veterans Accountabweyands rAugust 7, 201</a>

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**SIGNATURES**

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

Date: November 8, 2017

**OPKO**

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**EXECUTION VERSION**

**AMENDMENT NO. 4 TO CREDIT AGREEMENT**

AMENDMENT NO. 4 TO CREDIT AGREEMENT (this “Amendment”), dated as of August 7, 2017, is entered into among BIO-REFERENCE LABORAT

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

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

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

( e ) No Novation or o Ne Ni o Ni

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

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

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

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

[SIGNATURES ON FOLLOWING PAGES.]





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

By: /s/ Eric A. Anderson

Name: Eric A. Anderson

Title: Authorized Officer

[BRLI – Amendment No. 4 to Credit Agreement]



August 15, 2017

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

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

**Re: Commitment  
Letter**

Dear Mr. Nelson:

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

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

**1. Commitment.**

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

(the “Definitive Agreements”), which shall be due and payable on demand by Lender. The Definitive Agreements shall be customary for transactions of the type described in this letter, shall incorporate the terms and conditions set forth in this letter (or as otherwise agreed to by VACG and Lender) and shall be executed and delivered by VACG and Lender on or prior to the Award Date. The parties hereby agree that, except as provided elsewhere herein, no fees shall be payable by VACG or VACO to OPKO hereunder in respect of the Facility or any borrowings by VACG thereunder, or based on VACO being awarded a CCN Contract by the VHA; provided that, if OPKO or one or more of its affiliates is the Lender, then OPKO shall be entitled to the interest on the Facility as provided herein and customary fees and expenses under the Facility as set forth in the Definitive Agreements. OPKO hereby acknw

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4. **Information.** You hereby represent, warrant and covenant that: (a) all written information (other than the Projections (as defined below), other forward-looking information and information of a general economic or industry specific nature) that has been or will be made available to us by you or your representatives, or on your or their behalf, in connection with the Facility (the "Information") is and will be complete and correct when taken as a whole, in all material respects, and does not and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements contained therein, in the light of the circumstances under which such statements are made, not misleading, and (b) all financial projections concerning VACO and VACG that have been or are hereafter made available to us by you or any of your representatives, or on your or their behalf (the "Projections") in connection with the Facility have been or will be prepared in good <sup>2</sup>, honest

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

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

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

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

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

**9 . WAIVER OF JURY TRIAL.** EACH OF THE PARTIES HERETO IRREVOCABLY WAIVES ANY RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING,

Veteranse





Veterans Accountable Care Group, LLC

August 15, 2017

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(b) This letter constitutes the entire agreement and understanding between you and OPKO with respect to the transactions described in this letter and supersedes all prikas " w

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

Very truly yours,

OPKO HEALTH, INC.

By: /s/ Steven D. Rubin

Name: Steven D. Rubin

Title EVP Administration

Approved for Signature

OPKO Legal\Leg

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**CERTIFICATIONS**

I, Adam Logal, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health,  
Inc.;

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**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 F

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I, Phillip Frost, Chief Executive Officer of F

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

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

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

Date: November 8, 2017

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