

Opko Health, Inc.  
Form 10-Q  
November 09, 2015  
Table of Contents

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015.

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 001-33528

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

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)  
4400 Biscayne Blvd.  
Miami, FL 33137  
(Address of Principal Executive  
Offices) (Zip Code)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company"

(in Rule 12b-2 of the Exchange Act) (Check one):

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

Edgar Filing: Opko Health, Inc. - Form 10-Q

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

As of October 30, 2015, the registrant had 545,011,748 shares of Common Stock outstanding.

---

Table of Contents

## TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

	Page
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of September 30, 2015 (unaudited) and December 31, 2014</u>	<u>6</u>
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and 2014 (unaudited)</u>	<u>7</u>
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014 (unaudited)</u>	<u>8</u>
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014 (unaudited)</u>	<u>9</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>10</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>44</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>59</u>
<u>Item 4. Controls and Procedures</u>	<u>60</u>
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	<u>61</u>
<u>Item 1A. Risk Factors</u>	<u>61</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>69</u>
<u>Item 3. Defaults Upon Senior Securities</u>	<u>69</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>69</u>
<u>Item 5. Other Information</u>	<u>69</u>
<u>Item 6. Exhibits</u>	<u>70</u>
<u>Signatures</u>	<u>72</u>
<u>Exhibit Index</u>	<u>73</u>
EX-31.1	Section 302 Certification of CEO
EX-31.2	Section 302 Certification of CFO
EX-32.1	Section 906 Certification of CEO
EX-32.2	Section 906 Certification of CFO
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements,” as that term is defined under the Private Securities Litigation Reform Act of 1995 (“PSLRA”), Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in “Item 1A-Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2014, and described from time to time in our other reports filed with the Securities and Exchange Commission. Except as required by law, 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 operating losses and we do not expect to become profitable in the near future.
- We may fail to realize the anticipated benefits of the merger with Bio-Reference Laboratories, Inc. (“Bio-Reference”). The failure to integrate successfully the business and operations of Bio-Reference timely may adversely affect our future results.
- Combining our business with Bio-Reference may be more difficult, costly or time-consuming than expected, which may adversely affect our business results and negatively affect the value of our common stock following the merger.
- Our future results will suffer if we do not effectively manage our expanded operations following the merger with Bio-Reference.
- Third parties may terminate or alter existing contracts or relationships with us or Bio-Reference as a result of the merger.
- We may be unable to retain key Bio-Reference personnel following the merger.
- The market price of our common stock may decline as a result of the merger with Bio-Reference.
- Charges to earnings resulting from the application of the acquisition method of accounting may adversely affect the market value of our common stock following the merger.
- Our technologies are in an early stage of development and are unproven.
- Our business is substantially dependent on our ability to develop, launch and generate revenue from our pharmaceutical and diagnostic programs.
- Our research and development activities, or that of our investees, may not result in commercially viable products.
- Our estimates on the timing and expenditures associated with the build-up of pre-launch inventory and capacity expansion could be over or under actual needs and may adversely affect our operations and financial results.
- The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the United States (“U.S.”) Food and Drug Administration (“FDA”) or other non-U.S. regulatory authorities.
- We may require substantial additional funding, which may not be available to us on acceptable terms, or at all.
- We may finance future cash needs primarily through public or private offerings, debt financings or strategic collaborations, which may dilute your stockholdings in the Company.
- If our competitors develop and market products that are more effective, safer or less expensive than our future product candidates, our commercial opportunities will be negatively impacted.

Table of Contents

Material weaknesses in the design and operation of the internal control over financial reporting of companies that we acquire could have a material adverse effect on our financial statements.

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.

Failure to recruit and enroll patients for clinical trials may cause the development of our product candidates to be delayed.

Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our products.

The loss of Phillip Frost, M.D., our Chairman and Chief Executive Officer, could have a material adverse effect on our business and product development.

If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

As we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

If we fail to acquire and develop other products or product candidates, at all or on commercially reasonable terms, we may be unable to diversify or grow our business.

We have no experience manufacturing our pharmaceutical product candidates other than at one of our Israel facilities and one of our Irish facilities, and at our Mexican and Spanish facilities, and we have no experience in manufacturing our diagnostic product candidates. We will therefore likely rely on third parties to manufacture and supply our pharmaceutical and diagnostics product candidates, and we would need to meet various standards to satisfy FDA regulations in order to manufacture on our own.

We currently have no pharmaceutical or diagnostic marketing, sales or distribution capabilities other than in Chile, Mexico, Spain, and Uruguay for sales in those countries and our active pharmaceutical ingredients (“APIs”) business in Israel, and the sales force for our laboratory businesses at OPKO Lab and Bio-Reference. If we are unable to develop our sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical and diagnostic product candidates.

Certain elements of our business are dependent on the success of ongoing and planned phase 3 clinical trials for Alpharen (Fermagate Tablets), and hGH-CTP.

Independent clinical investigators and contract research organizations that we engage to conduct our clinical trials may not be diligent, careful or timely.

The success of our business is dependent on the actions of our collaborative partners.

Our exclusive worldwide agreement with Pfizer Inc. (“Pfizer”) is important to our business. If we do not successfully develop hGH-CTP and/or Pfizer does not successfully commercialize hGH-CTP, our business could be adversely affected.

Our license agreement with TESARO, Inc. (“TESARO”) is important to our business. If TESARO does not successfully commercialize Varubi, our business could be adversely affected.

If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We rely heavily on licenses from third parties.

Table of Contents

• We license patent rights to certain of our technology from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

• Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

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

• If our products have undesirable effects on patients, we could be subject to litigation or product liability claims that could impair our reputation and have a material adverse effect upon our business and financial condition.

• Medicare prescription drug coverage legislation and future legislative or regulatory reform of the health care system may adversely affect our ability to sell our products or provide our services profitably.

• Failure to obtain and maintain regulatory approval outside the U.S. will prevent us from marketing our product candidates abroad.

• We may not have the funding available to pursue acquisitions.

• Acquisitions may disrupt our business, distract our management, may not proceed as planned, and may also increase the risk of potential third party claims and litigation.

• We may encounter difficulties in integrating acquired businesses.

• Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.

• Political and economic instability in Europe and Latin America and political, economic, and military instability in Israel or neighboring countries could adversely impact our operations.

• We are subject to fluctuations in currency exchange rates in connection with our international businesses.

We have a large amount of goodwill and other intangible assets as a result of acquisitions and a significant

• write-down of goodwill and/or other intangible assets would have a material adverse effect on our reported results of operations and net worth.

• Our business may become subject to legal, economic, political, regulatory and other risks associated with international operations.

• The market price of our Common Stock may fluctuate significantly.

The conversion and redemption features of our January 2013 convertible senior notes due in 2033 are classified as embedded derivatives and may continue to result in volatility in our financial statements, including having a material impact on our result of operations and recorded derivative liability.

• Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you may not consider to be in your best interests or in the best interests of our stockholders.

• Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

• If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as they apply to us, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned and our Common Stock price may suffer.

• We may be unable to maintain our listing on the New York Stock Exchange (“NYSE”), which could cause our stock price to fall and decrease the liquidity of our Common Stock.

• Future issuances of Common Stock and hedging activities may depress the trading price of our Common Stock.

• Provisions in our charter documents and Delaware law could discourage an acquisition of us by a third party, even if the acquisition would be favorable to you.

• We do not intend to pay cash dividends on our Common Stock in the foreseeable future.

Table of Contents

## PART I. FINANCIAL INFORMATION

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

## Item 1. Financial Statements

## OPKO Health, Inc. and Subsidiaries

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share and per share data)

	September 30, 2015	December 31, 2014 <sup>(1)</sup>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$212,144	\$ 96,907
Accounts receivable, net	189,725	19,969
Inventory, net	40,693	16,604
Prepaid expenses and other current assets	74,854	9,389
Total current assets	517,416	142,869
Property, plant and equipment, net	126,822	16,411
Intangible assets, net	660,287	62,649
In-process research and development	812,723	793,152
Goodwill	761,234	224,292
Investments, net	34,695	22,453
Other assets, principally deferred tax assets	102,676	5,838
Total assets	\$3,015,853	\$ 1,267,664
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$77,969	\$ 8,744
Accrued expenses	201,113	60,912
Current portion of lines of credit and notes payable	78,508	13,455
Total current liabilities	357,590	83,111
2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	44,206	131,454
Deferred tax liabilities	408,213	167,153
Other long-term liabilities, principally deferred revenue and contingent consideration	236,476	50,205
Total long-term liabilities	688,895	348,812
Total liabilities	1,046,485	431,923
Equity:		
Common Stock - \$0.01 par value, 750,000,000 shares authorized; 545,951,707 and 433,421,677 shares issued at September 30, 2015 and December 31, 2014, respectively	5,459	4,334
Treasury Stock - 1,120,367 and 1,245,367 shares at September 30, 2015 and December 31, 2014, respectively	(3,645)	(4,051)
Additional paid-in capital	2,696,420	1,529,096
Accumulated other comprehensive income (loss)	(20,992)	(12,392)
Accumulated deficit	(706,474)	(674,843)
Total shareholders' equity attributable to OPKO	1,970,768	842,144
Noncontrolling interests	(1,400)	(6,403)

Edgar Filing: Opko Health, Inc. - Form 10-Q

Total shareholders' equity	1,969,368	835,741
Total liabilities and equity	\$3,015,853	\$ 1,267,664

As of December 31, 2014, total assets include \$7.6 million and total liabilities include \$12.1 million related to SciVac Ltd ("SciVac"). SciVac was a consolidated variable interest entity which we deconsolidated in July 2015.

(1) Refer to Note 5. SciVac's consolidated assets were owned by SciVac and SciVac's consolidated liabilities had no recourse against us.

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

6

---



Table of Contents

OPKO Health, Inc. and Subsidiaries

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share and per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2015	2014	2015	2014
Revenues:				
Revenue from services	\$103,919	\$2,482	\$107,929	\$6,606
Revenue from products	20,765	17,291	59,066	58,510
Other revenue, principally transfer of intellectual property	18,350	—	48,552	476
Total revenues	143,034	19,773	215,547	65,592
Costs and expenses:				
Cost of service revenue	56,670	2,359	61,434	7,088
Cost of product revenue	10,658	8,761	30,650	28,987
Selling, general and administrative	55,246	14,010	93,629	42,697
Research and development	18,937	20,517	74,010	57,744
In-process research and development	—	—	—	10,055
Contingent consideration	1,636	19,592	6,471	24,078
Amortization of intangible assets	8,110	2,735	14,011	8,304
Grant repayment (Note 12)	—	—	25,889	—
Total costs and expenses	151,257	67,974	306,094	178,953
Operating income (loss)	(8,223	) (48,201	) (90,547	) (113,361
Other income and (expense), net:				
Interest income	13	402	27	450
Interest expense	(2,745	) (2,402	) (6,296	) (10,572
Fair value changes of derivative instruments, net	32,244	3,305	(34,100	) 3,758
Other income (expense), net	17,482	(2,764	) 16,734	2,044
Other income and (expense), net	46,994	(1,459	) (23,635	) (4,320
Income (loss) before income taxes and investment losses	38,771	(49,660	) (114,182	) (117,681
Income tax benefit (provision)	92,978	(294	) 87,218	(1,009
Income (loss) before investment losses	131,749	(49,954	) (26,964	) (118,690
Loss from investments in investees	(3,502	) (60	) (6,067	) (2,486
Net income (loss)	128,247	(50,014	) (33,031	) (121,176
Less: Net loss attributable to noncontrolling interests	—	(1,345	) (1,400	) (2,481
Net income (loss) attributable to common shareholders	\$128,247	\$(48,669	) \$(31,631	) \$(118,695
Earnings (loss) per share:				
Earnings (loss) per share, basic	\$0.26	\$(0.11	) \$(0.07	) \$(0.28
Earnings (loss) per share, diluted	\$0.25	\$(0.11	) \$(0.07	) \$(0.28
Weighted average common shares outstanding, basic	500,562,254	427,577,102	469,931,486	418,649,421
Weighted average common shares outstanding, diluted	514,320,570	427,577,102	469,931,486	418,649,421

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

Table of Contents

OPKO Health, Inc. and Subsidiaries

## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(In thousands)

	For the three months ended September 30,		For the nine months ended September 30,	
	2015	2014	2015	2014
Net income (loss)	\$128,247	\$(50,014)	\$(33,031)	\$(121,176)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss) from equity investments	(1,452)	(3,169)	(5,998)	(4,781)
Available for sale investments:				
Change in unrealized gain (loss), net of tax	(661)	(5,834)	(2,602)	(6,781)
Less: reclassification adjustments for (gains) losses included in net income (loss), net of tax	—	—	—	(553)
Comprehensive loss	126,134	(59,017)	(41,631)	(133,291)
Less: Comprehensive loss attributable to noncontrolling interest	—	(1,345)	(1,400)	(2,481)
Comprehensive income (loss) attributable to common shareholders	\$126,134	\$(57,672)	\$(40,231)	\$(130,810)

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

8

Table of Contents

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

	For the nine months ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(33,031	) \$(121,176
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	20,073	11,269
Non-cash interest on 2033 Senior Notes	2,176	4,596
Amortization of deferred financing costs	1,175	1,907
Losses from investments in investees	6,067	2,486
Equity-based compensation – employees and non-employees	17,765	10,088
(Recovery of) provision for bad debts	8,308	(20
Provision for inventory obsolescence	683	773
Revenue from receipt of equity	(140	) (180
Realized gain on sale of equity securities	(216	) (1,273
(Gain) loss on conversion of 3.00% convertible senior notes	(943	) (2,668
Change in fair value of derivative instruments	34,100	(3,758
In-process research and development	—	10,055
Change in fair value of contingent consideration	6,471	24,078
Gain on deconsolidation of SciVac	(17,340	) —
Deferred income tax (benefit) expense	(96,713	) —
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable	(14,012	) (4,140
Inventory	(6,407	) (1,099
Prepaid expenses and other current assets	(4,225	) 3,487
Other assets	1,262	4,465
Accounts payable	(35,504	) (3,850
Foreign currency measurement	776	1,008
Deferred revenue	246,262	—
Accrued expenses and other liabilities	36,788	(1,666
Net cash provided by (used in) operating activities	173,375	(65,618
Cash flows from investing activities:		
Investments in investees	(3,000	) (589
Proceeds from sale of equity securities	—	1,331
Acquisition of businesses, net of cash	(78,862	) (1,683
Acquisition of intangible assets	(5,000	) —
Capital expenditures	(4,422	) (3,935
Net cash used in investing activities	(91,284	) (4,876
Cash flows from financing activities:		
Issuance of 2033 Senior Notes, net, including related parties	81	—
Proceeds from the exercise of Common Stock options and warrants	25,180	12,066
Cash from non-controlling interest	100	—
Contingent consideration payments	—	(6,435
Borrowings on lines of credit	111,359	19,326

Edgar Filing: Opko Health, Inc. - Form 10-Q

Repayments of lines of credit	(103,544	) (21,823	)
Net cash provided by financing activities	33,176	3,134	
Effect of exchange rate on cash and cash equivalents	(30	) (180	)
Net increase (decrease) in cash and cash equivalents	115,237	(67,540	)
Cash and cash equivalents at beginning of period	96,907	185,798	
Cash and cash equivalents at end of period	\$212,144	\$118,258	
SUPPLEMENTAL INFORMATION:			
Interest paid	\$2,917	\$5,222	
Income taxes paid, net	\$1,383	\$566	
Pharmsynthez common stock received	\$—	\$6,264	
Non-cash financing:			
Shares issued upon the conversion of:			
2033 Senior Notes	\$120,299	\$95,665	
Common Stock options and warrants, surrendered in net exercise	\$14,241	\$3,494	
Issuance of capital stock to acquire:			
Bio-Reference Laboratories, Inc.	\$950,010	\$—	
EirGen Pharma Limited	\$33,569	\$—	
Inspiro	\$—	\$8,566	
OPKO Health Europe	\$1,813	\$—	
OPKO Renal	\$20,113	\$21,155	
OPKO Uruguay Ltda.	\$—	\$159	

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

Table of Contents

OPKO Health, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

NOTE 1 BUSINESS AND ORGANIZATION

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes Bio-Reference Laboratories, the nation's third-largest clinical laboratory with a core genetic testing business and a 420-person sales force to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros® 1 in-office immunoassay platform. Our pharmaceutical business features Rayaldee™, a treatment for secondary hyperparathyroidism in stage 3-4 chronic kidney disease patients with vitamin D deficiency (March 29, 2016 PDUFA date) and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation approved by FDA and pending launch by partner TESARO). Our biologics business includes 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 (entering Phase 2). We are incorporated in Delaware and our principal executive offices are located in leased offices in Miami, Florida.

In August 2015, we completed the acquisition of Bio-Reference Laboratories, Inc. ("Bio-Reference") following a vote of Bio-Reference's shareholders to adopt the agreement and plan of merger ("Merger Agreement") and approve the merger. Bio-Reference is the third largest full service clinical laboratory in the United States and is known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Under the terms of the Merger Agreement, holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately \$950.0 million, based on a closing price per share of our Common Stock of \$12.38 as reported by the New York Stock Exchange, or \$34.05 per share of Bio-Reference common stock. Included in the transaction value is \$2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

Through our acquisition of Bio-Reference, we provide laboratory testing services, primarily to customers in the larger metropolitan areas across New York, New Jersey, Maryland, Pennsylvania, Delaware, Washington DC, Florida, California, Texas, Illinois and Massachusetts as well as to customers in a number of other states. We offer a comprehensive list of clinical diagnostic tests including blood and urine analysis, blood chemistry, hematology services, serology, radio-immuno analysis, toxicology (including drug screening), pap smears, tissue pathology (biopsies) and other tissue analysis. We perform cancer cytogenetic testing at our leased facilities in Elmwood Park, NJ, Smithtown, NY, Clarksburg, MD, Milford, MA, Miami Florida, and Campbell California and genetic testing at our leased facility in Gaithersburg, MD, as well as at our Elmwood Park facility. We perform cytology testing at our leased facilities Frederick, MD, Milford, MA, Columbus, OH, Houston, TX and at our Elmwood Park facility. We market our laboratory testing services directly to physicians, geneticists, hospitals, clinics, correctional and other health facilities.

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

We own established pharmaceutical platforms in Chile, Spain, Mexico, and Uruguay, 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 proprietary molecular diagnostic and therapeutic products.

Our research and development activities are primarily performed at leased facilities in Jupiter and Miramar, Florida, Woburn, Massachusetts, Nes Ziona, Israel, and Barcelona, Spain.



Table of Contents

## NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**Basis of presentation.** The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and notes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments or otherwise disclosed herein) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three and nine months ended September 30, 2015, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2015 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, 2014.

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

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

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

**Inventories.** Inventories are valued at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost or market. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories.

**Pre-launch inventories.** We may accumulate commercial quantities of certain product candidates prior to the date we anticipate that such products will receive final U.S. FDA approval. The accumulation of such pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever. This risk notwithstanding, we may accumulate pre-launch inventories of certain products when such action is appropriate in relation to the commercial value of the product launch opportunity. In accordance with our policy, this pre-launch inventory is expensed. At September 30, 2015 and December 31, 2014, there were no pre-launch inventories.

**Goodwill and intangible assets.** Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired when accounted for by the purchase method of accounting and arose from our acquisitions of Pharma Genexx, S.A. ("OPKO Chile"), Pharmacos Exakta S.A. de C.V. ("OPKO Mexico"), CURNA, Inc. ("CURNA"), Claros Diagnostics, Inc. ("OPKO Diagnostics"), FineTech Pharmaceuticals, Ltd. ("FineTech"), ALS Distribuidora Limitada ("ALS"), Farmadiet Group Holding, S.L. ("OPKO Health Europe"), previously known as OPKO Spain, Prost-Data, Inc. ("OPKO Lab"), Cytochroma Inc. ("OPKO Renal"), Silcon Comércio, Importacao E Exportacao de Produtos Farmaceuticos e Cosméticos Ltda. ("OPKO Brazil"), PROLOR Biotech, Inc. ("OPKO Biologics"), EirGen and Bio-Reference. Goodwill, in-process research and development ("IPR&D") and other intangible assets acquired in business combinations, licensing and other transactions at September 30, 2015 and December 31, 2014 were \$2.2 billion and \$1.1 billion, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. 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."

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



Table of Contents

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, currently 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 \$14.0 million and \$8.3 million for the nine months ended September 30, 2015 and 2014, respectively.

Fair value measurements. The carrying amounts of our cash and cash equivalents, accounts receivable, accounts payable and short-term debt approximate their fair value due to the short-term maturities of these instruments.

Investments that are considered available for sale as of September 30, 2015 and December 31, 2014, are carried at fair value.

Short-term investments, which we invest in from time to time, include bank deposits, corporate notes, U.S. treasury securities and U.S. government agency securities with original maturities of greater than 90 days and remaining maturities of less than one year. Long-term investments include corporate notes, U.S. treasury securities and U.S. government agency securities with maturities greater than one year.

In evaluating 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 contingent consideration income. 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 specific hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2015 and December 31, 2014, our forward contracts for inventory purchases did not meet the hedge effectiveness requirements to be designated as hedges. Accordingly, we recognize all changes in the fair values of our derivatives instruments, net, in our Condensed Consolidated Statement of Operations. Refer to Note 9.

Revenue recognition. Revenue for laboratory services is recognized on the accrual basis at the time test results are reported, which approximates when services are provided. Services are provided to patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in revenue net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue. For the three months ended September 30, 2015 and 2014, approximately 9% and 5%, respectively, of our revenues were derived directly from the Medicare and Medicaid programs. The increase in revenues from laboratory services, including revenue from Medicare and Medicaid programs, is due to the acquisition of Bio-Reference in August 2015.

Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Our estimates for sales returns and allowances are based upon the historical patterns of product returns and allowances taken, matched against the sales from which they originated, and management's evaluation of specific

factors that may increase or decrease the risk of product returns.

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

12

---

Table of Contents

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

The assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the relevant time period of research and development on a quarterly basis. For the three and nine months ended September 30, 2015, revenue from transfer of intellectual property includes \$17.7 million and \$47.8 million, respectively, of revenue related to the Pfizer Transaction. Refer to Note 12.

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

Total deferred revenue included in Accrued expenses and Other long-term liabilities was \$254.1 million and \$6.7 million at September 30, 2015 and December 31, 2014, respectively. The deferred revenue balance at September 30, 2015 relates primarily to the Pfizer Transaction. Refer to Note 12.

Concentration of Credit Risk and Allowance for doubtful accounts. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of accounts receivable. Substantially all of our accounts receivable are with companies in the health care industry and individuals. However, concentrations of credit risk are limited due to the number of our clients as well as their dispersion across many different geographic regions.

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk since the related health care programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. Accounts receivable balances (prior to allowance for doubtful accounts and net of contractual adjustments) from Medicare and Medicaid were \$22.8 million and \$0.6 million at September 30, 2015 and December 31, 2014, respectively.

The portion of our accounts receivable due from patients comprises the largest portion of credit risk. At September 30, 2015 and December 31, 2014, receivables due from patients represent approximately 9% and 0.5% of our consolidated accounts receivable (prior to allowance for doubtful accounts and net of contractual adjustments).

We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer's ability to pay. Actual results could differ from those estimates. Our reported net income (loss) is directly affected by our estimate of the collectability of accounts receivable. The allowance for doubtful accounts recognized in our Condensed Consolidated Balance Sheets was \$9.1 million and \$1.9 million at September 30, 2015 and December 31, 2014, respectively.

Equity-based compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow and as a reduction of taxes paid in cash flow from operations. Equity-based compensation arrangements to non-employees are

recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. During the nine months ended September 30, 2015 and 2014, we recorded \$17.8 million and \$10.1 million, respectively, of equity-based compensation expense.

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, generally five to ten years and includes amortization expense

## Table of Contents

for assets capitalized under capital leases. The estimated useful lives by asset class are as follows: software - 3 years, machinery and equipment - 5-8 years, furniture and fixtures - 5-10 years, leasehold improvements - the lesser of their useful life or the lease term, buildings and improvements - 10-40 years. Expenditures for repairs and maintenance are charged to expense as incurred.

**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, or carrying amount for cost basis assets, of the asset.

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

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

**Segment reporting.** Our chief operating decision-maker (“CODM”) is Phillip Frost, M.D., our Chairman and Chief Executive Officer. Our CODM reviews our operating results and operating plans and makes resource allocation decisions on a Company-wide or aggregate basis. We currently manage our operations in two reportable segments, pharmaceuticals and diagnostics. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, and vaccines, and (ii) the pharmaceutical operations we acquired in Chile, Mexico, Ireland, Israel, Spain, Uruguay and Brazil. The diagnostics segment consists of two operating segments, our (i) clinical laboratory operations we acquired through the acquisitions of Bio-Reference and OPKO Lab and (ii) point-of-care and molecular diagnostics operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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

**Investments.** We have made strategic investments in development stage and emerging companies. We record these investments as equity method investments or investments available for sale based on our percentage of ownership and whether we have significant influence over the operations of the investees. Investments for which it is not practical to estimate fair value and which we do not have significant influence are accounted for as cost method investments. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Losses from investments in investees in our Condensed Consolidated Statement of Operations. Refer to Note 5. For investments classified as available for sale, we record changes in their fair value as unrealized gain or loss in Other comprehensive income (loss) based on their closing price per share at the end of each reporting period. Refer to Note 5.

Income taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. We periodically evaluate the realizability of our net

Table of Contents

deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment.

Income tax benefit for the nine months ended September 30, 2015 was primarily due to a \$93.4 million release of a valuation allowance on our U.S. deferred tax assets as a result of the merger with Bio-Reference in August 2015. This was partially offset by expense recognized on taxable income from the Pfizer Transaction during the nine months ended September 30, 2015. Refer to Note 12 for a discussion of the Pfizer Transaction.

Included in income tax benefit is an accrual of \$2.3 million related to uncertain tax positions involving income recognition. We recognize that local tax law is inherently complex and the local taxing authorities may not agree with certain tax positions taken. Consequently, it is reasonably possible that the ultimate resolution of these matters in any jurisdiction may be significantly more or less than estimated. We evaluated the estimated tax exposure for a range of current likely outcomes to be from \$0 to approximately \$50.0 million and recorded our accrual to reflect our best expectation of ultimate resolution.

Recent accounting pronouncements. In May 2014, the FASB issued Accounting Standards Update (“ASU”), ASU No. 2014-09, “Revenue from Contracts with Customers.” ASU No. 2014-09 clarifies the principles for recognizing revenue and develops a common revenue standard for GAAP and International Financial Reporting Standards that removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. ASU No. 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Companies can choose to apply the ASU using either the full retrospective approach or a modified retrospective approach. We are currently evaluating both methods of adoption and the impact that the adoption of this ASU will have on our Condensed Consolidated Financial Statements.

In June 2014, the FASB issued ASU No. 2014-12, “Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force).” ASU No. 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU No. 2014-12 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. Earlier adoption is permitted. The amendments can be applied either prospectively to all awards granted or modified after the effective date or retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards. We expect to apply the ASU prospectively and do not expect the adoption to have an impact on our Condensed Consolidated Financial Statements.

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

In February 2015, the FASB issued ASU No. 2015-02, “Consolidation (Topic 810): Amendments to the Consolidation Analysis,” which amends current consolidation guidance including changes to both the variable and voting interest models used by companies to evaluate whether an entity should be consolidated. The requirements from ASU 2015-02 are effective for interim and annual periods beginning after December 15, 2015, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

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

In September 2015, the FASB issued ASU No. 2015-16, “Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments,” which replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015- 16 requires that the acquirer record, in the same period’s financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts,



Table of Contents

calculated as if the accounting had been completed at the acquisition date. For public business entities, ASU 2015-16 is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The guidance is to be applied prospectively to adjustments to provisional amounts that occur after the effective date of the guidance, with earlier application permitted for financial statements that have not been issued. Our early adoption of ASU 2015-16 in the third quarter of 2015 did not have a material impact on our Condensed Consolidated Financial Statements.

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

Basic earnings (loss) per share is computed by dividing our net income (loss) by the weighted average number of shares outstanding during the period. The dilutive impact of stock options and warrants is determined by applying the “treasury stock” method. In the periods in which their effect would be antidilutive, no effect has been given to outstanding options, warrants or the potentially dilutive shares issuable pursuant to 2033 Senior Notes (defined in Note 6) in the diluted computation. The following table sets forth the computation of basic and diluted earnings (loss) per share:

(Shares in thousands)	For the three months ended September 30,		For the nine months ended September 30,	
	2015	2014	2015	2014
<b>Numerator</b>				
Net income (loss) attributable to common shareholders, basic	\$ 128,247	\$(48,669)	\$(31,631)	\$(118,695)
Add: Interest on 2033 Senior Notes	779	—	—	—
Net income (loss) attributable to common shareholders, diluted	\$ 129,026	\$(48,669)	\$(31,631)	\$(118,695)
<b>Denominator</b>				
(Shares in thousands)				
Weighted average common shares outstanding, basic	500,562	427,577	469,931	418,649
Effect of dilutive securities:				
Stock options	6,349	—	—	—
Warrants	2,065	—	—	—
2033 Senior Notes	5,344	—	—	—
Dilutive potential shares	13,758	—	—	—
Weighted average common shares outstanding, diluted	514,320	427,577	469,931	418,649
Earnings (loss) per share, basic	\$0.26	\$(0.11)	\$(0.07)	\$(0.28)
Earnings (loss) per share, diluted	\$0.25	\$(0.11)	\$(0.07)	\$(0.28)

A total of 29,874,112 potential shares of Common Stock have been excluded from the calculation of diluted earnings (loss) per share for the three months ended September 30, 2014, because their inclusion would be antidilutive. A total of 12,348,652 and 29,231,538 potential shares of Common Stock have been excluded from the calculation of diluted earnings (loss) per share for the nine months ended September 30, 2015 and 2014, respectively, because their inclusion would be anti-dilutive.

During the three months ended September 30, 2015, 1,595,614 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 1,595,461 shares of Common Stock. Of the 1,595,614 Common Stock options and Common Stock warrants exercised, 153 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the nine months ended September 30, 2015, 25,437,929 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 24,231,123 shares of Common Stock. Of the 25,437,929 Common Stock options and Common Stock warrants exercised, 1,206,807 shares of

Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements. During the three months ended September 30, 2014, 3,556,688 Common Stock options and Common Stock warrants to

16

---

Table of Contents

purchase shares of our Common Stock were exercised, resulting in the issuance of 3,556,602 shares of Common Stock. Of the 3,556,688 Common Stock options exercised, 86 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the nine months ended September 30, 2014, 5,262,094 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 4,866,852 shares of Common Stock. Of the 5,262,094 Common Stock options and Common Stock warrants exercised, 395,242 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the warrant agreements.

Table of Contents

## NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	September 30, 2015	December 31, 2014
Accounts receivable, net		
Accounts receivable	\$ 198,840	\$ 21,875
Less: allowance for doubtful accounts	(9,115)	(1,906)
	\$ 189,725	\$ 19,969
Inventories, net		
Consumable supplies	\$ 21,119	\$ 279
Finished products	13,851	11,837
Work in-process	1,045	1,011
Raw materials	5,472	4,116
Less: inventory reserve	(794)	(639)
	\$ 40,693	\$ 16,604
Prepaid expenses and other current assets		
Deferred tax assets	\$ 55,527	\$ 1,892
Prepaid supplies	9,298	1,123
Other receivables	3,995	669
Taxes recoverable	3,083	2,417
Other	2,357	2,320
Prepaid insurance	594	968
	\$ 74,854	\$ 9,389
Intangible assets, net:		
Customer relationships	\$ 451,030	\$ 22,108
Technologies	151,791	52,508
Trade names	50,431	3,483
Licenses	25,399	572
Covenants not to compete	8,618	8,639
Product registrations	7,642	8,763
Other	11,342	507
Less: accumulated amortization	(45,966)	(33,931)
	\$ 660,287	\$ 62,649
Accrued expenses:		
Deferred revenue	\$ 75,763	\$ 4,185
Employee benefits	31,668	4,127
Contingent consideration	28,283	27,352
Taxes payable	24,024	77
Capital leases short-term	10,785	—
Clinical trials	4,351	8,643
Professional fees	1,375	1,860
Milestone payment	5,000	—
Other	19,864	14,668
	\$ 201,113	\$ 60,912

Table of Contents

(In thousands)	September 30, 2015	December 31, 2014
Other long-term liabilities:		
Deferred revenue	\$ 178,308	\$ 2,526
Contingent consideration – OPKO Renal	19,210	36,529
Contingent consideration – OPKO Health Europe	232	254
Contingent consideration – OPKO Diagnostics	7,683	6,992
Contingent consideration – CURNA	450	440
Mortgages and other debts payable	4,735	2,434
Capital leases long-term	7,120	—
Other	18,738	1,030
	\$ 236,476	\$ 50,205

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

At September 30, 2015, the changes in value of the intangible assets and goodwill are primarily due to the acquisitions of Bio-Reference and EirGen and foreign currency fluctuations between the Chilean and Mexican pesos, the Euro and the Shekel against the U.S. dollar.

The following table reflects the changes in Goodwill during the nine months ended September 30, 2015.

(In thousands)	2015			Balance at September 30th
	Balance at January 1st	Acquisitions and deconsolidation	Foreign exchange	
Pharmaceuticals				
CURNA	\$ 4,827	\$ —	\$ —	\$ 4,827
EirGen	—	66,823	273	67,096
FineTech	11,698	—	—	11,698
OPKO Chile	5,283	—	(739	) 4,544
OPKO Biologics	139,784	—	—	139,784
OPKO Health Europe	8,013	—	(600	) 7,413
OPKO Mexico	100	—	(13	) 87
OPKO Renal	2,069	—	—	2,069
SciVac	1,553	(1,553	) —	—
Diagnostics				
Bio Reference	—	472,751	—	472,751
OPKO Diagnostics	17,977	—	—	17,977
OPKO Lab	32,988	—	—	32,988
	\$ 224,292	\$ 538,021	\$(1,079	) \$ 761,234

Table of Contents

## NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

## Bio-Reference acquisition

In August 2015, we completed the acquisition of Bio-Reference following a vote of Bio-Reference's shareholders to adopt the Merger Agreement and approve the merger. Bio-Reference is the third largest full service clinical laboratory in the United States and is known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Under the terms of the Merger Agreement, holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately \$950.0 million, based on a closing price per share of our Common Stock of \$12.38 as reported by the New York Stock Exchange, or \$34.05 per share of Bio-Reference common stock. Included in the transaction value is \$2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

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

(In thousands)	Bio-Reference	
Purchase price:		
Value of OPKO Common Stock issued to Bio-Reference shareholders	\$947,889	
Value of replacement stock options awards to holders of Bio-Reference stock options	2,259	
Less: Equity issuance costs	(138	)
Total purchase price	\$950,010	
Preliminary value of assets acquired and liabilities assumed:		
Current assets		
Cash and cash equivalents	\$15,800	
Accounts receivable	162,940	
Inventory	19,825	
Other current assets, principally deferred tax assets	54,141	
Total current assets	252,706	
Property, plant and equipment	106,306	
Intangible assets:		
Trade name	47,100	
Customer relationships	395,200	
Technology	100,600	
Internally developed software	6,900	
Total intangible assets	549,800	
Goodwill	472,751	
Investments	5,326	
Other assets	12,164	
Total assets	1,399,053	
Accounts payable	(79,360	)
Accrued expenses	(29,249	)
Income taxes payable	(20,411	)
Lines of credit and notes payable	(65,701	)
Capital lease obligations	(18,293	)
Deferred tax liability (non-current)	(236,029	)
Total purchase price	\$950,010	

Table of Contents

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

Revenue and Net income (loss) in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2015 includes revenue and net income (loss) of Bio-Reference from the date of acquisition to September 30, 2015 of \$102.1 million and \$6.8 million, respectively.

The preliminary amortization periods for intangible assets acquired are 5 years for trade name, 10-20 years for customer relationships, 8-12 years for technology and 3 years for internally developed software.

We recognized \$6.2 million of acquisition related costs for the acquisition of Bio-Reference that were expensed in the current period as a component of Selling, general and administrative expense.

**Pro forma disclosure for Bio-Reference acquisition**

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

(In thousands)	For the three months ended		For the nine months ended	
	September 30, 2015	2014	September 30, 2015	2014
Revenues	\$282,461	\$241,826	\$813,018	\$670,280
Net income (loss)	121,086	(25,282)	(7,507)	(90,990)
Net income (loss) attributable to common shareholders	121,086	(23,937)	(6,107)	(67,841)

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

**EirGen Pharma Limited acquisition**

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

Table of Contents

The following table summarizes the preliminary purchase price allocation and the estimated fair value of the net assets acquired and liabilities assumed in the acquisition of EirGen at the date of acquisition. The purchase price allocation for EirGen is preliminary:

(In thousands)	EirGen	
Current assets <sup>(1)</sup>	\$11,795	
Intangible assets:		
IPR&D assets	19,597	
Customer relationships	34,155	
Currently marketed products	3,919	
Total intangible assets	57,671	
Goodwill	66,823	
Property, plant and equipment	8,117	
Other assets	1,232	
Accounts payable and other liabilities	(6,254	)
Deferred tax liability	(5,618	)
Total purchase price	\$133,766	

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

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

Revenue and Net income (loss) in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2015 includes revenue and earnings (loss) of EirGen from the date of acquisition to September 30, 2015 of \$7.6 million and \$0.1 million, respectively.

Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval, the IPR&D assets are then accounted for as finite-lived intangible assets and amortized on a straight-line basis over its estimated useful life. We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, currently ranging from 3 to 20 years.

We recognized \$0.5 million of acquisition related costs for the acquisition of EirGen that were expensed in the current period as a component of Selling, general and administrative expense.

Pro forma disclosure for EirGen acquisition

The following table includes the pro forma results for the three and nine months ended September 30, 2015 and 2014 of the combined companies as though the acquisition of EirGen had been completed as of the beginning of the period presented.

(In thousands)	For the three months ended		For the nine months ended	
	September 30, 2015	2014	September 30, 2015	2014
Revenues	\$143,034	\$22,730	\$219,803	\$75,470
Net income (loss)	128,247	(49,834)	(34,084)	(125,657)
Net income (loss) attributable to common shareholders	128,247	(48,489)	(32,684)	(123,176)

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



Table of Contents

## Inspiro Medical Ltd. acquisition

In May 2014, we acquired 100% of the issued and outstanding share capital of Inspiro Medical Ltd. (“Inspiro”), an Israeli medical device company developing a new platform to deliver small molecule drugs such as corticosteroids and beta agonists and larger molecules to treat respiratory diseases.

In connection with the transaction, we paid \$1.5 million in cash and delivered 999,556 shares of our Common Stock valued at \$8.6 million.

Inspiro’s Inspiromatic™ is a “smart” easy-to-use dry powder inhaler with several advantages over existing devices. We anticipate that this innovative device will play a valuable role in the improvement of therapy for asthma, chronic obstructive pulmonary disease, cystic fibrosis and other respiratory diseases. We recorded the transaction as an asset acquisition and recorded the assets and liabilities at fair value. As the asset had no alternative future use, we recorded \$10.1 million of acquired in-process research and development expenses. We record expense for in-process research and development projects accounted for as asset acquisitions which have not reached technological feasibility and which have no alternative future use.

## Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of September 30, 2015:

(in thousands)

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	\$25,693	\$30,722
Variable interest entity, equity method	303	—
Available for sale investments	3,156	
Warrants and options	5,543	
Total carrying value of investments	\$34,695	

## Equity Method Investments

Our equity method investments consist of investments in Pharmsynthez (ownership 17%), Cocystal Pharma, Inc. (“COCP”) (8%), Sevion Therapeutics, Inc. (“Sevion”) (3%), Non-Invasive Monitoring Systems, Inc. (1%), Neovasc (5%), STI (25%) and InCellDx, Inc. (27%) The total assets, liabilities, and net losses of our equity method investees as of and for the nine months ended September 30, 2015 were \$430.5 million, \$(100.3) million, and \$(64.3) 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 voting power. Accordingly, we account for our investment in these entities under the equity method. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Loss from investments in investees in our Condensed Consolidated Statement of Operations. The aggregate value of our equity method investments based on the quoted market price of their common stock and the number of shares held by us as of September 30, 2015 is \$85.9 million. See further discussion of our investment in Pharmsynthez below.

## Available for Sale Investments

Our available for sale investments consist of investments in RXi Pharmaceuticals Corporation (“RXi”) (ownership 3%), ChromaDex Corporation (2%) and ARNO Therapeutics, Inc. (“ARNO”) (4%). We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of our available for sale investments. Accordingly, we account for our investment in these entities as available for sale, and we record changes in these investments as an unrealized gain or loss in Other comprehensive income (loss) each reporting period.

## Sales of Investments

Gains (losses) included in earnings from sales of our investments for the nine months ended September 30, 2014 were \$1.3 million and were recorded in Other income (expense), net in our Condensed Consolidated Statement of Operations. We did not have any such activity in the nine months ended September 30, 2015. The cost of securities sold is based on the specific identification method.



## Table of Contents

### Warrants and Options

In addition to our equity method investments and available for sale investments, we hold options to purchase 1.0 million additional shares of Neovasc, which are fully vested as of December 31, 2014, and 1.0 million, 0.8 million, 0.5 million and 1.7 million of warrants to purchase additional shares of COCP, ARNO, Sevion and MabVax Therapeutics Holdings, Inc., respectively. We recorded the changes in the fair value of the options and warrants in Fair value changes of derivative instruments, net in our Consolidated Statements of Operations. We record the fair value of the options and warrants in Investments, net in our 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 840,000 shares of Zebra Series A-2 Preferred Stock and 900,000 shares of Zebra restricted common stock (ownership 28% at September 30, 2015). Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Dr. Richard Lerner, M.D., a member of our Board of Directors, is a founder of Zebra and, along with Dr. Frost, serves as a member of Zebra's Board of Directors. In order to determine the primary beneficiary of Zebra, we evaluated our investment and our related parties' investment, as well as our investment combined with the related party group's investment to identify if we had the power to direct the activities that most significantly impact the economic performance of Zebra. We determined that we do not have the power to direct the activities that most significantly impact Zebra's economic performance. Based on the capital structure, governing documents and overall business operations of Zebra, we determined that, while a VIE, we do not have the power to direct the activities that most significantly impact Zebra's economic performance. We did determine, however, that we can significantly influence the success of Zebra through our board representation and voting power. Therefore, we have the ability to exercise significant influence over Zebra's operations and account for our investment in Zebra under the equity method.

### Investment in SciVac

In June 2012, we acquired a 50% stock ownership in SciVac from FDS Pharma LLP ("FDS"). SciVac was a privately-held Israeli company that produces a third-generation hepatitis B-vaccine. From November 2012 through June 30, 2015, we loaned to SciVac a combined \$7.9 million for working capital purposes. We determined that we held variable interests in SciVac based on our assessment that SciVac does not have sufficient resources to carry out its principal activities without financial support. We had also determined we were the primary beneficiary of SciVac through our representation on SciVac's board of directors. SciVac's board of directors consisted of 5 members, of which 3 members had been appointed by us, representing 60% of SciVac's board. As a result of this conclusion, we consolidated the results of operations and financial position of SciVac through the second quarter of 2015 and recorded a reduction of equity for the portion of SciVac we do not own.

On July 9, 2015, SciVac Therapeutics Inc., formerly Levon Resources Ltd. ("STI") completed a reverse takeover transaction (the "Arrangement") pursuant to which STI acquired all of the issued and outstanding securities of SciVac in exchange for 517,514,016 common shares of STI, resulting in the former SciVac shareholders holding 68.4% of the issued and outstanding common shares of STI and Levon's shareholders immediately prior to consummation of the transaction controlling the remaining 31.6%. As a result of this transaction, OPKO's ownership in STI decreased to 24.5%.

Upon completion of the Arrangement, we determined that STI was not a VIE. We also determined that we do not have the power to direct the activities that most significantly impact the economic performance of STI that would require us to consolidate STI. STI's board of directors consists of 7 members, of which 3 independent members are initially members of our management. We do not have any rights to appoint members to STI's board. STI's board members are approved by a vote of the shareholders. We recorded a \$17.3 million gain on the deconsolidation of SciVac in Other income (expense), net in our Condensed Consolidated Statement of Operations for the three and nine months ended September 30, 2015. The recognized gain was primarily due to the fair value of the retained interest in STI of \$16.4

million as of July 9, 2015. We determined the fair value of our retained interest in STI based on Levon's cash contribution of CAD \$27.0 million under the Arrangement.

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

Table of Contents

In October 2015, STI announced it entered into an agreement and plan of merger pursuant to which a newly-formed wholly owned subsidiary of STI will merge with and into VBI Vaccines Inc. (“VBI”) with VBI surviving the merger as a wholly owned subsidiary of STI, and STI will change its name to VBI Vaccines Inc. At the effective time of the merger, each share of VBI common stock will be converted into the right to receive 20.808356 common shares of STI (the “Exchange Ratio”). In aggregate, VBI stockholders will receive approximately 541,573,712 common shares of STI, representing approximately 42% of the issued and outstanding shares and voting power of the combined company after giving effect to the merger. In total, upon consummation of the merger, holders of VBI’s securities will receive shares, options and warrants of STI representing approximately 46% of the fully diluted outstanding shares of the combined company.

The following table represents the consolidated assets and non-recourse liabilities related to SciVac as of December 31, 2014. These assets were owned by, and these liabilities were obligations of, SciVac, not us.

(In thousands)	December 31, 2014
Assets	
Current assets:	
Cash and cash equivalents	\$393
Accounts receivable, net	316
Inventories, net	1,649
Prepaid expenses and other current assets	718
Total current assets	3,076
Property, plant and equipment, net	1,725
Intangible assets, net	875
Goodwill	1,553
Other assets	384
Total assets	\$7,613
Liabilities	
Current liabilities:	
Accounts payable	\$445
Accrued expenses	4,446
Notes payable	5,189
Total current liabilities	10,080
Other long-term liabilities	2,042
Total liabilities	\$12,122

Table of Contents

## 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 “Purchaser”) in a private placement in reliance on exemptions from registration under the Securities Act of 1933, (the “Securities Act”). The Purchasers of the 2033 Senior Notes include Frost Gamma Investments Trust, a trust affiliated with Dr. Frost, and Hsu Gamma Investment, L.P., an entity affiliated with Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer. The 2033 Senior Notes were issued on January 30, 2013. The 2033 Senior Notes, which total \$175.0 million, bear interest at the rate of 3.00% per year, payable semiannually on February 1 and August 1 of each year, beginning August 1, 2013. The 2033 Senior Notes will mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change as defined in the instruments governing the 2033 Senior Notes, 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 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, 2015:

(In thousands)	Embedded conversion option	2033 Senior Notes	Discount	Total
Balance at December 31, 2014	\$65,947	\$87,642	\$(22,135)	) \$131,454
Amortization of debt discount	—	—	2,176	2,176
Change in fair value of embedded derivative	31,818	—	—	31,818
Conversion	(78,797)	) (55,442)	) 12,997	(121,242)
Balance at September 30, 2015	\$18,968	\$32,200	\$(6,962)	) \$44,206

The 2033 Senior Notes will be convertible at any time on or after November 1, 2032, through the second scheduled trading day immediately preceding the maturity date, at the option of the holders. Additionally, holders may convert their 2033 Senior Notes prior to the close of business on the scheduled trading day immediately preceding November 1, 2032, under the following circumstances: (1) conversion based upon satisfaction of the trading price condition relating to the 2033 Senior Notes; (2) conversion based on the Common Stock price; (3) conversion based upon the occurrence of specified corporate events; or (4) if we call the 2033 Senior Notes for redemption. The 2033 Senior Notes will be convertible into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our election unless we have made an irrevocable election of net share settlement. The initial conversion rate for the 2033 Senior Notes will be 141.48 shares of Common Stock per \$1,000 principal amount of 2033 Senior Notes (equivalent to an initial conversion price of approximately \$7.07 per share of Common Stock), and will be subject to adjustment upon the occurrence of certain events. In addition, we will, in certain circumstances, increase the conversion rate for holders who convert their 2033 Senior Notes in connection with a make-whole fundamental change (as defined in the Indenture) and holders who convert upon the occurrence of certain specific events prior to February 1, 2017 (other than in connection with a make-whole fundamental change). Holders of the 2033 Senior Notes may require us to repurchase the 2033 Senior Notes for 100% of their principal amount, plus accrued and unpaid interest, on February 1, 2019, February 1, 2023 and February 1, 2028, or following the occurrence of a fundamental change as defined in the indenture governing the 2033 Senior Notes. See further discussion in Note 14.

We may not redeem the 2033 Senior Notes prior to February 1, 2017. On or after February 1, 2017 and before February 1, 2019, we may redeem for cash any or all of the 2033 Senior Notes but only if the last reported sale price of our Common Stock exceeds 130% of the applicable conversion price for at least 20 trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date on which we deliver the redemption notice. The redemption price will equal 100% of the principal amount of the 2033 Senior Notes to be redeemed, plus any accrued and unpaid interest to but not including the redemption date. On or after February 1, 2019, we may redeem for cash any or all of the 2033 Senior Notes at a redemption price of 100% of the principal amount of the 2033 Senior Notes to be redeemed, plus any accrued and unpaid interest up to but not including the redemption

date.

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

26

---

Table of Contents

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

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

On August 30, 2013, one of the conversion rights in the 2033 Senior Notes was triggered. Holders of the 2033 Senior Notes converted \$16.9 million principal amount into 2,396,145 shares of our Common Stock at a rate of 141.4827 shares of Common Stock per \$1,000 principal amount of 2033 Senior Notes. In June 2014, we entered into an exchange agreement with a holder of the Company's 2033 Senior Notes pursuant to which such holder exchanged \$70.4 million in aggregate principal amount of 2033 Senior Notes for 10,974,431 shares of the Company's Common Stock and approximately \$0.8 million in cash representing accrued interest through the date of completion of the exchange.

In March 2015, we entered into exchange agreements with certain holders of our 2033 Senior Notes pursuant to which such holders exchanged \$36.4 million in aggregate principal amount of 2033 Senior Notes for 5,363,896 shares of the Company's Common Stock and approximately \$0.2 million in cash representing accrued interest through the date of completion of the exchange. We recorded a \$0.3 million non-cash loss related to the exchange. The loss on exchange is included within Other income (expense) in our Condensed Consolidated Statement of Operations.

On April 1, 2015, we announced that our 2033 Senior Notes are convertible by holders of such notes. We have elected to satisfy our conversion obligation under the 2033 Senior Notes in shares of our Common Stock. This conversion right was triggered because the closing price per share of our Common Stock has exceeded \$9.19, or 130% of the initial conversion price of \$7.07, for at least 20 of 30 consecutive trading days during the period ending on March 31, 2015. The 2033 Senior Notes were convertible until June 30, 2015, and may be convertible thereafter, if one or more of the conversion conditions specified in the Indenture, dated as of January 30, 2013, by and between the Company and Wells Fargo Bank N.A., is satisfied during future measurement periods. Refer to Note 14. 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. On July 1, 2015 and October 1, 2015, we announced that our 2033 Senior Notes continue to be convertible by holders of such notes during the third and fourth quarters of 2015, respectively.

In May 2015, pursuant to the conversion right, a holder of our 2033 Senior Notes converted \$5.0 million in aggregate principal amount of 2033 Senior Notes for 726,036 shares of the Company's Common Stock. We recorded a \$30,000 non-cash gain related to the exchange. The gain on exchange is included within Other income (expense) in our Condensed Consolidated Statement of Operations.

In August and September 2015, pursuant to the conversion right, holders of our 2033 Senior Notes converted \$14.0 million in aggregate principal amount of 2033 Senior Notes for 2,028,130 shares of the Company's Common Stock. We recorded a \$1.2 million non-cash gain related to the exchange. The gain on exchange is included within Other income (expense) in our Condensed Consolidated Statement of Operations.

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

Using this lattice model, we valued the embedded derivatives using the “with-and-without method,” where the value of the 2033 Senior Notes including the embedded derivatives is defined as the “with,” and the value of the 2033 Senior Notes excluding the embedded derivatives is defined as the “without.” This method estimates the value of the embedded



derivatives by looking at the difference in the values between the 2033 Senior Notes with the embedded derivatives and the value of the 2033 Senior Notes without the embedded derivatives.

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

Table of Contents

The following table sets forth the inputs to the lattice model used to value the embedded derivative:

	September 30, 2015
Stock price	\$8.41
Conversion Rate	141.4827
Conversion Price	\$7.07
Maturity date	February 1, 2033
Risk-free interest rate	1.00%
Estimated stock volatility	49%
Estimated credit spread	1,411 basis points

The following table sets forth the fair value of the 2033 Senior Notes with and without the embedded derivatives, and the fair value of the embedded derivatives at September 30, 2015. At September 30, 2015 the principal amount of the 2033 Senior Notes was \$32.2 million:

(In thousands)	September 30, 2015
Fair value of 2033 Senior Notes:	
With the embedded derivatives	\$41,398
Without the embedded derivatives	\$22,430
Estimated fair value of the embedded derivatives	\$18,968

Changes in certain inputs into the lattice model can have a significant impact on changes in the estimated fair value of the embedded derivatives. For example, a decrease in our estimated credit spread results in an increase in the estimated value of the embedded derivatives. Conversely, a decrease in the price of our Common Stock results in a decrease in the estimated fair value of the embedded derivatives. For the nine months ended September 30, 2015, we observed an increase in the average market price of our Common Stock which resulted in a \$31.8 million increase in the estimated fair value of our embedded derivatives recorded in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations.

In connection with the Bio-Reference merger, Bio-Reference entered into a Fifteenth Amendment to Loan Documents, dated as of August 18, 2015 (the "Loan Amendment"), with PNC Bank, National Association ("PNC"), as lender and as agent, amending the Amended and Restated Loan and Security Agreement, dated as of September 30, 2004, by and among Bio-Reference and GeneDx, Inc., as borrowers, and PNC, as lender and agent, as amended (the "Credit Facility"). The Loan Amendment includes PNC's consent to the Merger and amendments to certain provisions in the Credit Facility to, among other things, (i) permit Bio-Reference to amend its organizational documents and change its fiscal year as a result of the Merger, (ii) modify the event of default triggered upon a change in the existing management of Bio-Reference and (iii) allow termination of the Credit Facility upon 20 days' (or such shorter period as is acceptable to PNC) prior written notice and payment in full of the outstanding obligations under the Credit Facility.

The Credit Facility provides Bio-Reference with a line of credit of up to the lesser of \$120 million and 50% of certain eligible receivables of Bio-Reference, subject to the terms and conditions set forth therein. Borrowings under the Credit Facility may be used for working capital needs and to reimburse drawings under letters of credit. Interest on advances under the Credit Facility is payable based on PNC's prime rate, and may also be based in part on a "Euro-Rate" linked to the London interbank offer rate for US dollars, in each case, plus an additional interest percentage. The Credit Facility is secured by substantially all assets of Bio-Reference and is guaranteed by certain subsidiaries of Bio-Reference. The Credit Facility contains certain affirmative and negative covenants (subject to certain exceptions and baskets), which limit the ability of Bio-Reference, the guarantors thereunder and certain of their subsidiaries to, among other things, pay dividends, incur indebtedness, create liens, enter into certain acquisition transactions and make capital expenditures. Additionally, the Credit Facility contains financial covenants which require Bio-Reference to maintain a minimum fixed charge coverage ratio. The Credit Facility also contains customary events of default, including events of default arising from non-payment, material misrepresentations, breaches of covenants, cross default to certain indebtedness, bankruptcy and changes in management.

In September 2015, we notified PNC of our intent to terminate the Credit Facility and pay in full all amounts due to PNC. We will incur an fee of approximately \$0.5 million for the early termination of the Credit Facility. As of September 30, 2015, approximately \$67.9 million was outstanding under the Credit Facility. At September 30, 2015, the interest rates on borrowings under the Credit Facility ranged from 3.5% to 7.58%.

Table of Contents

On November 5, 2015, Bio-Reference and certain of its subsidiaries entered into a new credit agreement with JPMorgan Chase Bank, N.A. (“CB”), as lender and administrative agent (the “New Credit Agreement”), which replaces Bio-Reference’s existing Credit Facility with PNC. The New Credit Agreement provides for a \$175.0 million secured revolving credit facility and includes a \$20.0 million sub-facility for swingline loans and a \$20.0 million sub-facility for the issuance of letters of credit. Bio-Reference may increase the credit facility to up to \$275.0 million on a secured basis, subject to the satisfaction of specified conditions. The new credit facility matures on November 5, 2020 and is guaranteed by all of Bio-Reference’s domestic subsidiaries. The new credit facility is also secured by substantially all assets of Bio-Reference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in Bio-Reference. Availability under the New Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of Bio-Reference and certain of its subsidiaries, as specified therein. The proceeds of the new credit facility will be used to refinance existing indebtedness, including amounts outstanding under the Credit Facility which has been terminated in accordance with its terms, to finance working capital needs and for general corporate purposes of Bio-Reference and its subsidiaries.

At Bio-Reference’s option, borrowings under the New 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 New Credit Agreement also calls for other customary fees and charges, including an unused commitment fee of 0.25% of the lending commitments.

The New Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require Bio-Reference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws, and restrictions on the ability of Bio-Reference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the New Credit Agreement, notwithstanding the ability of Bio-Reference to meet its debt service obligations. The New 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 New Credit Agreement and execution upon the collateral securing obligations under the New Credit Agreement.

The foregoing description of the New Credit Agreement is only a summary and is qualified in its entirety by reference to the full text of the New Credit Agreement, which will be filed with the Company’s Annual Report on Form 10-K for the year ending December 31, 2015.

We have line of credit agreements with ten financial institutions as of September 30, 2015 and twelve financial institutions as of December 31, 2014 in United States, Chile and Spain. These lines of credit are used primarily as a source of working capital for inventory purchases.

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

Lender	Interest rate on borrowings at September 30, 2015	Credit line capacity	Balance Outstanding	
			September 30, 2015	December 31, 2014
PNC Bank	3.50%	\$120,000	\$67,892	\$—
Itau Bank	6.00%	1,800	980	965

Edgar Filing: Opko Health, Inc. - Form 10-Q

Bank of Chile	5.50%	2,250	2,101	1,410
BICE Bank	6.16%	2,300	1,591	1,249
BBVA Bank	5.00%	2,300	1,418	795
Penta Bank	7.58%	290	289	1,008
Security Bank	6.16%	940	346	361
Estado Bank	5.30%	2,800	2,112	1,870
BBVA Bank	3.90%	281	—	—
Santander Bank	5.30%	2,000	750	—
Total		\$134,961	\$77,479	\$7,658

29

---

Table of Contents

At September 30, 2015 and December 31, 2014, the weighted average interest rate on our lines of credit was approximately 4.6% and 6.1%, respectively.

At September 30, 2015 and December 31, 2014, we had mortgage notes and other debt (excluding the 2033 Senior Notes, the Credit Facility and amounts outstanding under lines of credit) as follows:

(In thousands)	September 30, 2015	December 31, 2014
Current portion of notes payable	\$ 1,029	\$ 608
Other long-term liabilities	2,347	2,435
Total mortgage notes and other debt	\$ 3,376	\$ 3,043

The mortgages and other debts mature at various dates ranging from 2015 through 2024 bearing variable interest rates from 2.7% up to 6.3%. The weighted average interest rate on the mortgage notes and other debt at September 30, 2015 and December 31, 2014, was 3.3% and 3.4%, respectively. The mortgages are secured by our office space in Barcelona.

**NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)**

For the nine months ended September 30, 2015, 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, 2014	\$(6,717	) \$(5,675	) \$(12,392 )
Other comprehensive income before reclassifications, net of tax	(5,998	) (2,602	) (8,600 )
Amounts reclassified from accumulated other comprehensive income, net of tax	—	—	—
Net other comprehensive loss	(5,998	) (2,602	) (8,600 )
Balance at September 30, 2015	\$(12,715	) \$(8,277	) \$(20,992 )

Table of Contents

## NOTE 8 FAIR VALUE MEASUREMENTS

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

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

As of September 30, 2015					
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Realized Gain/(Loss) in Accumulated Deficit	Fair value
Common stock investments, available for sale	\$11,479	\$715	\$(7,596)	\$(1,442)	\$3,156
Common stock options/warrants	3,925	—	—	1,618	5,543
Total assets	\$15,404	\$715	\$(7,596)	\$176	\$8,699
As of December 31, 2014					
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Realized Gain/(Loss) in Accumulated Deficit	Fair value
Common stock investments, available for sale	\$11,479	\$293	\$(4,573)	\$(1,441)	\$5,758
Common stock options/warrants	1,425	216	—	4,673	6,314
Total assets	\$12,904	\$509	\$(4,573)	\$3,232	\$12,072

Any future fluctuation in fair value related to our available for sale investments that is judged to be temporary, and any recoveries of previous write-downs, will be recorded in Accumulated other comprehensive income or loss. If we determine that any future valuation adjustment was other-than-temporary, we will record a loss during the period such determination is made. Any future changes in the fair value of option and warrant instruments will be recorded in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations.

As of September 30, 2015, we have money market funds that qualify as cash equivalents, forward contracts for inventory purchases (Refer to Note 9) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe, and OPKO Renal that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with Neovasc, we record the related Neovasc options at fair value as well as the warrants from COCP, ARNO, Sevion and MabVax.

Table of Contents

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

(In thousands)	Fair value measurements as of September 30, 2015			Total
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Money market funds	\$99,394	\$—	\$—	\$99,394
Common stock investments, available for sale	3,156	—	—	3,156
Common stock options/warrants	—	5,543	—	5,543
Forward contracts	—	65	—	65
Total assets	\$102,550	\$5,608	\$—	\$108,158
Liabilities:				
Embedded conversion option	\$—	\$—	\$18,968	\$18,968
Contingent consideration:				
CURNA	—	—	450	450
OPKO Diagnostics	—	—	14,170	14,170
OPKO Renal	—	—	40,760	40,760
OPKO Health Europe	—	—	477	477
Total liabilities	\$—	\$—	\$74,825	\$74,825

(In thousands)	Fair value measurements as of December 31, 2014			Total
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Money market funds	\$71,286	\$—	\$—	\$71,286
Common stock investments, available for sale	5,758	—	—	5,758
Common stock options/warrants	—	6,314	—	6,314
Forward contracts	—	36	—	36
Total assets	\$77,044	\$6,350	\$—	\$83,394
Liabilities:				
Embedded conversion option	\$—	\$—	\$65,947	\$65,947
Contingent consideration:				
CURNA	—	—	440	440
OPKO Diagnostics	—	—	13,578	13,578
OPKO Renal	—	—	55,780	55,780
OPKO Health Europe	—	—	1,769	1,769
Total liabilities	\$—	\$—	\$137,514	\$137,514

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

September 30, 2015



Edgar Filing: Opko Health, Inc. - Form 10-Q

(In thousands)	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2033 Senior Notes	\$25,238	\$22,430	\$—	\$—	\$22,430

32

---

Table of Contents

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

As of September 30, 2015 and December 31, 2014, the carrying value of our other assets and liabilities approximates their fair value due to their short-term nature.

The following tables reconcile the beginning and ending balances of our Level 3 assets and liabilities as of September 30, 2015:

(In thousands)	September 30, 2015	
	Contingent consideration	Embedded conversion option
Balance at December 31, 2014	\$71,567	\$65,947
Total losses (gains) for the period:		
Included in results of operations	6,471	31,818
Foreign currency impact	(255	) —
Payments	(21,926	) —
Conversion	—	(78,797
Balance at September 30, 2015	\$55,857	\$18,968

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

Contingent consideration – We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to OPKO Diagnostics, CURNA, OPKO Health Europe and OPKO Renal transactions. The discount rates used range from 6% to 27% and were based on the weighted average cost of capital for those businesses. If the discount rates were to increase by 1%, on each transaction, the contingent consideration would decrease by \$0.9 million. If estimated future sales were to decrease by 10%, the contingent consideration related to OPKO Renal would decrease by \$1.8 million. As of September 30, 2015, of the \$55.9 million of contingent consideration, \$28.3 million is recorded in Accrued expenses and \$27.6 million is recorded in Other long-term liabilities. As of December 31, 2014, of the \$71.6 million of contingent consideration, \$27.4 million is recorded in Accrued expenses and \$44.2 million is recorded in Other long-term liabilities.

Deferred payments – We estimate the fair value of the deferred payments utilizing a discounted cash flow model for the expected payments.

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

Table of Contents

## NOTE 9 DERIVATIVE CONTRACTS

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

(In thousands)	Balance Sheet Component	September 30, 2015	December 31, 2014
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	\$ 5,543	\$ 6,314
Embedded conversion option	2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	\$ 18,968	\$ 65,947
Forward contracts	Unrealized gains on forward contracts are recorded in Prepaid expenses and other current assets. Unrealized losses on forward contracts are recorded in Accrued expenses.	\$ 65	\$ 36

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

To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2015 and December 31, 2014, our derivative financial instruments do not meet the documentation requirements to be designated as hedges. Accordingly, we recognize the changes in Fair value of derivative instruments, net in our Condensed Consolidated Statements of Operations. The following table summarizes the losses and gains recorded for the three and nine months ended September 30, 2015 and 2014:

(In thousands)	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Derivative gain (loss):				
Common Stock options/warrants	\$(4,070	) \$651	\$(2,645	) \$388
2033 Senior Notes	36,132	2,521	(31,818	) 3,291
Forward contracts	182	133	363	79
Total	\$32,244	\$3,305	\$(34,100	) \$3,758

The outstanding forward contracts at September 30, 2015 and December 31, 2014, have been recorded at fair value, and their maturity details are as follows:

(In thousands)	Contract value	Fair value at September 30, 2015	Effect on income (loss)
Days until maturity			
0 to 30	\$2,790	\$2,840	\$50
31 to 60	1,966	1,979	13
61 to 90	195	197	2
91 to 120	—	—	—
More than 120	—	—	—
Total	\$4,951	\$5,016	\$65
(In thousands)	Contract value	Fair value at December 31, 2014	Effect on income (loss)
Days until maturity			
0 to 30	\$750	\$780	\$30
31 to 60	90	93	3
61 to 90	—	—	—
91 to 120	68	71	3
121 to 180	—	—	—

Edgar Filing: Opko Health, Inc. - Form 10-Q

More than 180  
Total

—  
\$908

—  
\$944

—  
\$36

34

---

Table of Contents

## NOTE 10 RELATED PARTY TRANSACTIONS

In February 2014, Dr. Frost, our Chairman and Chief Executive Officer, paid a filing fee of \$280,000 to the Federal Trade Commission (the “FTC”) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (“HSR Act”) in connection with filings made by us and Dr. Frost. We reimbursed Dr. Frost for the HSR filing fee.

In August 2013, we acquired OPKO Biologics (formerly PROLOR) pursuant to an Agreement and Plan of Merger dated as of April 23, 2013 in an all-stock transaction. Until completion of the acquisition, Dr. Frost was PROLOR’s Chairman of the Board and a greater than 5% stockholder of PROLOR. Dr. Hsiao and Mr. Rubin were also directors and less than 5% stockholders of PROLOR.

In January 2013, we sold \$175.0 million aggregate principal amount of 2033 Senior Notes in a private placement in reliance on exemptions from registration under the Securities Act. The Purchasers of the 2033 Senior Notes include the Gamma Trust and Hsu Gamma. The 2033 Senior Notes were issued on January 30, 2013.

During the nine months ended September 30, 2014, FineTech recorded revenue of \$0.3 million, respectively, for the sale of APIs to Teva Pharmaceutical Industries, Limited (“Teva”). Dr. Frost previously served as the Chairman of the Board of Directors of Teva until 2015. No revenue was recorded for the nine months ended September 30, 2015.

In 2012, we made a \$1.7 million investment in Biozone. Effective January 2, 2014, Biozone completed a merger with Cocystal Discovery, Inc. (“Cocystal”), another entity in which we had an equity investment. The name of the issuer was changed to Cocystal Pharma, Inc. (“COCP”). Dr. Frost previously invested in both Biozone and Cocystal.

Effective January 16, 2014, we invested an additional \$0.5 million in the company as part of a \$2.75 million private placement and received 1.0 million shares of common stock and 1.0 million 10-year warrants exercisable at \$0.50 per share. At September 30, 2015, we hold an 8% ownership interest in COCP.

We hold investments in Zebra (ownership 28%), Sevion (3%), Neovasc (5%), ChromaDex Corporation (2%), MabVax (0%), and ARNO (4%). The acquisition of 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 May 2015, we agreed to make an additional \$500 thousand investment in Sevion as part of a private placement transaction completed in the third quarter. In July 2015, we made an additional \$500,000 investment in a private placement transaction with Sevion pursuant to which we acquired 66,667 shares of Series C Convertible Preferred Stock convertible into 666,667 shares of common stock and warrants to purchase 333,333 shares of common stock. In October 2015, we made an additional \$375 thousand investment in MabVax pursuant to which we acquired 340,909 shares of common stock at \$1.10 and 170,454 warrants to purchase shares of common stock.

We lease office space from Frost Real Estate Holdings, LLC (“Frost Holdings”) in Miami, Florida, where our principal executive offices are located. Effective May 28, 2015, we entered into an amendment to our lease agreement with Frost Holdings. The lease, as amended, is for approximately 25,000 square feet of space. The lease provides for payments of approximately \$66 thousand per month in the first year increasing annually to \$75 thousand per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking. The rent was reduced by \$216 thousand for the cost of tenant improvements.

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. Prior to 2015, we reimbursed Dr. Frost in an amount equal to the cost of a first class airline ticket between the travel cities for each executive, including Dr. Frost, traveling on the airplane for Company-related business. Beginning in the first quarter of 2015, we reimburse Dr. Frost for out-of-pocket operating costs for the use of the airplane by Dr. Frost or Company executives for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive. For the three and nine months ended September 30, 2015, we recognized approximately \$66 thousand and \$359 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2014, we reimbursed Dr. Frost approximately \$110 thousand and \$118 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

Table of Contents

## NOTE 11 COMMITMENTS AND CONTINGENCIES

In connection with our acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe, and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of September 30, 2015, we recorded \$55.9 million as contingent consideration, with \$28.3 million recorded within Accrued expenses and \$27.6 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

In July 2012, OPKO Lab received a letter from AdvanceMed Corporation (“AdvanceMed”) regarding a post-payment review conducted by AdvanceMed (the “Post-Payment Review Letter”). The Post-Payment Review Letter originated with a post payment review audit by AdvanceMed of 183 claims submitted by OPKO Lab to the Medicare program. OPKO Lab believes that its billing practices were appropriate and it is following the appeal process set forth by Medicare. OPKO Lab received a partially favorable determination, which reduced the amount of the alleged overpayment, and it continues to appeal the remaining alleged overpayments. No assurances can be given about the outcome of the appeal.

On or around October 21, 2014, we received a Civil Investigative Demand (“Demand”) from the U.S. Attorney’s Office for the Middle District of Tennessee (“Attorney’s Office”). The Demand concerns an investigation of allegations that the Company or one of its affiliated entities or other parties submitted false claims for payment related to services provided to government healthcare program beneficiaries in violation of the False Claims Act, 31 U.S.C. Section 3729. We intend to fully cooperate with the investigation and produce documents responsive to the Demand. It is too early to assess the probability of a favorable or unfavorable outcome in this matter or the loss or range of loss, if any. Following the announcement of entry into an agreement and plan of merger with Bio-Reference, four putative class action complaints challenging the merger were filed in the Superior Court of New Jersey in Bergen County (the “Court”). After the complaints were filed, on July 24, 2015, the parties executed a stipulated consent order that the actions would be consolidated for all purposes, including trial, in the Chancery Division under Docket No. C-207-15, bearing the caption In re Bio-Reference Laboratories, Inc. Shareholder Litigation. The complaints name Bio-Reference, OPKO, a wholly-owned merger subsidiary of OPKO (“Merger Sub”) and members of the Bio-Reference board as defendants. The complaints generally allege, among other things, that members of the Bio-Reference board breached their fiduciary duties to Bio-Reference’s shareholders by agreeing to sell Bio-Reference for an inadequate price and agreeing to inappropriate deal protection provisions in the merger agreement that may preclude Bio-Reference from soliciting any potential acquirers and limit the ability of the Bio-Reference board to act with respect to investigating and pursuing superior proposals and alternatives. The complaints also allege that Bio-Reference, OPKO and Merger Sub have aided and abetted the Bio-Reference board members’ breaches of their fiduciary duties. The complaints sought injunctive relief enjoining Bio-Reference and OPKO from consummating the merger at the agreed upon price unless and/or until the defendants cured their breaches of fiduciary duty (or, in the event the merger is consummated, rescinding the merger or awarding rescissory damages). The complaints also sought to recover costs and disbursement from the defendants, including attorneys’ fees and experts’ fees. In August, the parties executed a memorandum of understanding reflecting terms of a settlement, which was replaced in September 2015 by a stipulation and agreement of compromise, settlement and release resolving all matters between them. On September 25, 2015, the Court entered an order preliminarily approving the settlement and setting a scheduling for the Court’s final review of the settlement and notice to the class. A settlement hearing is scheduled for January 5, 2016. Under a license agreement one of our subsidiaries has with Washington University in St. Louis, we are obligated to pay Washington University a single digit percentage of any sublicensing payment we receive in connection with a sublicense of our rights to Washington University patents subject to certain exceptions. In connection with the Pfizer Transaction, we sublicensed to Pfizer the sole remaining patent licensed to us by Washington University and paid to Washington University the sublicensing payment we believe is due under the license agreement. Washington University has questioned the computation of the sublicense payment and has notified us that it would like to review additional information relating to the sublicense and the Pfizer Transaction to determine whether additional amounts are owed to it.

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect

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

Table of Contents

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

We expect to incur substantial losses as we continue the development of our product candidates, continue our other research and development activities, and establish a sales and marketing infrastructure in anticipation of the commercialization of our diagnostic and pharmaceutical product candidates. We currently have limited commercialization capabilities, and it is possible that we may never successfully commercialize any of our diagnostic and pharmaceutical product candidates. We do not currently generate significant revenue from any of our diagnostic and pharmaceutical product candidates. Our research and development activities are budgeted to expand over a period of time and will require further resources if we are to be successful. As a result, we believe that our operating losses are likely to be substantial over the next several years. We may need to obtain additional funds to further develop our research and development programs, and there can be no assurance that additional capital will be available to us on acceptable terms, or at all.

We have employment agreements with certain executives which provide for compensation and certain other benefits and for severance payments under certain circumstances.

At September 30, 2015, we were committed to make future purchases for inventory and other items that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating \$19.3 million.



Table of Contents

NOTE 12 STRATEGIC ALLIANCES

Pfizer Inc.

We plan to develop a portfolio of product candidates through a combination of internal development and external partnerships. In December 2014, we entered into an exclusive worldwide agreement with Pfizer Inc. (“Pfizer”) for the development and commercialization of our long-acting hGH-CTP for the treatment of growth hormone deficiency (“GHD”) in adults and children, as well as for the treatment of growth failure in children born small for gestational age (“SGA”) (the “Pfizer Transaction”).

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

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

We will lead the clinical activities and will be responsible for funding the development programs for the key indications, which includes Adult and Pediatric GHD and Pediatric SGA. Pfizer will be responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer will fund the commercialization activities for all indications and lead the manufacturing activities covered by the global development plan.

For revenue recognition purposes, we viewed the Pfizer Transaction as a multiple-element arrangement.

Multiple-element arrangements are analyzed to determine whether the various performance obligations, or elements, can be separated or whether they must be accounted for as a single unit of accounting. We evaluated whether the delivered element under the arrangement has standalone value and qualifies for treatment as a separate unit of accounting. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. For a single unit of accounting, payments received are recognized in a manner consistent with the final deliverable. We determined that the deliverables under the Pfizer Transaction, including the licenses granted to Pfizer, as well as our obligations to provide various research and development services, will be accounted for as a single unit of account. This determination was made because the ongoing research and development services to be provided by us are essential to the overall arrangement as we have significant knowledge and technical know-how that is important to realizing the value of the licenses granted. The performance period over which the revenue will be recognized is expected to continue from the first quarter of 2015 through 2019, when we anticipate completing the various research and development services that are specified in the Pfizer Transaction and our performance obligations are completed. We will continue to review the timing of when our research and development services will be completed in order to assess that the estimated performance period over which the revenue is to be recognized is appropriate. Any significant changes in the timing of the performance period will result in a change in the revenue recognition period. We are recognizing the non-refundable \$295.0 million upfront payments on a straight-line basis over the performance period. We recognized \$47.8 million of revenue related to the Pfizer Transaction in Revenue from transfer of intellectual property in our Condensed Consolidated Statement of Operations during the nine months ended September 30, 2015, and had deferred revenue related to the Pfizer Transaction of \$247.2 million at September 30, 2015. As of September 30, 2015, \$70.6 million of deferred revenue related to the Pfizer Transaction was classified in Accrued expenses and \$176.6 million was classified in Other long-term liabilities in our Condensed Consolidated

Balance Sheet.

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

Table of Contents

associated milestone is achieved, assuming all other revenue recognition criteria are met. To date, no revenue has been recognized related to the achievement of the milestones.

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

**TESARO**

In November 2009, we entered into an asset purchase agreement (the “NK-1 Agreement”) under which we acquired Varubi™ (rolapitant) and other neurokinin-1 (“NK-1”) assets from Merck. In December 2010, we entered into an exclusive license agreement with TESARO, in which we out-licensed the development, manufacture, commercialization and distribution of our lead NK-1 candidate, Varubi™ (the “TESARO License”). Under the terms of the license, we received a \$6.0 million upfront payment from TESARO and are eligible to receive milestone payments of up to \$30 million upon achievement of certain regulatory and commercial sale milestones (of which \$5 million has been paid to date) and additional commercial milestone payments of up to \$85 million if specified levels of annual net sales are achieved. During the nine months ended September 30, 2015 and 2014, no revenue has been recognized related to the achievement of the milestones under the TESARO License. TESARO is also obligated to pay us tiered royalties on annual net sales achieved in the United States and Europe at percentage rates that range from the low double digits to the low twenties, and outside of the United States and Europe at low double-digit percentage rates. TESARO assumed responsibility for clinical development and commercialization of licensed products at its expense. Under the Agreement, we will continue to receive royalties on a country-by-country and product-by-product basis until the later of the date that all of the patent rights licensed from us and covering Varubi™ expire, are invalidated or are not enforceable and 12 years from the first commercial sale of the product.

If TESARO elects to develop and commercialize Varubi™ in Japan through a third-party licensee, TESARO will share equally with us all amounts it receives in connection with such activities, subject to certain exceptions and deductions. In addition, we will have an option to market the products in Latin America.

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

TESARO’s New Drug Application (NDA) for approval of oral Varubi™, an investigational neurokinin-1 receptor antagonist in development for the prevention of chemotherapy-induced nausea and vomiting, was approved by the U.S. FDA in September 2015. Under the terms of the NK-1 Agreement, upon approval by the FDA of the TESARO’s NDA for oral Varubi™, we were required to pay Merck a \$5.0 million milestone payment. In addition, \$5.0 million will be due and payable each year thereafter for the next four (4) years on the anniversary date of the NDA approval. We recognized the total milestone payments of \$25.0 million as an intangible asset which will be amortized to expense over the expected useful life of the asset, which is approximately 13 years. We recognized the \$20.0 million of future payments to Merck as a liability in our Condensed Consolidated Balance Sheet at September 30, 2015, with \$5.0 million in Accrued expenses and \$15.0 million in Other long-term liabilities.

Table of Contents

Pharmsynthez

In April 2013, we entered into a series of concurrent transactions with Pharmsynthez, a Russian pharmaceutical company traded on the Moscow Stock Exchange pursuant to which we acquired an equity method investment in Pharmsynthez (ownership 17%). We also granted rights to certain technologies in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan (the “Territories”) to Pharmsynthez and agreed to perform certain development activities. We will receive from Pharmsynthez royalties on net sales of products incorporating the technologies in the Territories, as well as a percentage of any sublicense income from third parties for the technologies in the Territories. In July 2015, we entered into a Note Purchase Agreement with Pharmsynthez pursuant to which we delivered \$3.0 million to Pharmsynthez in exchange for a \$3.0 million note (the “Pharmsynthez Note Receivable”). The Pharmsynthez Note Receivable is due on or before July 1, 2016, and Pharmsynthez may satisfy the note either in cash or shares of its capital stock. We recorded the Pharmsynthez Note Receivable within Prepaid expenses and other current assets in our Condensed Consolidated Balance Sheet.

RXi Pharmaceuticals Corporation

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

Other

We have completed strategic deals with the UT Southwestern, Washington University, INEOS Healthcare, TSRI, the President and Fellows of Harvard College, and Academia Sinica, among others. In connection with these agreements, upon the achievement of certain milestones we are obligated to make certain payments and have royalty obligations upon sales of products developed under the license agreements. At this time, we are unable to estimate the timing and amounts of payments as the obligations are based on future development of the licensed products.

NOTE 13 SEGMENTS

We currently manage our operations in two reportable segments, pharmaceuticals and diagnostics. The pharmaceuticals segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, and vaccines, and (ii) the pharmaceutical operations we acquired in Chile, Mexico, Ireland, Israel, Spain, Brazil, and Uruguay. The diagnostics segment consists of two operating segments, our (i) clinical laboratory operations we acquired through the acquisitions of Bio-Reference and OPKO Lab and (ii) point-of-care and molecular diagnostics 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.

Table of Contents

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		For the nine months ended	
	September 30, 2015	2014	September 30, 2015	2014
Revenue from services:				
Pharmaceuticals	\$ 160	\$—	\$ 192	\$—
Diagnostics	103,739	2,422	107,597	6,426
Corporate	20	60	140	180
	\$ 103,919	\$ 2,482	\$ 107,929	\$ 6,606
Product revenues:				
Pharmaceuticals	\$ 20,765	\$ 17,291	\$ 59,066	\$ 58,510
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	\$ 20,765	\$ 17,291	\$ 59,066	\$ 58,510
Revenue from transfer of intellectual property:				
Pharmaceuticals	\$ 18,350	\$—	\$ 48,552	\$ 285
Diagnostics	—	—	—	191
Corporate	—	—	—	—
	\$ 18,350	\$—	\$ 48,552	\$ 476
Operating (loss) income:				
Pharmaceuticals	\$ 5,300	\$ (34,480)	\$ (36,861)	\$ (71,421)
Diagnostics	(1,961)	(6,738)	(17,961)	(20,621)
Corporate	(11,562)	(6,384)	(34,444)	(19,557)
Less: Operating loss attributable to noncontrolling interests	—	(599)	(1,281)	(1,762)
	\$ (8,223)	\$ (48,201)	\$ (90,547)	\$ (113,361)
Depreciation and amortization:				
Pharmaceuticals	\$ 2,775	\$ 2,020	\$ 6,902	\$ 6,061
Diagnostics	9,602	1,717	13,103	5,136
Corporate	22	31	68	72
	\$ 12,399	\$ 3,768	\$ 20,073	\$ 11,269
Net loss from investment in investees:				
Pharmaceuticals	\$ (3,502)	\$ (60)	\$ (6,067)	\$ (2,486)
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	\$ (3,502)	\$ (60)	\$ (6,067)	\$ (2,486)
Revenues:				
United States	\$ 104,358	\$ 2,482	\$ 109,359	\$ 7,082
Ireland	22,308	—	53,807	—
Chile	7,779	7,622	22,929	22,758
Spain	3,447	4,414	12,303	16,230
Israel	4,154	3,710	14,309	14,563
Mexico	988	1,528	2,840	4,905
Other	—	17	—	54
	\$ 143,034	\$ 19,773	\$ 215,547	\$ 65,592



Table of Contents

(In thousands)	September 30, 2015	December 31, 2014
Assets:		
Pharmaceuticals	\$1,262,373	\$1,064,498
Diagnostics	1,287,854	108,072
Corporate	465,626	95,094
	\$3,015,853	\$1,267,664
Goodwill:		
Pharmaceuticals	\$237,518	\$173,327
Diagnostics	523,716	50,965
Corporate	—	—
	\$761,234	\$224,292

During the three and nine months ended September 30, 2015, revenue recognized under the Pfizer Transaction represented 11% and 21% of our total revenue. Refer to Note 12. During the three months ended September 30, 2014, no customer represented more than 10% of our total revenue and during the nine months ended September 30, 2014, one customer represented 13% of our total revenue. As of September 30, 2015, one customer represented more than 10% of our accounts receivable balance. As of December 31, 2014, no customer represented more than 10% of our accounts receivable balance.

**NOTE 14 SUBSEQUENT EVENTS**

On October 1, 2015, we announced that our 2033 Senior Notes continue to be convertible by holders of such notes. We have elected to satisfy our conversion obligation under the 2033 Senior Notes in shares of our Common Stock. This conversion right has been triggered because the closing price per share of our Common Stock has exceeded \$9.19, or 130% of the initial conversion price of \$7.07, for at least 20 of 30 consecutive trading days during the period ending on September 30, 2015. The conversion right was previously triggered during the quarters ended March 31, 2015 and June 30, 2015. The 2033 Senior Notes will continue to be convertible until December 31, 2015, and may be convertible thereafter, if one or more of the conversion conditions specified in the Indenture, dated as of January 30, 2013, by and between the Company and Wells Fargo Bank N.A., 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.

On November 5, 2015, Bio-Reference and certain of its subsidiaries entered into a new credit agreement with JPMorgan Chase Bank, N.A. (“CB”), as lender and administrative agent (the “New Credit Agreement”), which replaces Bio-Reference’s existing loan agreement with PNC (the “Existing Loan Agreement”). The New Credit Agreement provides for a \$175.0 million secured revolving credit facility and includes a \$20.0 million sub-facility for swingline loans and a \$20.0 million sub-facility for the issuance of letters of credit. Bio-Reference may increase the credit facility to up to \$275.0 million on a secured basis, subject to the satisfaction of specified conditions. The new credit facility matures on November 5, 2020 and is guaranteed by all of Bio-Reference’s domestic subsidiaries. The new credit facility is also secured by substantially all assets of Bio-Reference and its domestic subsidiaries, as well as a non-recourse pledge by the Company of its equity interest in Bio-Reference. Availability under the New Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of Bio-Reference and certain of its subsidiaries, as specified therein. The proceeds of the new credit facility will be used to refinance existing indebtedness, including amounts outstanding under the Existing Loan Agreement which has been terminated in accordance with its terms, to finance working capital needs and for general corporate purposes of Bio-Reference and its subsidiaries.

At Bio-Reference’s option, borrowings under the New 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 New Credit Agreement also calls for other customary fees and charges, including an unused commitment fee of 0.25% of the lending commitments.

The New Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require Bio-Reference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new



Table of Contents

credit facility falls below a specified amount and to comply with laws, and restrictions on the ability of Bio-Reference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the New Credit Agreement, notwithstanding the ability of Bio-Reference to meet its debt service obligations. The New 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 New Credit Agreement and execution upon the collateral securing obligations under the New Credit Agreement.

The foregoing description of the New Credit Agreement is only a summary and is qualified in its entirety by reference to the full text of the New Credit Agreement, which will be filed with the Company's Annual Report on Form 10-K for the year ending December 31, 2015.

We have reviewed all subsequent events and transactions that occurred after the date of our September 30, 2015 Condensed Consolidated Balance Sheet date, through the time of filing this Quarterly Report on Form 10-Q.

Table of Contents

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

OVERVIEW

You should read this discussion together with the 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, 2014 (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, 2014, 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, the nation's third-largest clinical laboratory with a core genetic testing business and a 420-person salesforce to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros®1 in-office immunoassay platform. Our pharmaceutical business features Rayaldee™, a treatment for secondary hyperparathyroidism in stage 3-4 chronic kidney disease patients with vitamin D deficiency (March 29, 2016 PDUFA date) and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation approved by FDA and pending launch by partner TESARO). Our biologics business includes 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 (entering Phase 2).

We own established pharmaceutical platforms in Spain, Ireland, Chile, Mexico, and Uruguay which are generating revenue and from which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. EirGen, our specialty pharmaceutical company incorporated in Ireland, is focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products. In addition, we operate a specialty active pharmaceutical ingredients ("APIs") manufacturer in Israel, which we expect will facilitate the development of our pipeline of molecules and compounds for our proprietary products.

RECENT DEVELOPMENTS

In May 2015, we submitted a NDA for Rayaldee™ to the FDA requesting marketing approval for Rayaldee for the prevention and treatment of secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency. Our NDA was accepted by the FDA for review in July 2015.

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

In August 2015, we completed the acquisition of Bio-Reference following a vote of Bio-Reference's shareholders to adopt the agreement and plan of merger ("Merger Agreement") and approve the merger. Bio-Reference is the third largest full service clinical laboratory in the United States and is known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Under the terms of the Merger Agreement, holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately \$950.0 million, based on a closing price per share of our Common Stock of \$12.38 as reported by the New York Stock Exchange, or \$34.05 per share of Bio-Reference common stock. Included in the transaction value is \$2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

Our licensee, TESARO's NDA for approval of oral Varubi™, an investigational neurokinin-1 receptor antagonist in development for the prevention of chemotherapy-induced nausea and vomiting, was approved by the U.S. FDA in September 2015. Under the terms of the TESARO license, TESARO is obligated to pay us tiered royalties on annual net sales of licensed products 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.



Table of Contents

## RESULTS OF OPERATIONS

## FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

Revenues. Revenues for the three months ended September 30, 2015 increased \$123.3 million compared to the prior year period. Our acquisition of Bio-Reference in August 2015 accounted for \$102.1 million of the quarter-over-quarter revenue growth. Revenues for the three months ended September 30, 2015 and 2014 were as follows:

Revenues (In thousands)	For the three months ended September 30,		
	2015	2014	Change
Revenue from services	\$ 103,919	\$ 2,482	\$ 101,437
Revenue from products	20,765	17,291	3,474
Other revenue	18,350	—	18,350
Total revenues	\$ 143,034	\$ 19,773	\$ 123,261

The increase in Revenue from services is attributable to the acquisition of Bio-Reference in August 2015. The increase in Revenue from products principally reflects \$4.6 million of revenue from EirGen, which we acquired in May 2015, which was partially offset by a decrease in pharmaceutical product revenue from our Spanish and Mexican operations and STI (formerly SciVac), a VIE we deconsolidated in July 2015. The increase in Other revenue principally reflects \$17.7 million of revenue from the transfer of intellectual property related to the Pfizer Transaction. We are recognizing the non-refundable \$295.0 million upfront payments received in the Pfizer Transaction on a straight-line basis over the expected performance period. The performance period is expected to continue through 2019, when we anticipate completing the various research and development services that are specified in the Pfizer Transaction.

Costs of revenue. Cost of revenue for the three months ended September 30, 2015 increased \$56.2 million compared to the prior year period. Our acquisition of Bio-Reference in August 2015 accounted for \$53.9 million of the quarter-over-quarter cost of revenue growth. Costs of revenue for the three months ended September 30, 2015 and 2014 were as follows:

Cost of Revenue (In thousands)	For the three months ended September 30,		
	2015	2014	Change
Cost of service revenue	\$56,670	\$2,359	\$54,311
Cost of product revenue	10,658	8,761	1,897
Total cost of revenue	\$67,328	\$11,120	\$56,208

The increase in cost of service revenue is attributable to the acquisition of Bio-Reference in August 2015. The increase in cost of product revenue principally reflects cost of revenue of \$2.3 million from EirGen, which we acquired in May 2015, and was partially offset by decreased pharmaceutical product sales from our Spanish and Mexican operations and the deconsolidation of STI in July 2015.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2015 and 2014, were \$55.2 million and \$14.0 million, respectively. The increase in selling, general and administrative expenses for the three months ended September 30, 2015 was primarily due to the acquisitions of Bio-Reference and EirGen in 2015, increased personnel expenses as we expand our sales, marketing and administrative staff and add infrastructure, and an increase in professional fees attributable to our acquisitions of Bio-Reference and EirGen. Selling, general and administrative expenses for the three months ended September 30, 2015 include \$35.3 million and \$0.6 million from Bio-Reference and EirGen. Selling, general and administrative expenses during the three months ended September 30, 2015 and 2014, include bad debt expense of \$7.7 million and \$0.1 million, respectively, and equity-based compensation expense of \$3.2 million and \$2.3 million, respectively. The increase in bad debt expense is due to the acquisition of Bio-Reference.

Research and development expenses. Research and development expenses for the three months ended September 30, 2015 and 2014, were \$18.9 million and \$20.5 million, respectively. Research and development costs include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements.

External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and PMA's (pre-market approval) for diagnostics tests, if any. Internal

45

---

Table of Contents

expenses include employee-related expenses including salaries, benefits and stock-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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

Research and Development Expenses	For the three months ended September 30,	
	2015	2014
External expenses:		
Phase 3 clinical trials	\$3,218	\$3,898
CMC expense for biological products	3,122	5,316
Earlier-stage programs	1,266	1,927
Research and development employee-related expenses	5,145	4,801
Other internal research and development expenses	6,792	5,188
Third-party grants and funding from collaboration agreements	(606	) (613
Total research and development expenses	\$18,937	\$20,517

The decrease in research and development expenses during the three months ended September 30, 2015, is primarily due to decreased expenses incurred by OPKO Renal related to phase 3 clinical trials for Rayaldee. Research and development expenses for the three months ended September 30, 2015 includes \$10.4 million of expense related to hGH-CTP, a long acting human growth hormone which was outlicensed to Pfizer in 2015, including clinical manufacturing costs (“CMC”). Research and development expenses for the three months ended September 30, 2015 also include \$0.4 million and \$1.1 million from Bio-Reference and EirGen which we acquired in August 2015 and May 2015, respectively. In addition, during the three months ended September 30, 2015 and 2014, we recorded, as an offset to research and development expenses, \$0.6 million and \$0.6 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the three months ended September 30, 2015 and 2014 include equity-based compensation expense of \$0.2 million and \$0.7 million, respectively. We expect our research and development expense to increase as we continue to expand our research and development of potential future products.

Contingent consideration. Contingent consideration income (expense) for the three months ended September 30, 2015 and 2014, were \$1.6 million and \$19.6 million, respectively. The decrease in contingent consideration expense was attributable to OPKO Renal resulting from an increase in the fair value of our contingent obligations to OPKO Renal in the third quarter of 2014 due to changes in assumptions regarding probabilities of successful achievement of future milestones driven by the two successful phase 3 trials of Rayaldee in the third quarter of 2014. The contingent consideration liabilities at September 30, 2015 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets for the three months ended September 30, 2015 and 2014, were \$8.1 million and \$2.7 million, respectively. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the three months ended September 30, 2015 includes \$4.9 million and \$0.6 million from Bio-Reference and EirGen which we acquired in August 2015 and May 2015, respectively. Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, the IPR&D assets will then be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Interest income. Interest income for the three months ended September 30, 2015 and 2014, was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

Interest expense. Interest expense for the three months ended September 30, 2015 and 2014, was \$2.7 million and \$2.4 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes and by the amortization of related deferred financing costs. The increase in interest expense for the three months ended September 30, 2015 compared to the same period in 2014 is due to interest expense of \$(0.8) million from Bio-Reference due to outstanding debt under the Credit Facility with PNC, which was partially offset by a decrease in

the principal amount of the 2033 Senior Notes outstanding from \$87.6 million at September 30, 2014 to \$32.2 million as of September 30, 2015. Interest expense for the three months ended September 30, 2015 also reflect non-cash write-offs of deferred financing costs of \$0.2 million as interest expense related to conversion of \$14.0 million principal of 2033 Senior Notes in August and September 2015.

Table of Contents

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended September 30, 2015 and 2014, were \$32.2 million and \$3.3 million of income, respectively. Fair value changes of derivative instruments, net principally related to non-cash income related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes of \$36.1 million and \$2.5 million for the three months ended September 30, 2015 and 2014, respectively. For the three months ended September 30, 2015, 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. Income for the three months ended September 30, 2015 was partially offset by expense of \$(4.1) million related to the change in the fair value of options and warrants to purchase additional shares of Neovasc and MabVax.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2015 and 2014, were \$17.5 million and \$(2.8) million, respectively. The increase in other income (expense), net for the three months ended September 30, 2015 compared to the same period in 2014 is due to a \$17.3 million gain recognized on the deconsolidation of STI in the third quarter of 2015.

Income tax benefit (provision). Our income tax benefit is due to a \$93.4 million release of OPKO's valuation allowance on our U.S. deferred tax assets as a result of the merger with Bio-Reference. In addition, our income tax benefit (provision) reflects the projected income tax payable in the U.S., Ireland, Israel, Chile, Spain, Mexico, and Luxembourg.

Loss from investments in investees. We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will continue to report a net loss. Loss from investments in investees was \$3.5 million and \$0.1 million for the three months ended September 30, 2015 and 2014, respectively. The increase in loss from investments in investees is primarily due to losses from our investment in Pharmsynthez and STI. In the third quarter of 2015 we deconsolidated STI, and account for our retained interest in STI as an equity method investment.

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014**

Revenues. Revenues for the nine months ended September 30, 2015 increased \$150.0 million compared to prior year. Our acquisition of Bio-Reference in August 2015 accounted for \$102.1 million of the quarter-over-quarter revenue growth. Revenues for the nine months ended September 30, 2015 and 2014 were as follows:

Revenues (In thousands)	For the nine months ended September 30,		
	2015	2014	Change
Revenue from services	\$107,929	\$6,606	\$101,323
Revenue from products	59,066	58,510	556
Other revenue	48,552	476	48,076
Total revenues	\$215,547	\$65,592	\$149,955

The increase in Revenue from services is attributable to the acquisition of Bio-Reference in August 2015. The increase in Revenue from products principally reflects \$6.9 million of revenue from EirGen, which we acquired in May 2015, which was partially offset by a decrease in pharmaceutical product revenue from our Spanish and Mexican operations and STI, a VIE we deconsolidated in July 2015. The increase in Other revenue principally reflects \$47.8 million of revenue from the transfer of intellectual property related to the Pfizer Transaction.

Costs of revenue. Costs of revenue for the nine months ended September 30, 2015 increased \$56.0 million compared to prior year. Our acquisition of Bio-Reference in August 2015 accounted for \$53.9 million of the quarter-over-quarter cost of revenue growth. Costs of revenue for the nine months ended September 30, 2015 and 2014 were as follows:

Cost of Revenue (In thousands)	For the nine months ended September 30,		
	2015	2014	Change
Cost of service revenue	\$61,434	\$7,088	\$54,346



Edgar Filing: Opko Health, Inc. - Form 10-Q

Cost of product revenue	30,650	28,987	1,663
Total cost of revenue	\$92,084	\$36,075	\$56,009

47

---

Table of Contents

The increase in cost of service revenue is attributable to the acquisition of Bio-Reference in August 2015. The increase in cost of product revenue principally reflects cost of revenue of \$3.9 million from EirGen, which we acquired in May 2015, and was partially offset by decreased pharmaceutical product sales from our Spanish and Mexican operations and the deconsolidation of SciVac in July 2015.

**Selling, general and administrative expenses.** Selling, general and administrative expenses for the nine months ended September 30, 2015 and 2014, were \$93.6 million and \$42.7 million, respectively. The increase in selling, general and administrative expenses for the nine months ended September 30, 2015 was primarily due to the acquisitions of Bio-Reference and EirGen in 2015, increased personnel expenses as we expand our sales, marketing and administrative staff and add infrastructure, and an increase in professional fees attributable to our acquisitions of Bio-Reference and EirGen. Selling, general and administrative expenses for the nine months ended September 30, 2015 include \$35.3 million and \$1.1 million from Bio-Reference and EirGen. Selling, general and administrative expenses during the nine months ended September 30, 2015 and 2014, include bad debt expense of \$8.3 million and \$0.0 million, respectively, and equity-based compensation expense of \$11.3 million and \$6.7 million, respectively. The increase in bad debt expense is due to the acquisition of Bio-Reference.

**Research and development expenses.** Research and development expenses for the nine months ended September 30, 2015 and 2014, were \$74.0 million and \$57.7 million, respectively. Research and development costs include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and PMA's (pre-market approval) for diagnostics tests, if any. Internal expenses include employee-related expenses including salaries, benefits and stock-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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

Research and Development Expenses	For the nine months ended September 30,	
	2015	2014
External expenses:		
Phase 3 clinical trials	\$9,243	\$10,344
CMC expense for biological products	17,223	11,499
Earlier-stage programs	5,780	5,507
Research and development employee-related expenses	20,631	15,778
Other internal research and development expenses	22,760	16,029
Third-party grants and funding from collaboration agreements	(1,627	) (1,413
Total research and development expenses	\$74,010	\$57,744

The increase in research and development expenses during the nine months ended September 30, 2015, is primarily due to a \$16.5 million increase in research and development expenses related to hGH-CTP, a long acting human growth hormone which was outlicensed to Pfizer in 2015, including CMC, and the recognition of \$2.3 million of expense for our NDA submission to the FDA for oral Rayaldee in May 2015. Research and development expenses for the nine months ended September 30, 2015 also include \$0.4 million and \$1.7 million from Bio-Reference and EirGen which we acquired in August 2015 and May 2015, respectively. This was partially offset by decreased expenses incurred by OPKO Renal related to phase 3 clinical trials for Rayaldee. In addition, during the nine months ended September 30, 2015 and 2014, we recorded, as an offset to research and development expenses, \$1.6 million and \$1.4 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the nine months ended September 30, 2015 and 2014 include equity-based compensation expense of \$6.1 million and \$3.3 million, respectively. We expect our research and development expense to increase as we continue to expand our research and development of potential future products.

**In-Process Research and Development.** In May 2014, we acquired Inspiro in a stock for stock transaction. We recorded the transaction as an asset acquisition and recorded the assets and liabilities at fair value, and as a result, we

recorded \$10.1 million of acquired in-process research and development expense. We did not have any such activity during the nine months ended September 30, 2015.

Table of Contents

**Contingent consideration.** Contingent consideration expenses for the nine months ended September 30, 2015 and 2014, were \$6.5 million and \$24.1 million, respectively. The decrease in contingent consideration expense was attributable to OPKO Renal resulting from an increase in the fair value of our contingent obligations to OPKO Renal in the third quarter of 2014 due to changes in assumptions regarding probabilities of successful achievement of future milestones driven by the two successful phase 3 trials of Rayaldee in the third quarter of 2014. The contingent consideration liabilities at September 30, 2015 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011, August 2012 and March 2013, respectively.

**Amortization of intangible assets.** Amortization of intangible assets for the nine months ended September 30, 2015 and 2014, were \$14.0 million and \$8.3 million, respectively. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the nine months ended September 30, 2015 includes \$4.9 million and \$1.1 million from Bio-Reference and EirGen which we acquired in August 2015 and May 2015, respectively. Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, the IPR&D assets will then be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

**Grant repayment.** During the nine months ended September 30, 2015, we made a payment of \$25.9 million to the Office of the Chief Scientist of the Israeli Ministry of Economy (“OCS”) in connection with repayment obligations resulting from grants previously made by the OCS to OPKO Biologics to support development of hGH-CTP and the outlicense of the technology outside of Israel.

**Interest income.** Interest income for the nine months ended September 30, 2015 and 2014, was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

**Interest expense.** Interest expense for the nine months ended September 30, 2015 and 2014, was \$6.3 million and \$10.6 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes and by the amortization of related deferred financing costs. The decrease in interest expense for the nine months ended September 30, 2015 compared to the same period in 2014 is due to a decrease in the principal amount of 2033 Senior Notes outstanding from \$87.6 million at September 30, 2014 to \$32.2 million as of September 30, 2015. This was partially offset by interest expense of \$(0.8) million from Bio-Reference due to outstanding debt under the Credit Facility with PNC. Interest expense for the nine months ended September 30, 2015 and 2014 also reflect non-cash write-offs of deferred financing costs of \$1.0 million and \$1.5 million as interest expense related to exchange or conversion of \$55.4 million and \$70.4 million principal of 2033 Senior Notes during the nine months ended September 30, 2015 and 2014, respectively.

**Fair value changes of derivative instruments, net.** Fair value changes of derivative instruments, net for the nine months ended September 30, 2015 and 2014, were \$(34.1) million of expense and \$3.8 million of income, respectively. Fair value changes of derivative instruments, net principally related to non-cash income (expense) related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes of \$(31.8) million and \$3.3 million for the nine months ended September 30, 2015 and 2014, respectively. For the nine months ended September 30, 2015, we observed an increase in the average market price of our Common Stock which resulted in an increase in the estimated fair value of our embedded derivatives recorded in the in the 2033 Senior Notes.

**Other income and (expense), net.** Other income and (expense), net for the nine months ended September 30, 2015 and 2014, were \$16.7 million and \$2.0 million, respectively. The increase in other income and (expense), net for the nine months ended September 30, 2015 compared to the same period in 2014 is primarily due to is primarily due to a \$17.3 million gain recognized on the deconsolidation of STI in the third quarter of 2015.

**Income tax benefit (provision).** Our income tax benefit is due to a \$93.4 million release of OPKO’s valuation allowance on our U.S. deferred tax assets as a result of the merger with Bio-Reference. This was partially offset by expense recognized on taxable income from the Pfizer Transaction during the nine months ended September 30, 2015. In addition, our income tax benefit (provision) reflects the projected income tax payable in the U.S., Ireland, Israel, Chile, Spain, Mexico, and Luxembourg.

**Loss from investments in investees.** We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We

account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will continue to report a net loss. Loss from investments in investees was \$6.1 million and \$2.5 million for the nine months ended September 30, 2015 and 2014, respectively. In the third quarter of 2015 we deconsolidated STI (formerly SciVac), and account for our retained interest in STI as an equity method investment.

Table of Contents

## LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2015, we had cash and cash equivalents of approximately \$212.1 million. Cash provided by operations during 2015 principally reflects the \$295.0 million upfront payments received from the Pfizer Transaction, partially offset by a payment of \$25.9 million to the OCS for obligations from grants previously made by the OCS to OPKO Biologics, expenses related to selling, general and administrative activities related to our corporate operations, research and development activities and our operations at OPKO Biologics, OPKO Renal and OPKO Diagnostics. We recognized \$47.8 million of revenue related to the \$295.0 million upfront payments during the nine months ended September 30, 2015, and will recognize the remainder as revenue on a straight-line basis over the expected performance period. Cash used in investing activities includes the net cash used in acquisitions of \$78.9 million, which reflects cash used to acquire EirGen, net and cash provided by the Bio-Reference acquisition. Cash provided by financing activities primarily reflects \$25.2 million received from Common Stock option and Common Stock warrant exercises. In addition to cash contingent consideration payments made during the nine months ended September 30, 2015, we also satisfied a \$20.0 million contingent payment to the former owners of OPKO Renal through the issuance of 1,194,337 shares of our common stock in the third quarter of 2015. Since our inception, we have not generated gross margins sufficient to offset our operating and other expenses and our primary source of cash has been from the public and private placement of stock, the issuance of the 2033 Senior Notes and credit facilities available to us. In 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.

The transactions with Pfizer closed in January 2015 following the termination of the waiting period under the Hart-Scott-Rodino Act. Under the terms of the agreements with Pfizer, we received non-refundable and non-creditable upfront payments of \$295.0 million in the first quarter of 2015 and are eligible to receive up to an additional \$275 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both hGH-CTP and Pfizer's Genotropin®.

We will lead the clinical activities and will be responsible for funding the development programs for the key indications, which includes Adult and Pediatric GHD and Pediatric SGA. Pfizer will be responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer will fund the commercialization activities for all indications and lead the manufacturing activities covered by the global development plan.

In the first quarter of 2015, we made a payment of \$25.9 million to the OCS in connection with repayment obligations resulting from grants previously made by the OCS to OPKO Biologics to support development of hGH-CTP and from the outlicense of the technology outside of Israel.

In August 2015, we completed the acquisition of Bio-Reference following a vote of Bio-Reference's shareholders to adopt the Merger Agreement and approve the merger. Bio-Reference is the third largest full service clinical laboratory in the United States and is known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Under the terms of the Merger Agreement, holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately \$950.0 million, based on a closing price per share of our Common Stock of \$12.38 as reported by the New York Stock Exchange, or \$34.05 per share of Bio-Reference common stock. Included in the transaction value is \$2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

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

as reported by the New York Stock Exchange on the closing date of the acquisition, \$13.88 per share. Our licensee, TESARO submitted a NDA to the FDA for approval of oral Varubi™, an investigational neurokinin-1 receptor antagonist in development for the prevention of chemotherapy-induced nausea and vomiting, which was approved by the U.S. FDA in September 2015. Under the terms of the license, we received a \$6.0 million upfront payment from TESARO and are eligible to receive milestone payments of up to \$30 million upon achievement of certain regulatory and commercial sale milestones (of which \$5 million has been paid to date) and additional commercial milestone payments of up to \$85 million if specified levels of annual net sales are achieved. During the nine months ended September 30, 2015 and 2014, no revenue has been recognized related to the achievement of the milestones under the TESARO License. TESARO is also obligated to

Table of Contents

pay us tiered royalties on annual net sales achieved in the United States and Europe at percentage rates that range from the low double digits to the low twenties, and outside of the United States and Europe at low double-digit percentage rates. TESARO assumed responsibility for clinical development and commercialization of licensed products at its expense.

If TESARO elects to develop and commercialize Varubi™ in Japan through a third-party licensee, TESARO will share equally with us all amounts it receives in connection with such activities, subject to certain exceptions and deductions. In addition, we will have an option to market the products in Latin America.

Under the terms of our agreement with Merck, upon approval by the FDA of the TESARO's NDA for oral Varubi™, which occurred in September 2015, we were required to pay Merck a \$5.0 million milestone payment. In addition, \$5.0 million will be due and payable each year thereafter for the next four (4) years on the anniversary date of the NDA approval. We recognized the total milestone payments of \$25.0 million as an intangible asset which will be amortized to expense over the expected useful life of the asset, which is approximately 13 years. We recognized the \$20.0 million of future payments to Merck as a liability in our balance sheet, with \$5.0 million in Accrued expenses and \$15.0 million in Other long-term liabilities.

2033 Senior Notes. In January 2013, we issued \$175.0 million of the 2033 Senior Notes. The 2033 Senior Notes were sold in a private placement in reliance on exemptions from registration under the Securities Act. A \$4.5 million discount was granted to the placement agent and an additional \$0.4 million in deferred charges were recorded for professional fees related to the issuance. Net cash proceeds from the offering totaled \$170.2 million. Interest on the 2033 Senior Notes is payable semiannually on February 1 and August 1, beginning August 1, 2013. 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.

In August 2013 and June 2014, holders exchanged or converted \$16.9 million and \$70.4 million principal amount of 2033 Senior Notes, respectively.

In March 2015, we entered into an exchange agreement with certain holders of the Company's Notes pursuant to which such holders exchanged \$36.4 million in aggregate principal amount of Notes for 5,363,896 shares of the Company's Common Stock and approximately \$0.2 million in cash representing accrued interest through the date of completion of the exchange.

On April 1, 2015, we announced that our 2033 Senior Notes were convertible through June 2015 by holders of such notes because the closing price per share of our Common Stock had exceeded \$9.19, or 130% of the initial conversion price of \$7.07, for at least 20 of 30 consecutive trading days during the period ending on March 31, 2015. On July 1, 2015 and October 1, 2015, we announced that our 2033 Senior Notes continue to be convertible by holders of such notes during the third and fourth quarters of 2015, respectively. In May 2015, a holder of our 2033 Senior Notes elected to convert \$5.0 million in aggregate principal amount of 2033 Senior Notes for 726,036 shares of the Company's Common Stock. In August and September 2015, holders of our 2033 Senior Notes converted \$14.0 million in aggregate principal amount of 2033 Senior Notes for 2,028,130 shares of the Company's Common Stock.

In connection with our acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events, including up to an additional \$19.1 million in shares of our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones; and up to an additional \$150.0 million in either shares of our Common Stock or cash, at our option subject to the achievement of certain milestones, to the former shareholders of OPKO Renal.

As of September 30, 2015, we have outstanding lines of credit in the aggregate amount of \$135.0 million with 10 financial institutions in Chile and Spain and our Credit Facility with PNC Bank, of which \$57.5 million is unused. The weighted average interest rate on these lines of credit is approximately 4.6%. These lines of credit are short-term and are generally due within three months. These lines of credit are used primarily as a source of working capital for inventory purchases. The highest balance at any time during the nine months ended September 30, 2015, was \$77.5 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.



In September 2015, we notified PNC of our intent to terminate the Credit Facility with Bio-Reference and pay in full all amounts due to PNC. As of September 30, 2015, approximately \$67.9 million was outstanding under the Credit Facility.

Table of Contents

On November 5, 2015, Bio-Reference and certain of its subsidiaries entered into a new credit agreement with JPMorgan Chase Bank, N.A. (“CB”), as lender and administrative agent (the “New Credit Agreement”), which replaces Bio-Reference’s existing loan agreement with PNC (the “Existing Loan Agreement”). The New Credit Agreement provides for a \$175.0 million secured revolving credit facility and includes a \$20.0 million sub-facility for swingline loans and a \$20.0 million sub-facility for the issuance of letters of credit. Bio-Reference may increase the credit facility to up to \$275.0 million on a secured basis, subject to the satisfaction of specified conditions. The new credit facility matures on November 5, 2020 and is guaranteed by all of Bio-Reference’s domestic subsidiaries. The new credit facility is also secured by substantially all assets of Bio-Reference and its domestic subsidiaries, as well as a non-recourse pledge by the Company of its equity interest in Bio-Reference. Availability under the New Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of Bio-Reference and certain of its subsidiaries, as specified therein. The proceeds of the new credit facility will be used to refinance existing indebtedness, including amounts outstanding under the Existing Loan Agreement which has been terminated in accordance with its terms, to finance working capital needs and for general corporate purposes of Bio-Reference and its subsidiaries.

At Bio-Reference’s option, borrowings under the New 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 New Credit Agreement also calls for other customary fees and charges, including an unused commitment fee of 0.25% of the lending commitments.

The New Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require Bio-Reference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws, and restrictions on the ability of Bio-Reference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the New Credit Agreement, notwithstanding the ability of Bio-Reference to meet its debt service obligations. The New 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 New Credit Agreement and execution upon the collateral securing obligations under the New Credit Agreement.

The foregoing description of the New Credit Agreement is only a summary and is qualified in its entirety by reference to the full text of the New Credit Agreement, which will be filed with the Company’s Annual Report on Form 10-K for the year ending December 31, 2015.

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

We believe that the cash and cash equivalents on hand at September 30, 2015 and the amounts available to be borrowed under our lines of credit and the New Credit Agreement 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, our merger with Bio-Reference, possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing,

and our success in developing markets for our product candidates. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions.

Table of Contents

The following table provides information as of September 30, 2015, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining Three Months ending December 31, 2015	2016	2017	2018	2019	Thereafter	Total
Open purchase orders	\$ 16,812	\$ 2,468	\$ —	\$ —	\$ —	\$ —	\$ 19,280
Operating leases	8,213	21,982	15,406	15,299	6,445	7,455	74,800
2033 Senior Notes	—	—	—	—	32,200	—	32,200
Deferred payments	—	5,000	5,000	5,000	5,000	—	20,000
Mortgages and other debts payable	2,716	333	302	252	244	1,226	5,073
Lines of credit	77,479	—	—	—	—	—	77,479
Interest commitments	597	1,044	1,033	1,022	209	51	3,956
Total	\$ 105,817	\$ 30,827	\$ 21,741	\$ 21,573	\$ 44,098	\$ 8,732	\$ 232,788

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

- Contractual obligations in connection with clinical trials, which span over two years, and that depend on patient enrollment. The total amount of expenditures is dependent on the actual number of patients enrolled and as such, the contracts do not specify the maximum amount we may owe.
- Product license agreements effective during the lesser of 15 years or patent expiration whereby payments and amounts are determined by applying a royalty rate on uncapped future sales.
- Contingent consideration that includes payments upon achievement of certain milestones including meeting development milestones such as the completion of successful clinical trials, NDA approvals by the FDA and revenue milestones upon the achievement of certain revenue targets all of which are anticipated to be paid within the next 7 years and are payable in either shares of our Common Stock or cash, at our option, and that may aggregate up to \$189.6 million.

Table of Contents

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

Goodwill and Intangible Assets. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired when accounted for by the purchase method of accounting. Goodwill and other intangible assets, including IPR&D, acquired in business combinations, licensing and other transactions was \$2.2 billion and \$1.1 billion at September 30, 2015 and December 31, 2014, respectively, representing approximately 74% and 85% of total assets, respectively.

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

Unit of account – Most intangible assets are valued as single global assets rather than multiple assets for each jurisdiction or indication after considering the development stage, expected levels of incremental costs to obtain additional approvals, risks associated with further development, amount and timing of benefits expected to be derived in the future, expected patent lives in various jurisdictions and the intention to promote the asset as a global brand.

Estimated useful life – The asset life expected to contribute meaningful cash flows is determined after considering all pertinent matters associated with the asset, including expected regulatory approval dates (if unapproved), exclusivity periods and other legal, regulatory or contractual provisions as well as the effects of any obsolescence, demand, competition, and other economic factors, including barriers to entry.

Probability of Technical and Regulatory Success (“PTRS”) Rate – PTRS rates are determined based upon industry averages considering the respective programs development stage and disease indication and adjusted for specific information or data known at the acquisition date. Subsequent clinical results or other internal or external data obtained could alter the PTRS rate and materially impact the estimated fair value of the intangible asset in subsequent periods leading to impairment charges.

Projections – Future revenues are estimated after considering many factors such as initial market opportunity, pricing, sales trajectories to peak sales levels, competitive environment and product evolution. Future costs and expenses are estimated after considering historical market trends, market participant synergies and the timing and level of additional development costs to obtain the initial or additional regulatory approvals, maintain or further enhance the product. We generally assume initial positive cash flows to commence shortly after the receipt of expected regulatory approvals which typically may not occur for a number of years. Actual cash flows attributed to the project are likely to be different than those assumed since projections are subjected to multiple factors including trial results and regulatory matters which could materially change the ultimate commercial success of the asset as well as significantly alter the costs to develop the respective asset into commercially viable products.

Tax rates – The expected future income is tax effected using a market participant tax rate. Our recent valuations typically use a U.S. tax rate (and applicable state taxes) after considering the jurisdiction in which the intellectual property is held and location of research and manufacturing infrastructure. We also considered that any repatriation of earnings would likely have U.S. tax consequences.

•

Discount rate – Discount rates are selected after considering the risks inherent in the future cash flows; the assessment of the asset’s life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

Table of Contents

Goodwill was \$761.2 million and \$224.3 million, respectively, at September 30, 2015 and December 31, 2014. The increase in goodwill from December 31, 2014 to September 30, 2015 is due to goodwill recognized from the acquisitions of Bio-Reference and EirGen in August 2015 and May 2015, respectively. 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, on an enterprise level 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 performed in the prior year.

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

Intangible assets were \$1.5 billion and \$855.8 million, including IPR&D of \$812.7 million and \$793.2 million, respectively, at September 30, 2015 and December 31, 2014. The increase in intangible assets and IPR&D from December 31, 2014 to September 30, 2015 is due to intangible assets and IPR&D recognized from the acquisitions of Bio-Reference and EirGen in August 2015 and May 2015, respectively. Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the project is completed or abandoned. Upon obtaining regulatory approval, the IPR&D asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the IPR&D asset is charged to expense. Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products or IPR&D. These assets are initially measured at fair value and therefore any reduction in expectations used in the valuations could potentially lead to impairment. Some of the more common potential risks leading to impairment include competition, earlier than expected loss of exclusivity, pricing pressures, adverse regulatory changes or clinical trial results, delay or failure to obtain regulatory approval and additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation.

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

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, currently 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 \$14.0 million and \$8.3 million for the nine months ended September 30, 2015 and 2014, respectively. Revenue recognition. Revenue for laboratory services is recognized on the accrual basis at the time test results are reported, which approximates when services are provided. Services are provided to patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in revenue net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue. For the three months ended September 30, 2015 and 2014, approximately 9% and 5%, respectively, of our revenues were derived directly from the Medicare and Medicaid programs. The increase in revenues from laboratory services, including revenue from Medicare and Medicaid

programs, is due to the acquisition of Bio-Reference in August 2015.

Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Our estimates for sales returns and allowances are based upon the historical patterns of product returns and allowances taken, matched against the sales from which they originated, and management's evaluation of specific factors that may increase or decrease the risk of product returns.

Revenue from transfer of intellectual property includes revenue related to the sale, license or transfer of intellectual property such as upfront license payments, license fees and milestone payments received through our license, collaboration and



Table of Contents

commercialization agreements. We analyze our multiple-element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting.

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

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

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

Concentration of Credit Risk and Allowance for doubtful accounts. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of accounts receivable. Substantially all of our accounts receivable are with companies in the health care industry and individuals. However, concentrations of credit risk are limited due to the number of our clients as well as their dispersion across many different geographic regions.

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk since the related health care programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. Accounts receivable balances (prior to allowance for doubtful accounts and net of contractual adjustments) from Medicare and Medicaid were \$22.8 million and \$0.6 million at September 30, 2015 and December 31, 2014, respectively.

The portion of our accounts receivable due from patients comprises the largest portion of credit risk. At September 30, 2015 and December 31, 2014, receivables due from patients represent approximately 9% and 0.5% of our consolidated accounts receivable (prior to allowance for doubtful accounts and net of contractual adjustments).

We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer's ability to pay. Actual results could differ from those estimates. Our reported net income (loss) is directly affected by our estimate of the collectability of accounts receivable. The allowance for doubtful accounts recognized in our Condensed Consolidated Balance Sheets was \$9.1 million and \$1.9 million at September 30, 2015 and December 31, 2014, respectively.

Equity-based compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow and as a reduction of taxes paid in cash flow from operations. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. 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

Table of Contents

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

**Inventories.** Inventories are valued at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost or market.

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

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

**RECENT ACCOUNTING PRONOUNCEMENTS**

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers." ASU No. 2014-09 clarifies the principles for recognizing revenue and develops a common revenue standard for GAAP and International Financial Reporting Standards that removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. ASU No. 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Companies can choose to apply the ASU using either the full retrospective approach or a modified retrospective approach. We are currently evaluating both methods of adoption and the impact that the adoption of this ASU will have on our Condensed Consolidated Financial Statements.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force)." ASU No. 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU No. 2014-12 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. Earlier adoption is permitted. The amendments can be applied either prospectively to all awards granted or modified after the effective date or retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards. We expect to apply the ASU prospectively and do not expect the adoption to have an impact on our Condensed Consolidated Financial Statements as our existing share-based payment awards do not fall within the scope of this ASU.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. ASU

2014-15 is effective for annual periods ending after December 15, 2016 with early adoption permitted. We do not believe the impact of our pending adoption of ASU 2014-15 on our Condensed Consolidated Financial Statements will be material.

In February 2015, the FASB issued ASU No. 2015-02, "Consolidation (Topic 810): Amendments to the Consolidation Analysis," which amends current consolidation guidance including changes to both the variable and voting interest models used by companies to evaluate whether an entity should be consolidated. The requirements from ASU 2015-02 are effective for interim and annual periods beginning after December 15, 2015, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

Table of Contents

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

In September 2015, the FASB issued ASU No. 2015-16, “Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments,” which replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 requires that the acquirer record, in the same period’s financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. For public business entities, ASU 2015-16 is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The guidance is to be applied prospectively to adjustments to provisional amounts that occur after the effective date of the guidance, with earlier application permitted for financial statements that have not been issued. Our early adoption of ASU 2015-16 in the third quarter of 2015 did not have a material impact on our Condensed Consolidated Financial Statements.

Table of Contents

## 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 Euro, the Mexican peso 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 are 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 at current spot rates, with gains and losses included in earnings.

Our derivative activities, which consist of foreign exchange forward contracts, are initiated to hedge forecasted cash flows that are exposed to foreign currency risk. The foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity dates. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the Condensed Consolidated Statement of Operations, and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. If the counterparties to the exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. We had \$5.0 million in foreign exchange forward contracts outstanding at September 30, 2015, primarily to hedge Chilean-based operating cash flows against U.S. dollars. 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. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment.

At September 30, 2015, we had cash and cash equivalents and marketable securities of \$212.1 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2015 was 0%. As of September 30, 2015, the principal value of our credit lines was \$77.5 million at a weighted average interest rate of approximately 4.6%.

Our \$32.2 million aggregate principal amount of our 2033 Senior Notes has a fixed interest rate, and therefore is not subject to fluctuations in market interest rates.

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

**Equity Price Risk** – We are subject to equity price risk related to the (i) rights to convert into shares of our Common Stock, including upon a fundamental change; and (ii) a coupon make-whole payment in the event of a conversion by the holders of the 2033 Senior Notes on or after February 1, 2017 but prior to February 1, 2019. These terms are considered to be embedded derivatives. On a quarterly basis, we are required to record these embedded derivatives at fair value with the changes being recorded in our Condensed Consolidated Statement of Operations. Accordingly, our

results of operations are subject to exposure associated with increases or decreases in the estimated fair value of our embedded derivatives.

Table of Contents

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 our 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, 2015.

Changes to the Company’s Internal Control Over Financial Reporting

In connection with the acquisitions of EirGen Pharma Limited (“EirGen”) in May 2015 and Bio-Reference Laboratories, Inc. (“Bio-Reference”) in August 2015, we began implementing standards and procedures at EirGen and Bio-Reference, including establishing controls over accounting systems and establishing controls over the preparation of financial statements in accordance with U.S. GAAP to ensure that we have in place appropriate internal control over financial reporting at EirGen and Bio-Reference. We are continuing to integrate the acquired operations of EirGen and Bio-Reference into our overall internal control over financial reporting process.

These changes to the Company’s internal control over financial reporting that occurred during the most recent quarter ended September 30, 2015 have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.



Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Following the announcement of entry into an agreement and plan of merger with Bio-Reference, four putative class action complaints challenging the merger were filed in the Superior Court of New Jersey in Bergen County (the “Court”). After the complaints were filed, on July 24, 2015, the parties executed a stipulated consent order that the actions would be consolidated for all purposes, including trial, in the Chancery Division under Docket No. C-207-15, bearing the caption In re Bio-Reference Laboratories, Inc. Shareholder Litigation. The complaints name Bio-Reference, OPKO, a wholly-owned merger subsidiary of OPKO (“Merger Sub”) and members of the Bio-Reference board as defendants. The complaints generally allege, among other things, that members of the Bio-Reference board breached their fiduciary duties to Bio-Reference’s shareholders by agreeing to sell Bio-Reference for an inadequate price and agreeing to inappropriate deal protection provisions in the merger agreement that may preclude Bio-Reference from soliciting any potential acquirers and limit the ability of the Bio-Reference board to act with respect to investigating and pursuing superior proposals and alternatives. The complaints also allege that Bio-Reference, OPKO and Merger Sub have aided and abetted the Bio-Reference board members’ breaches of their fiduciary duties. The complaints sought injunctive relief enjoining Bio-Reference and OPKO from consummating the merger at the agreed upon price unless and/or until the defendants cured their breaches of fiduciary duty (or, in the event the merger is consummated, rescinding the merger or awarding rescissory damages). The complaints also sought to recover costs and disbursement from the defendants, including attorneys’ fees and experts’ fees. In August, the parties executed a memorandum of understanding reflecting terms of a settlement, which was replaced in September 2015 by a stipulation and agreement of compromise, settlement and release resolving all matters between them. On September 25, 2015, the Court entered an order preliminarily approving the settlement and setting a scheduling for the Court’s final review of the settlement and notice to the class. A settlement hearing is scheduled for January 5, 2016.

On December 18, 2013, Bio-Reference filed an action in the Superior Court of New Jersey against Horizon Blue Cross Blue Shield of New Jersey (“Horizon”), captioned Bio-Reference Laboratories, Inc. v. Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey, Docket No. BER L-009748-13 (N.J. Super. Ct. Bergen Cnty.). Bio-Reference has been an in-network provider to Horizon’s preferred provider organization (“PPO”) members for more than 20 years and filed the lawsuit after attempts to resolve its dispute with Horizon were unsuccessful.

Bio-Reference currently provides services to Horizon pursuant to an Ancillary Services Provider Agreement entered into in 2003 and amended in 2007. The central claims in the lawsuit arise from Bio-Reference’s performance of laboratory services since at least 2008 for members of Horizon’s NJ DIRECT plan, who receive benefits under a program that Horizon has bid, promoted, and represented to be a PPO product for New Jersey state, county, and municipal workers and teachers. The lawsuit alleges that, despite these representations, Horizon has been improperly treating NJ DIRECT as a Managed Care program in its dealings with Bio-Reference, thereby costing Bio-Reference more than \$20,000,000 in unreimbursed services and depriving state beneficiaries of valuable rights and benefits to which they are entitled. The lawsuit alleges that Horizon furthered its fraud against Bio-Reference by means of a sham Request for Proposal issued in 2011 and through false and incorrect communications to Bio-Reference and other providers. Bio-Reference asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and fraud against Horizon. In addition to compensatory damages, Bio-Reference seeks to recover punitive damages from Horizon due to Horizon’s intentional and malicious misconduct. Bio-Reference also seeks declaratory and injunctive relief.

On February 5, 2014, Horizon filed a motion to dismiss the complaint, which Bio-Reference opposed. On March 28, 2014, the Honorable Robert C. Wilson of the Superior Court of New Jersey issued an oral ruling denying Horizon’s motion to dismiss without prejudice pending the completion of discovery. Bio-Reference and Horizon are conducting discovery, which is currently scheduled to close on December 18, 2015. Trial in the matter is currently set for early

2016. Bio-Reference intends to vigorously prosecute its claims against Horizon.

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, 2014, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common and capital stock.

## Table of Contents

In connection with the acquisition of Bio-Reference in August 2015, we are subject to the following additional risks and uncertainties which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common and capital stock.

### Risks Related to the Acquisition of Bio-Reference

We may fail to realize the anticipated benefits of the merger with Bio-Reference.

The success of the merger will depend on, among other things, our ability to combine our business with that of Bio-Reference in a manner that facilitates growth opportunities and realizes anticipated growth and cost savings. We believe that the merger will provide an opportunity for revenue growth in development and commercialization of drugs and diagnostics and other areas, including a number of new business areas for the Company. Our current diagnostic services are in the process of being merged with the Bio-Reference operations throughout the United States and we believe that Bio-Reference's national presence will add valuable distribution capability to our diagnostic services and provide key areas of opportunity for our services, including the 4Kscore test.

However, we must successfully combine our and Bio-Reference's businesses in a manner that permits these benefits to be realized. In addition, we must achieve the anticipated growth and cost savings without adversely affecting current revenues and investments in future growth. If we are not able to successfully achieve these objectives, the anticipated benefits of the merger may not be realized fully, or at all, or may take longer to realize than expected.

The failure to integrate successfully the business and operations of Bio-Reference in the expected time frame may adversely affect our future results.

Historically, we and Bio-Reference have operated as independent companies. There can be no assurances that our and Bio-Reference's businesses can be integrated successfully. It is possible that the integration process could result in the loss of our or Bio-Reference's key employees, the loss of customers, the disruption of either company's or both companies' ongoing businesses or in unexpected integration issues, higher than expected integration costs and an overall post-completion integration process that takes longer than originally anticipated. See the risk factor entitled "-We may be unable to retain Bio-Reference personnel following the merger" below. Specifically, the following issues, among others, must be addressed in integrating our operations with Bio-Reference's operations in order to realize the anticipated benefits of the merger so we perform as expected:

- combining the companies' operations and corporate functions, as well as obtaining anticipated synergies;
- combining our business with Bio-Reference's business and meeting the capital requirements of the combined company, in a manner that permits us to achieve the cost savings or revenue synergies anticipated to result from the merger, the failure of which would result in the anticipated benefits of the merger not being realized in the time frame currently anticipated or at all;
- integrating the companies' technologies;
- integrating and unifying the offerings and services available to customers;
- identifying and eliminating redundant and underperforming functions and assets;
- harmonizing and/or addressing differences in the companies' operating practices, employee development and compensation programs, internal controls and other policies, procedures and processes;
- maintaining existing agreements with customers, distributors, providers and vendors and avoiding delays in entering into new agreements with prospective customers, distributors, providers and vendors;
- addressing possible differences in business backgrounds, corporate cultures and management philosophies;
  - consolidating the companies' administrative and information technology infrastructure;
- coordinating distribution and marketing efforts;
- managing the movement of certain positions to different locations;
- coordinating geographically dispersed organizations; and
- effecting actions that may be required in connection with obtaining regulatory approvals.



## Table of Contents

In addition, at times the attention of our management and resources may be focused on the integration of the businesses of the two companies and diverted from day-to-day business operations, which may disrupt our ongoing business.

Combining our business with Bio-Reference may be more difficult, costly or time-consuming than expected, which may adversely affect our business results and negatively affect the value of our common stock following the merger. We believe that the merger was in the best interests of our stockholders and that combining our business with Bio-Reference will produce benefits and cost savings. If we are not able to successfully combine our business with Bio-Reference in an efficient and effective manner, the anticipated benefits and cost savings of the merger may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common stock may be affected adversely.

An inability to realize the full extent of the anticipated benefits of the merger and the other transactions contemplated by the merger agreement, as well as any delays encountered in the integration process, could have an adverse effect upon our revenues, level of expenses and operating results, which may adversely affect the value of our common stock after the completion of the merger.

In addition, the actual integration may result in additional and unforeseen expenses, and the anticipated benefits of the integration plan may not be realized. Actual growth and cost savings, if achieved, may be lower than what we expect and may take longer to achieve than anticipated. If we are not able to adequately address integration challenges, we may be unable to successfully integrate our operations with Bio-Reference's operations or to realize the anticipated benefits of the integration of the two companies.

Our future results will suffer if we do not effectively manage our expanded operations following the merger. Following the merger, the size of our company's business is larger than our and Bio-Reference's businesses prior to the merger. Our future success depends, in part, upon our ability to manage this expanded business, which will pose substantial challenges for our management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. We cannot assure you that we will be successful or that we will realize the expected operating efficiencies, annual net operating synergies, revenue enhancements and other benefits currently anticipated to result from the merger.

We incurred significant transaction and merger-related costs in connection with the merger.

We incurred a number of non-recurring costs associated with the merger with Bio-Reference. These costs and expenses included fees paid to financial, legal and accounting advisors, facilities and systems consolidation costs, severance and other potential employment-related costs, including payments to certain Bio-Reference executives, filing fees, printing expenses and other related charges. There are also a large number of processes, policies, procedures, operations, technologies and systems that must be integrated in connection with the merger and the integration of the two companies' businesses. While we have assumed that a certain level of expenses would be incurred in connection with the merger, there are many factors beyond our control that could affect the total amount or the timing of the integration and implementation expenses.

There may also be additional unanticipated significant costs in connection with the merger that we may not recoup. These costs and expenses could reduce the realization of efficiencies, strategic benefits and additional income we expect to achieve from the merger.

Third parties may terminate or alter existing contracts or relationships with us or Bio-Reference.

Bio-Reference has contracts with customers, suppliers, vendors, landlords, licensors and other business partners which may require Bio-Reference to obtain consent from these other parties in connection with the merger. If these consents cannot be obtained, Bio-Reference may suffer a loss of potential future revenue and may lose rights that are material

to its business and the business of the combined company. In addition, third parties with whom Bio-Reference or we currently have relationships may terminate or otherwise reduce the scope of their relationship with either party as a result of the merger. Any such disruptions could limit our ability to achieve the anticipated benefits of the merger.

We may be unable to retain Bio-Reference personnel following the merger.

The success of the merger will depend in part on our ability to retain the talents and dedication of the professionals employed by Bio-Reference. It is possible that these employees may decide not to remain with us following the merger. If key employees terminate their employment, or if we are unable to retain a sufficient number of employees to maintain effective operations, our business activities may be adversely affected and management's attention may be diverted from successfully

Table of Contents

integrating Bio-Reference to hiring suitable replacements, all of which may cause our business to suffer. In addition, we may not be able to locate suitable replacements for any key employees that leave either company or offer employment to potential replacements on reasonable terms.

The market price of our common stock may decline as a result of the merger.

The market price of our common stock may decline as a result of the merger for a number of reasons, including if:

- we do not achieve the perceived benefits of the merger as rapidly or to the extent anticipated;
- the effect of the merger on our business and prospects is not consistent with the expectations of financial analysts; or
- investors react negatively to the effect of the merger on our business and prospects.

Charges to earnings resulting from the application of the acquisition method of accounting may adversely affect the market value of our common stock following the merger.

In accordance with GAAP, we are considered the acquirer of Bio-Reference for accounting purposes. We will account for the merger using the acquisition method of accounting. As a result, there may be charges related to the acquisition that are required to be recorded to our earnings that could adversely affect the market value of our common stock following the completion of the merger. Under the acquisition method of accounting, we will allocate the total purchase price to the assets acquired, including identifiable intangible assets, and liabilities assumed from Bio-Reference based on their fair values as of the date of the completion of the merger, and record any excess of the purchase price over those fair values as goodwill. For certain tangible and intangible assets, revaluing them to their fair values as of the completion date of the merger may result in our incurring additional depreciation and amortization expense that may exceed the combined amounts recorded by OPKO and Bio-Reference prior to the merger. We will record this increased expense over the useful lives of the underlying assets. In addition, to the extent the value of goodwill or intangible assets become impaired after the merger, we may be required to incur charges relating to the impairment of those assets.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act, including with respect to companies we acquire, could have a material adverse effect on our business and operating results. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of our Common Stock.

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm on the effectiveness of internal control over financial reporting as of year end. We are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal control that, or that are reasonably likely to, materially affect internal control over financial reporting. A “material weakness” is a significant deficiency or combination of significant deficiencies that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We cannot assure you that we will at all times in the future be able to report that our internal controls are effective. In addition, material weaknesses in the design and operation of the internal control over financial reporting of companies that we acquire could have a material adverse effect on our business and operating results. Our acquisition of Bio-Reference and possible future acquisitions may increase this risk by expanding the scope and nature of operations over which we must develop and maintain internal control over financial reporting.

If we cannot provide reliable financial reports or prevent fraud, our results of operation could be harmed. Our failure to maintain the effective internal control over financial reporting could cause the cost related to remediation to increase and could cause our stock price to decline. In addition, we may not be able to accurately report our financial results, may be subject to regulatory sanction, and investors may lose confidence in our financial statements.

Failure to comply with environmental, health and safety laws and regulations, including the federal Occupational Safety and Health Administration Act, the Needlestick Safety and Prevention Act and the Comprehensive Medical

Waste Management Act, could result in fines and penalties and loss of licensure, and have a material adverse effect upon our business.

We are subject to licensing and regulation under federal, state and local laws and regulations relating to the protection of the environment and human health and safety, including laws and regulations relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials, as well as regulations relating to the safety and health of laboratory employees. The federal Occupational Safety and Health Administration has established



Table of Contents

extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis B virus. These requirements, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that we include in our safety programs the evaluation and use of engineering controls such as safety needles if found to be effective at reducing the risk of needlestick injuries in the workplace.

Waste management is subject to federal and state regulations governing the transportation and disposal of medical waste including bodily fluids. Federal regulations require licensure of interstate transporters of medical waste. In New Jersey, we are subject to the Comprehensive Medical Waste Management Act (“CMWMA”), which requires us to register as a generator of special medical waste. All of our medical waste is disposed of by a licensed interstate hauler. The hauler provides a manifest of the disposition of the waste products as well as a certificate of incineration, which is retained by us. These records are audited by the State of New Jersey on a yearly basis. We are also subject to the Federal Hazardous materials transportation law, 49 U.S.C. 5101 et seq., and the Hazardous Materials Regulations (HMR), 49 CFR parts 171-180. The federal government has classified hazardous medical waste as hazardous materials for the purpose of regulation. These regulations preempt state regulation, which must be “substantively the same,” “the non-federal requirement must conform “in every significant respect to the federal requirement. Editorial and other similar de minimis changes are permitted,” 49 CFR 107.202(d).

Failure to comply with such federal, state and local laws and regulations could subject us to denial of the right to conduct business, fines, criminal penalties and/or other enforcement actions, any of which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements on us, which may be costly.

Changes in regulation and policies, including increasing downward pressure on health care reimbursement, may adversely affect reimbursement for diagnostic services and could have a material adverse impact on our business. Reimbursement levels for health care services are subject to continuous and often unexpected changes in policies, and we face a variety of efforts by government payors to reduce utilization and reimbursement for diagnostic testing services. Changes in governmental reimbursement may result from statutory and regulatory changes, retroactive rate adjustments, administrative rulings, competitive bidding initiatives, and other policy changes.

The U.S. Congress has considered, at least yearly in conjunction with budgetary legislation, changes to one or both of the Medicare fee schedules under which we receive reimbursement, which include the physician fee schedule for anatomical pathology services, and the clinical laboratory fee schedule for our clinical laboratory services. For example, currently there is no copayment or coinsurance required for clinical laboratory services, although there is for our physician services. However, Congress has periodically considered imposing a 20 percent coinsurance on laboratory services. If enacted, this would require us to attempt to collect this amount from patients, although in many cases the costs of collection would exceed the amount actually received.

Our reimbursement for our pathology services is paid primarily under the physician fee schedule of Medicare and Medicaid and is therefore governed by a complex formula, referred to as the Sustainable Growth Rate, or SGR. As the use of this formula could result in a significant reduction in reimbursement for all physician services, Congress usually acts each year to prevent the full amount of such reductions from taking effect. In 2011, Congress acted to prevent reductions in for 2012, and on January 1, 2013, Congress acted to prevent significant reductions for 2013. The SGR has currently been postponed until March 2014 and Congress continues to work on both a short term and a long term fix to this annual problem. If Congress fails to take such action in the future, implementation of this formula could adversely affect our business.

The Center for Medicare and Medicaid Services (CMS) pays laboratories on the basis of a fee schedule that is reviewed and re-calculated on an annual basis. CMS may change the fee schedule upward or downward on billing codes that we submit for reimbursement on a regular basis. Our revenue and business may be adversely affected if the reimbursement rates associated with such codes are reduced. Even when reimbursement rates are not reduced, policy changes add to our costs by increasing the complexity and volume of administrative requirements. Medicaid reimbursement, which varies by state, is also subject to administrative and billing requirements and budget pressures. Recently, state budget pressures have caused states to consider several policy changes that may impact our financial condition and results of operations, such as delaying payments, reducing reimbursement, restricting coverage eligibility and service coverage, and imposing taxes on our services.

Table of Contents

Change in the billing and/or reimbursement procedures by the federal government could affect our ability to be paid as we have in the past for services rendered.

CMS has changed or discussed making changes to certain types of reimbursement which could affect our rate of reimbursement. Certain cases are comprised of both a technical component (TC) and a professional component (PC). In certain specified areas of testing, primarily in the area of anatomic pathology, CMS has determined that some providers have over-utilized these testing procedures and CMS has introduced changes in reimbursement policies to discourage over-utilization. While we do not currently over-utilize services for self-gain, we are always subject to review by CMS and cannot be certain that CMS won't interpret our practices differently than we do.

CMS has announced planned changes in the area of Molecular Diagnostics' reimbursement, primarily designed to improve transparency in billing. Molecular Diagnostics is a rapidly changing and evolving area of clinical testing. Whereas other areas of clinical testing are well vetted and established with specific codes for reimbursement, Molecular Diagnostics has moved at a faster pace than CMS can proceed. Clinical laboratories accordingly use a process called cross-walking to get reimbursed by CMS. Cross-walking requires that the clinical laboratory identify the individual processes used to process the patient's specimen and identify diagnostic results that are already reimbursed in established tests. CMS seeks to specifically identify the testing routine being done and reimburse providers universally for the test actually being performed. CMS has not established all of the molecular diagnostic tests that will be included in this revised schedule for reimbursement and it has not determined how much will be reimbursed to providers for these tests. We expect CMS to implement fair and reasonable reimbursement for such tests, but until such pricing decisions are disclosed we cannot be certain what CMS will finally implement.

Effective July 1, 2012, CMS eliminated an exemption that had been in place since 1999, which allowed commercial laboratories to bill for certain diagnostic tests performed on in-patient and certain outreach recipients by commercial laboratories. From 1999 through July 1, 2012, commercial laboratories were allowed to bill CMS for such tests despite the fact that the recipient was a hospital patient as long as the hospital had been submitting such tests for diagnosis to commercial laboratories prior to 1999. Upon termination of the exemption, we were required to find out from the hospital submitting the test whether the recipient's bill for diagnostic testing will be reimbursed by the hospital or should be billed to CMS. We have systems in place to manage this change, but these systems are dependent upon our getting proper information from the hospital clients.

The Federal Government is faced with significant economic decisions in the coming years. Some solutions being offered in the government could substantially change the way laboratory testing is reimbursed by government entities. We cannot be certain what or how any such government changes may affect our business.

Increased competition, including price competition, could have a material adverse impact on our net revenues and profitability.

The clinical laboratory business is characterized by intense competition. Our major competitors in the New York metropolitan super-region, Quest Diagnostics and Laboratory Corporation of America, are large national laboratories that possess greater name recognition, larger customer bases, significantly greater financial resources and employ substantially more personnel than we do. Many of our competitors have long established relationships with their customers and third-party payors. We cannot assure you that we will be able to compete successfully with such entities in the future.

The clinical laboratory business is intensely competitive both in terms of price and service. Pricing of laboratory testing services is often one of the most significant factors used by health care providers and third-party payors in selecting a laboratory. As a result of the clinical laboratory industry undergoing significant consolidation, larger clinical laboratory providers are able to increase cost efficiencies afforded by large-scale automated testing. This consolidation results in greater price competition. We may be unable to increase cost efficiencies sufficiently, if at all, and as a result, our net earnings and cash flows could be negatively impacted by such price competition. Additionally,

we may also face changes in fee schedules, competitive bidding for laboratory services or other actions or pressures reducing payment schedules as a result of increased or additional competition.

Additional competition, including price competition, could have a material adverse impact on our net revenues and profitability.

If patent regulations or standards are modified, such changes could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, USPTO, may change the standards of patentability and validity and any such changes could have a negative impact on

Table of Contents

our business. In addition, competitors may develop their own versions of our test in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

There have been several cases involving “gene patents” and diagnostic claims that have been considered by the U.S. Supreme Court. A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics, or Myriad, and the USPTO involves certain of Myriad’s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. The Federal Circuit issued a written decision on July 29, 2011 that reversed the U.S. District Court for the Southern District of New York holding instead that the breast cancer genes are patentable subject matter. Subsequently, on March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or *Prometheus*, a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus’ claims failed to add enough inventive content to the underlying correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws. The Supreme Court subsequently granted certiorari in the Myriad case, vacated the judgment, and remanded the case back to the Federal Circuit for further consideration in light of their decision in the Prometheus case. The Federal Circuit issued a decision on August 16, 2012, reaffirming its earlier decision.

On July 3, 2012, the USPTO issued a memorandum to patent examiners providing guidelines for examining process claims for patent eligibility in view of the Supreme Court decision in *Prometheus*. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory subject matter. We cannot assure you that our patent portfolio will not be negatively impacted by the decision described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

The Supreme Court granted ACLU’s petition for a writ of certiorari and issued a decision on June 13, 2013. In the ruling, the Supreme Court held that claims to “isolated” DNA molecules and the information they encode are not patent eligible, whereas DNA, not a “product of nature,” is patent eligible. On July 12, 2013, Senator Patrick Leahy wrote to the National Institutes of Health, or NIH, urging that the NIH take the extremely unusual step of exercising its “march in” rights to force Myriad to license certain patents to others on “reasonable” terms due to the public health and cost considerations.

Congress directed the USPTO to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. This study will examine the impact that independent second opinion testing has on providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO was directed to report the findings of the study to Congress and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by June 16, 2012. In August 2012, the Department of Commerce advised the House and Senate Judiciary Committee leadership that given the complexity and significant policy implications, that further review, discussion and analysis are required before a final report can be submitted to Congress. To that end, the USPTO held an additional public hearing in late fall 2012, plans to review the comments received during the last year, and then plans to finalize its recommendations to Congress. It is unclear whether the results of this study will be acted upon by the USPTO or result in Congressional efforts to change the law or process in a manner that could negatively impact our patent portfolio or our future research and development efforts.

In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These include changes to transition from a “first-to-invent” system to a “first-to-file” system, changes to the way issued patents are challenged and changes to the way patent

applications are disputed during the examination process. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The USPTO has developed new regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the Act, and in particular the first to file provisions, which became effective in March 2013. Substantive changes to patent law associated with the Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents, all of which could have a material adverse effect on our business.

We are facing, and may in the future face, intellectual property infringement claims that could be time-consuming and costly to defend, and could result in our loss of significant rights and the assessment of treble damages.

In October 2013, a lawsuit was filed against Bio-Reference by Myriad Genetics alleging we are infringing upon their intellectual property by offering OncoGeneDx, our comprehensive series of inherited cancers testing, including testing for

Table of Contents

BRCA1/2. We may from time to time receive additional notices of claims of infringement and misappropriation or misuse of other parties' proprietary rights. Some of these additional claims may also lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or the validity of our patents, will not be asserted or prosecuted against us.

We may also initiate claims to defend our intellectual property or to seek relief on allegations that we use, sell, or offer to sell technology that incorporates third party intellectual property. Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party's patent) to the party claiming infringement, develop non-infringing technology, stop selling our tests or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business.

It is possible that a third party or patent office might take the position that one or more patents or patent applications constitute prior art in the field of genomic-based diagnostics. In such a case, we might be required to pay royalties, damages and costs to firms who own the rights to these patents, or we might be restricted from using any of the inventions claimed in those patents.

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 and in the design, manufacture and marketing of our products could adversely affect the results of our operations and adversely impact our reputation.

The provision of clinical testing services, including anatomic pathology services, and related services, and the design, manufacture and marketing of diagnostic products involve certain inherent risks. The services that we provide and the products that we design, manufacture and market are intended to provide information for healthcare providers in providing patient care. Therefore, users of our services and products may have a greater sensitivity to errors than the users of services or products that are intended for other purposes.

Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of the products can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by governmental authorities) and could result, in certain cases, in the removal of a product from the market. Any recall could result in significant costs as well as negative publicity that could reduce demand for our products. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

Similarly, negligence in performing our services can lead to injury or other adverse events. We may be sued under physician liability or other liability law for acts or omissions by our pathologists, laboratory personnel and hospital employees who are under the supervision of our hospital-based pathologists. We are subject to the attendant risk of substantial damages awards and risk to our reputation.

Discontinuation or recalls of existing testing products, failure to develop, or acquire, licenses for new or improved testing technologies; or our clients using new technologies to perform their own tests could adversely affect our business.

From time to time, manufacturers discontinue or recall reagents, test kits or instruments used by us to perform laboratory testing. Such discontinuations or recalls could adversely affect our costs, testing volume and revenue.

The clinical laboratory industry is subject to changing technology and new product introductions. Our success in maintaining a leadership position in genomic and other advanced testing technologies will depend, in part, on our ability to develop, acquire or license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. We may not be able to negotiate acceptable licensing arrangements and it cannot be certain that such arrangements will yield commercially successful diagnostic tests. If we are unable to license these testing methods at competitive rates, our research and development costs may increase as a result. In addition, if we are unable to license new or improved technologies to expand our esoteric testing operations, our testing methods may become outdated when compared with our competition and testing volume and revenue may be materially and adversely affected.

Currently, most clinical laboratory testing is categorized as “high” or “moderate” complexity, and thereby is subject to extensive and costly regulation under CLIA. The cost of compliance with CLIA makes it impractical for most physicians to



Table of Contents

operate clinical laboratories in their offices, and other laws limit the ability of physicians to have ownership in a laboratory and to refer tests to such a laboratory. Manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point-of-care laboratory equipment to physicians and by selling test kits approved for home or physician office use to both physicians and patients. Diagnostic tests approved for home use are automatically deemed to be “waived” tests under CLIA and may be performed in physician office laboratories as well as by patients in their homes with minimal regulatory oversight. Other tests meeting certain FDA criteria also may be classified as “waived” for CLIA purposes. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used by clinical laboratories and has taken responsibility from the Centers for Disease Control for classifying the complexity of tests for CLIA purposes. Increased approval of “waived” test kits could lead to increased testing by physicians in their offices or by patients at home, which could affect our market for laboratory testing services and negatively impact our revenues.

## 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 5, 2015, our wholly-owned subsidiary, Bio-Reference Laboratories, Inc. (“Bio-Reference”), and certain of its subsidiaries entered into a new credit agreement with JPMorgan Chase Bank, N.A. (“CB”), as lender and administrative agent (the “New Credit Agreement”), which replaces Bio-Reference’s existing loan agreement with PNC Bank, National Association (the “Existing Loan Agreement”). The New Credit Agreement provides for a \$175.0 million secured revolving credit facility and includes a \$20.0 million sub-facility for swingline loans and a \$20.0 million sub-facility for the issuance of letters of credit. Bio-Reference may increase the credit facility to up to \$275.0 million on a secured basis, subject to the satisfaction of specified conditions. The new credit facility matures on November 5, 2020 and is guaranteed by all of Bio-Reference’s domestic subsidiaries. The new credit facility is also secured by substantially all assets of Bio-Reference and its domestic subsidiaries, as well as a non-recourse pledge by the Company of its equity interest in Bio-Reference. Availability under the New Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of Bio-Reference and certain of its subsidiaries, as specified therein. The proceeds of the new credit facility will be used to refinance existing indebtedness, including amounts outstanding under the Existing Loan Agreement which has been terminated in accordance with its terms, to finance working capital needs and for general corporate purposes of Bio-Reference and its subsidiaries.

At Bio-Reference’s option, borrowings under the New 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 New Credit Agreement also calls for other customary fees and charges, including an unused commitment fee of 0.25% of the lending commitments.

The New Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require Bio-Reference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws, and restrictions on the ability of Bio-Reference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the New Credit Agreement, notwithstanding the ability of Bio-Reference to meet its debt service obligations. The New 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 New Credit Agreement and execution upon the collateral securing obligations under the New Credit

Agreement.

The foregoing description of the New Credit Agreement is only a summary and is qualified in its entirety by reference to the full text of the New Credit Agreement, which will be filed with the Company's Annual Report on Form 10-K for the year ending December 31, 2015.

69

---

Table of Contents

Item 6. Exhibits

Exhibit 2.1 <sup>(1)</sup>	Agreement and Plan of Merger, dated June 3, 2015, by and among, Opko Health, Inc., Bamboo Acquisition, Inc. and Bio-Reference Laboratories, Inc.
Exhibit 3.1 <sup>(2)</sup>	Amended and Restated Certificate of Incorporation.
Exhibit 3.2 <sup>(3)</sup>	Amended and Restated By-Laws.
Exhibit 3.3 <sup>(4)</sup>	Certificate of Designation of Series D Preferred Stock.
Exhibit 4.3 <sup>(5)</sup>	Indenture, dated as of January 30, 2013, between OPKO Health, Inc. and Wells Fargo Bank, National Association.
Exhibit 23.1	Consent of MSPC Certified Public Accountants and Advisors, P.C. relating to Bio-Reference Laboratories, Inc.'s financial statements.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2015.
Exhibit 31.2	Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2015.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2015.
Exhibit 32.2	Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2015.
Exhibit 99.1 <sup>(6)</sup>	The audited consolidated balance sheets of Bio-Reference Laboratories, Inc. and its subsidiaries as of October 31, 2014 and 2013, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the years in the three-year period ended October 31, 2014, and the notes and the independent auditor's reports thereto.
Exhibit 99.2 <sup>(7)</sup>	The unaudited consolidated balance sheet of Bio-Reference Laboratories, Inc. and its subsidiaries as of April 30, 2015, the related unaudited consolidated statements of operations, and statements of cash flows for the three and six months ended April 30, 2015, and the notes thereto.
Exhibit 99.3 <sup>(8)</sup>	The unaudited pro forma condensed combined financial statements of the Company and Bio-Reference Laboratories, Inc.
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

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

(2) Filed with the Company's 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.

- (3) 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.
- (4) 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.
- (5) 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.

Table of Contents

- (6) Filed under Part II, Item 8, of the Bio-Reference Laboratories, Inc. Form 10-K filed with the Securities and Exchange Commission on January 13, 2015 (File No. 0-15266), and incorporated herein by reference.
- (7) Filed under Part I, Item 1, of the Bio-Reference Laboratories, Inc. Form 10-Q filed with the Securities and Exchange Commission on June 9, 2015 (File No. 0-15266), and incorporated herein by reference.  
Filed under the heading “Unaudited Pro Forma Condensed Combined Financial Statements” beginning on page 27 of
- (8) the Company’s Registration Statement on Form S-4/A filed with the Securities and Exchange Commission on July 15, 2015 (File No. 333-205480), and incorporated herein by reference.

Table of Contents

SIGNATURES

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

Date: November 9, 2015

OPKO Health, Inc.

/s/ Adam Logal

Adam Logal

Senior Vice President, Chief Financial  
Officer,

Chief Accounting Officer and Treasurer

Table of Contents

Exhibit Index

Exhibit Number	Description
Exhibit 23.1	Consent of MSPC Certified Public Accountants and Advisors, P.C. relating to Bio-Reference Laboratories, Inc.'s financial statements.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2015.
Exhibit 31.2	Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2015.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2015.
Exhibit 32.2	Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2015.
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
	+ Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.