

Opko Health, Inc.  
Form 10-Q  
August 05, 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 June 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 July 31, 2015, the registrant had 463,617,245 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 June 30, 2015 (unaudited) and December 31, 2014</u>	6
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2015 and 2014 (unaudited)</u>	7
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2015 and 2014 (unaudited)</u>	8
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2015 and 2014 (unaudited)</u>	9
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	10
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	36
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	49
<u>Item 4. Controls and Procedures</u>	50
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	51
<u>Item 1A. Risk Factors</u>	51
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	51
<u>Item 3. Defaults Upon Senior Securities</u>	51
<u>Item 4. Mine Safety Disclosures</u>	51
<u>Item 5. Other Information</u>	51
<u>Item 6. Exhibits</u>	52
<u>Signatures</u>	53
<u>Exhibit Index</u>	54
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.
- 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.
- The timing and expenditures associated with the build-up of pre-launch inventory and capacity expansion. 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.
- 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 complete the proposed merger with Bio-Reference Laboratories, Inc. (“Bio-Reference”), or to successfully integrate Bio-Reference with our business, could have a negative impact on our financial condition, results of operations, cash flows and stock price.
- 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.



Table of Contents

In the event that we successfully 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 business based in Nashville, Tennessee. 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 develop and commercialize rolapitant, 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.

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.

Table of Contents

- 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)

	June 30, 2015 <sup>(1)</sup>	December 31, 2014 <sup>(1)</sup>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$221,217	\$ 96,907
Accounts receivable, net	26,980	19,969
Inventory, net	20,519	16,604
Prepaid expenses and other current assets	9,623	9,389
Total current assets	278,339	142,869
Property, plant, equipment, and investment properties, net	23,405	16,411
Intangible assets, net	94,247	62,649
In-process research and development	812,446	793,152
Goodwill	289,607	224,292
Investments, net	21,434	22,453
Other assets	6,013	5,838
Total assets	\$1,525,491	\$ 1,267,664
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$16,039	\$ 8,744
Accrued expenses	149,843	60,912
Current portion of lines of credit and notes payable	14,599	13,455
Total current liabilities	180,481	83,111
2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	109,203	131,454
Other long-term liabilities, principally deferred revenue and deferred tax liabilities	408,821	217,358
Total long-term liabilities	518,024	348,812
Total liabilities	698,505	431,923
Equity:		
Common Stock - \$0.01 par value, 750,000,000 shares authorized; 464,567,632 and 433,421,677 shares issued at June 30, 2015 and December 31, 2014, respectively	4,646	4,334
Treasury Stock - 1,120,367 and 1,245,367 shares at June 30, 2015 and December 31, 2014, respectively	(3,645	) (4,051
Additional paid-in capital	1,687,389	1,529,096
Accumulated other comprehensive income (loss)	(18,880	) (12,392
Accumulated deficit	(834,721	) (674,843
Total shareholders' equity attributable to OPKO	834,789	842,144
Noncontrolling interests	(7,803	) (6,403
Total shareholders' equity	826,986	835,741
Total liabilities and equity	\$1,525,491	\$ 1,267,664



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

As of June 30, 2015 and December 31, 2014, total assets include \$7.1 million and \$7.6 million, respectively, and total liabilities include \$12.7 million and \$12.1 million, respectively, related to SciVac Ltd (“SciVac”), now known (1) as SciVac Therapeutics, Inc., a consolidated variable interest entity. SciVac’s consolidated assets are owned by SciVac and SciVac’s consolidated liabilities have no recourse against us. Refer to Note 5.

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 June 30,		For the six months ended June 30,	
	2015	2014	2015	2014
Revenues:				
Products	\$22,848	\$21,392	\$38,334	\$41,219
Revenue from services	1,908	2,153	3,977	4,123
Revenue from transfer of intellectual property	17,673	—	30,202	476
Total revenues	42,429	23,545	72,513	45,818
Costs and expenses:				
Costs of revenues	14,434	12,565	24,755	24,955
Selling, general and administrative	20,937	14,874	38,382	28,686
Research and development	29,570	16,234	55,072	37,227
In-process research and development	—	10,055	—	10,055
Contingent consideration	(339)	) 1,876	4,836	4,486
Amortization of intangible assets	3,236	2,826	5,901	5,569
Grant repayment (Note 12)	—	—	25,889	—
Total costs and expenses	67,838	58,430	154,835	110,978
Operating loss	(25,409)	) (34,885)	) (82,322)	) (65,160)
Other income and (expense), net:				
Interest income	5	7	12	48
Interest expense	(986)	) (4,685)	) (3,551)	) (8,171)
Fair value changes of derivative instruments, net	(16,556)	) 10,967	(66,344)	) 594
Other income (expense), net	760	2,990	(748)	) 4,666
Other income and (expense), net	(16,777)	) 9,279	(70,631)	) (2,863)
Loss before income taxes and investment losses	(42,186)	) (25,606)	) (152,953)	) (68,023)
Income tax benefit (provision)	(251)	) (101)	) (5,760)	) (714)
Loss before investment losses	(42,437)	) (25,707)	) (158,713)	) (68,737)
Loss from investments in investees	(804)	) (370)	) (2,565)	) (2,426)
Net loss	(43,241)	) (26,077)	) (161,278)	) (71,163)
Less: Net loss attributable to noncontrolling interests	(475)	) (597)	) (1,400)	) (1,137)
Net loss attributable to common shareholders	\$(42,766)	) \$(25,480)	) \$(159,878)	) \$(70,026)
Loss per share, basic and diluted:				
Net loss per share	\$(0.09)	) \$(0.06)	) \$(0.35)	) \$(0.17)
Weighted average number of common shares outstanding, basic and diluted	462,253,161	413,339,679	454,361,137	413,125,932

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 LOSS

(Unaudited)

(In thousands)

	For the three months ended		For the six months ended	
	June 30,	June 30,	June 30,	June 30,
	2015	2014	2015	2014
Net loss	\$ (43,241	) \$ (26,077	) \$ (161,278	) \$ (71,163
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss) from equity investments	(694	) 188	(4,547	) (1,613
Available for sale investments:				
Change in unrealized gain (loss), net of tax	(682	) (1,283	) (1,941	) (948
Less: reclassification adjustments for (gains) losses included in net loss, net of tax	—	—	—	(553
Comprehensive loss	(44,617	) (27,172	) (167,766	) (74,277
Less: Comprehensive loss attributable to noncontrolling interest	(475	) (597	) (1,400	) (1,137
Comprehensive loss attributable to common shareholders	\$ (44,142	) \$ (26,575	) \$ (166,366	) \$ (73,140

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 six months ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(161,278	) \$(71,163
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,685	7,591
Non-cash interest on 2033 Senior Notes	1,681	3,557
Amortization of deferred financing costs	895	1,807
Losses from investments in investees	2,565	2,426
Equity-based compensation – employees and non-employees	14,090	6,993
(Recovery of) provision for bad debts	626	(68
Provision for inventory obsolescence	710	583
Revenue from receipt of equity	(120	) (120
Realized gain on sale of equity securities	(216	) (1,274
(Gain) loss on conversion of 3.00% convertible senior notes	291	(2,668
Change in fair value of derivative instruments	66,344	(594
In-process research and development	—	10,055
Change in fair value of contingent consideration	4,836	4,486
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable	(4,812	) (4,321
Inventory	(3,257	) (1,413
Prepaid expenses and other current assets	1,142	3,466
Other assets	(512	) 3,911
Accounts payable	7,101	(3,308
Foreign currency measurement	300	(824
Deferred revenue	263,926	(846
Accrued expenses and other liabilities	2,741	(2,817
Net cash provided by (used in) operating activities	204,738	(44,541
Cash flows from investing activities:		
Investments in investees	(2,345	) (500
Proceeds from sale of equity securities	—	1,331
Acquisition of businesses, net of cash	(94,674	) (1,695
Capital expenditures	(1,439	) (2,467
Net cash used in investing activities	(98,458	) (3,331
Cash flows from financing activities:		
Proceeds from the exercise of Common Stock options and warrants	17,366	2,747
Cash from non-controlling interest	100	—
Contingent consideration payments	—	(6,435
Borrowings on lines of credit	11,038	14,258
Repayments of lines of credit	(10,022	) (14,571
Net cash provided by financing activities	18,482	(4,001
Effect of exchange rate on cash and cash equivalents	(452	) 85
Net increase (decrease) in cash and cash equivalents	124,310	(51,788
Cash and cash equivalents at beginning of period	96,907	185,798

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

Cash and cash equivalents at end of period	\$221,217	\$134,010
SUPPLEMENTAL INFORMATION:		
Interest paid	\$1,724	\$2,771
Income taxes paid, net	\$757	\$796
Pharmsynthez common stock received	\$—	\$6,264
Non-cash financing:		
Shares issued upon the conversion of:		
2033 Senior Notes	\$92,172	\$95,665
Common Stock options and warrants, surrendered in net exercise	\$14,239	\$3,493
Issuance of capital stock to acquire:		
OPKO Health Europe	\$1,813	\$—
OPKO Uruguay Ltda.	\$—	\$159
Inspiro	\$—	\$8,566
EirGen Pharma Limited	\$33,569	\$—

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

9

---

Table of Contents

OPKO Health, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

NOTE 1 BUSINESS AND ORGANIZATION

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. We are developing a range of solutions to diagnose, treat and prevent various conditions, including point-of-care tests, molecular diagnostics tests, laboratory developed tests, and proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets.

On June 3, 2015, we entered into an agreement and plan of merger pursuant to which we agreed to acquire Bio-Reference Laboratories, Inc. ("Bio-Reference"). 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 agreement, which has been approved by the Boards of Directors of both companies, holders of Bio-Reference common stock will receive 2.75 shares of OPKO common stock for each share of Bio-Reference common stock. Assuming a closing price of \$16.74 per share of OPKO common stock, the transaction is valued at approximately \$1.3 billion, or \$46.04 per share of Bio-Reference common stock. We expect the transaction to be completed during the second half of 2015. Closing of the transaction is subject to approval of Bio-Reference's shareholders and other customary conditions. Although we have entered into the merger agreement, there is no guarantee that the merger will be completed. A meeting of the shareholders of Bio-Reference will be held on August 20, 2015 to vote on a proposal to approve and adopt the merger agreement and approve the merger.

On May 5, 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.

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. In the U.S., we own a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, as amended ("CLIA"), with a urologic focus that generates revenue and serves as the commercial platform for the U.S. launch of the 4Kscore test to improve cancer risk stratification of patient candidates prior to prostate biopsy.

We are incorporated in Delaware and our principal executive offices are located in leased offices in Miami, Florida. We lease office and lab space in Jupiter and Miramar, Florida, and Nes Ziona, Israel, which is where our molecular diagnostics research and development, oligonucleotide research and development and carboxyl terminal peptide research and development operations are based, respectively. We lease office, manufacturing and warehouse space in Woburn, Massachusetts for our point-of-care diagnostics business, and in Neshar, Israel for our API business. We lease laboratory and office space in Nashville, Tennessee, Burlingame, California, and Miramar, Florida for our CLIA-certified laboratory business. Our Chilean and Uruguayan operations are located in leased offices and warehouse facilities in Santiago and Montevideo, respectively. Our Mexican operations are based in owned offices, an owned manufacturing facility and a leased warehouse facility in Guadalajara and in leased offices in Mexico City. Our Spanish operations are based in owned offices in Barcelona, in an owned manufacturing facility in Banyoles and a leased warehouse facility in Palol de Revardit. Our Brazilian operations are located in leased offices in Sao Paulo. Our Irish operations are located in leased offices in Waterford and Dublin.



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) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three and six months ended June 30, 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 and a variable interest entity in which we are deemed to be the primary beneficiary. 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.

**Pre-launch inventories.** We may accumulate commercial quantities of certain product candidates prior to the date we anticipate that such products will receive final U.S. FDA approval. The accumulation of such pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever. This risk notwithstanding, we may accumulate pre-launch inventories of certain products when such action is appropriate in relation to the commercial value of the product launch opportunity. In accordance with our policy, this pre-launch inventory is expensed. At June 30, 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 Cosmeticos Ltda. ("OPKO Brazil"), PROLOR Biotech, Inc. ("OPKO Biologics") and EirGen Pharma Limited ("EirGen"). Goodwill, in-process research and development ("IPR&D") and other intangible assets acquired in business combinations, licensing and other transactions at June 30, 2015 and December 31, 2014 were \$1.2 billion and \$1.1 billion, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are 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 warrant a review, 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.

## Table of Contents

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, currently ranging from 3 to 20 years, and review for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. 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 \$5.9 million and \$5.6 million for the six months ended June 30, 2015 and 2014, respectively.

Fair value measurements. The carrying amounts of our cash and cash equivalents, accounts receivable and accounts payable approximate their fair value due to the short-term maturities of these instruments. Investments that are considered available for sale as of June 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 June 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. 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 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 certain 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.

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. 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.

Table of Contents

The assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the relevant time period of research and development on a quarterly basis. For the three and six months ended June 30, 2015, revenue from transfer of intellectual property includes \$17.7 million and \$30.2 million, respectively, of revenue related to the Pfizer Transaction. Refer to Note 12.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as Revenue from transfer of intellectual property upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; there was substantive uncertainty at the date of entering into the arrangement that the milestone would be achieved; the milestone is commensurate with either 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 \$272.4 million and \$6.7 million at June 30, 2015 and December 31, 2014, respectively. The deferred revenue balance at June 30, 2015 relates primarily to the Pfizer Transaction. Refer to Note 12.

Allowance for doubtful accounts. We assess the collectability of accounts receivable balances by considering factors such as historical experience, customer credit worthiness, the age of accounts receivable balances and current economic conditions and trends that may affect a customer's ability to pay. The allowance for doubtful accounts is based on our assessment of the collectability of customer accounts. Our reported net loss is directly affected by our estimate of the collectability of accounts receivable. The amount of the allowance for doubtful accounts was \$2.1 million and \$1.9 million at June 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 six months ended June 30, 2015 and 2014, we recorded \$14.1 million and \$7.0 million, respectively, of equity-based compensation expense.

Research and development expenses. Research and development expenses include external and internal expenses, partially offset by third-party grants and fundings arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. Research and development employee-related expenses include salaries, benefits and stock-based compensation expense. Other unallocated 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

## Table of Contents

consists of two operating segments, our (i) pathology operations we acquired through the acquisition of 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 deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment.

Income tax expense was primarily attributable to taxable income recognized from the Pfizer Transaction and related transactions during the six months ended June 30, 2015. Refer to Note 12. Included in income tax expense 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, 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. 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

Table of Contents

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)," 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.

**NOTE 3 LOSS PER SHARE**

Basic loss per share is computed by dividing our net loss by the weighted average number of shares outstanding during the period. Diluted loss per share is computed by dividing our net loss increased by dividends on preferred stock by the weighted average number of shares outstanding and the impact of all dilutive potential common shares, primarily stock options. 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 convertible Preferred Stock in the diluted computation. Potentially dilutive shares issuable pursuant to the 2033 Senior Notes (defined in Note 6) were not included in the computation of net loss per share for the three and six months ended June 30, 2015, because their inclusion would be antidilutive.

A total of 11,261,582 and 29,132,527 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for the three months ended June 30, 2015 and 2014, respectively, because their inclusion would be antidilutive. A total of 14,375,502 and 29,503,319 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for the six months ended June 30, 2015 and 2014, respectively, because their inclusion would be anti-dilutive.

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

During the six months ended June 30, 2015, 24,168,461 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 22,635,661 shares of Common Stock. Of the 24,168,461 Common Stock options and Common Stock warrants exercised, 1,206,654 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.



Table of Contents

## NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	June 30, 2015	December 31, 2014
Accounts receivable, net		
Accounts receivable	\$29,045	\$21,875
Less: allowance for doubtful accounts	(2,065)	(1,906)
	\$26,980	\$19,969
Inventories, net		
Finished products	\$13,830	\$12,116
Work in-process	1,619	1,011
Raw materials	5,782	4,116
Less: inventory reserve	(712)	(639)
	\$20,519	\$16,604
Prepaid expenses and other current assets		
Prepaid supplies	\$1,441	\$1,123
Prepaid insurance	613	968
Other receivables	1,107	669
Taxes recoverable	3,074	2,417
Other	3,388	4,212
	\$9,623	\$9,389
Intangible assets, net:		
Technologies	\$52,287	\$52,508
Customer relationships	55,750	22,108
Product registrations	8,088	8,763
Trade names	3,411	3,483
Covenants not to compete	8,620	8,639
Other	4,889	1,079
Less: accumulated amortization	(38,798)	(33,931)
	\$94,247	\$62,649
Accrued expenses:		
Taxes payable	\$2,592	\$77
Deferred revenue	75,159	4,185
Clinical trials	8,534	8,643
Professional fees	1,724	1,860
Employee benefits	5,456	4,127
Contingent consideration	41,146	27,352
Other	15,232	14,668
	\$149,843	\$60,912

Table of Contents

(In thousands)	June 30, 2015	December 31, 2014
Other long-term liabilities:		
Contingent consideration – OPKO Renal	\$ 19,183	\$ 36,529
Contingent consideration – OPKO Health Europe	225	254
Contingent consideration – OPKO Diagnostics	13,342	6,992
Contingent consideration – CURNA	433	440
Mortgages and other debts payable	2,148	2,434
Deferred tax liabilities	172,458	167,153
Deferred revenue	197,279	2,526
Other	3,753	1,030
	\$ 408,821	\$ 217,358

All of the intangible assets and goodwill acquired relate to our acquisitions of OPKO Chile, including the intangible assets and goodwill related to the ALS acquisition, OPKO Mexico, CURNA, OPKO Diagnostics, FineTech, OPKO Health Europe, OPKO Lab, OPKO Brazil, OPKO Renal, OPKO Biologics, OPKO Uruguay Ltda., EirGen and SciVac, a consolidated VIE. 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 the U.S., Chile, Canada, Mexico, Spain, Ireland, or Israel.

At June 30, 2015, the changes in value of the intangible assets and goodwill are primarily due to the acquisition of 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 six months ended June 30, 2015.

(In thousands)	2015 Balance at January 1st	Acquisitions	Foreign exchange	Balance at June 30th
Pharmaceuticals				
CURNA	\$ 4,827	\$ —	\$ —	\$ 4,827
OPKO Mexico	100	—	(5	) 95
OPKO Chile	5,283	—	(243	) 5,040
OPKO Health Europe	8,013	—	(699	) 7,314
FineTech	11,698	—	—	11,698
SciVac	1,553	—	49	1,602
OPKO Renal	2,069	—	—	2,069
OPKO Biologics	139,784	—	—	139,784
EirGen Pharma Ltd	—	66,823	(610	) 66,213
Diagnostics				
OPKO Diagnostics	17,977	—	—	17,977
OPKO Lab	32,988	—	—	32,988
	\$ 224,292	\$ 66,823	\$ (1,508	) \$ 289,607

Table of Contents

## NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

## Pending Bio-Reference acquisition

On June 3, 2015, we entered into an agreement and plan of merger pursuant to which we agreed to acquire Bio-Reference. 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, which has been approved by the Boards of Directors of both companies, all holders of Bio-Reference common stock will receive 2.75 shares of OPKO common stock for each share of Bio-Reference common stock. Assuming a closing price of \$16.74 per share of OPKO common stock, the transaction is valued at approximately \$1.3 billion, or \$46.04 per share of Bio-Reference common stock. We expect the transaction to be completed during the second half of 2015. Closing of the transaction is subject to approval of Bio-Reference's shareholders and other customary conditions. Although we have entered into the merger agreement, there is no guarantee that the merger will be completed.

## EirGen Pharma Limited acquisition

On May 5, 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.

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

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



Table of Contents

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 six months ended June 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 June 30,		For the six months ended June 30,	
	2015	2014	2015	2014
Revenues	\$43,848	\$25,659	\$76,769	\$50,185
Net loss	(43,420)	(28,356)	(162,331)	(75,879)
Net loss attributable to common shareholders	(42,945)	(27,759)	(160,931)	(74,742)
Basic and diluted net loss per share	\$(0.09)	\$(0.07)	\$(0.35)	\$(0.18)

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.

## Inspiro Medical Ltd. acquisition

On April 17, 2014, we entered into a stock purchase agreement to acquire 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 Inspiomatic™ 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 June 30, 2015:

(in thousands)

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	\$6,746	\$23,735
Variable interest entity, equity method	903	—
Available for sale investments	3,816	
Warrants and options	9,969	
Total carrying value of investments	\$21,434	

## Equity Method Investments

Our equity method investments consist of investments in Pharmsynthez (ownership 17%), Cocystal Pharma, Inc. (“COCP”) (8%), Sevion Therapeutics, Inc. (“Sevion”) (4%), Non-Invasive Monitoring Systems, Inc. (1%) and Neovasc (5%). The total assets, liabilities, and net losses of our equity method investees as of and for the six months ended June 30, 2015 were \$403.2 million, \$(96.7) million, and \$(52.5) 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

19

---

Table of Contents

accounting, we record our proportionate share of their losses in Loss from investments in investees in our Condensed Consolidated Statement of Operations. The aggregate value of our equity method investments based on the quoted market price of their common stock and the number of shares held by us as of June 30, 2015 is \$88.1 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 10%), 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 six months ended June 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 six months ended June 30, 2015. The cost of securities sold is based on the specific identification method.

Warrants and Options

In addition to our equity method investments and available for sale investments, we hold options to purchase 1.0 million additional shares of Neovasc, which are fully vested as of December 31, 2014, and 1.0 million, 0.8 million, 0.1 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.

Pharmsynthez transactions

In April 2013, we entered into a series of concurrent transactions with Pharmsynthez, a Russian pharmaceutical company traded on the Moscow Stock Exchange. The transactions consisted of:

- We delivered approximately \$9.6 million in cash to Pharmsynthez.
- Pharmsynthez issued to us approximately 13.6 million of its common shares.
- Pharmsynthez agreed, at its option, to issue approximately 12.0 million common shares to us or to pay us cash in Russian Rubles (“RUR”) 265.0 million (\$8.1 million at December 31, 2013) on or before December 31, 2013 (the “Pharmsynthez Note Receivable”). In January 2014, Pharmsynthez delivered to us approximately 12.0 million shares of its common stock in satisfaction of the Pharmsynthez Notes Receivable.
- We had a right to purchase additional shares in Pharmsynthez at a fixed price if Pharmsynthez paid us in cash rather than delivering to us the 12.0 million Pharmsynthez common shares (the “Purchase Option”), however in connection with the settlement of the Pharmsynthez Note Receivable in January 2014, this right terminated.
- We granted rights to certain technologies in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan (the “Territories”) to Pharmsynthez.
- 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.
- Pharmsynthez paid us \$9.5 million under the various collaboration and funding agreements for the grant of rights and development of the technologies (the “Collaboration Payments”).

We recorded the shares received in Pharmsynthez as an equity method investment. We initially recorded the Pharmsynthez Note Receivable, and the Purchase Option, as financial instruments and elected the fair value option for subsequent measurement. Changes in the fair value of the Pharmsynthez Note Receivable and the Purchase Option were recorded in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations. Upon settlement in January 2014, we recorded the additional shares at fair value as an equity method investment.

We have accounted for the license and development activities as a multi-element arrangement, and allocated the total arrangement consideration based on the relative selling prices of the elements. We record the allocated consideration for development activities as an offset to Research and development expenses over the three-year term of the Collaboration Payments. We recorded revenue in connection with the grant of rights to the technologies proportionately as the payments were received.

20

---



Table of Contents

During the six months ended June 30, 2015 and 2014, we recorded \$0 million and \$0.5 million, respectively, in Revenue from transfer of intellectual property and \$0.5 million and \$0.8 million, respectively, as an offset to Research and development expenses related to the Collaboration Payments.

Investments in variable interest entities

We have determined that we hold variable interests in SciVac and Zebra Biologics, Inc. (“Zebra”). We made this determination as a result of our assessment that they do not have sufficient resources to carry out their 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 June 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.

Consolidated variable interest entities

In June 2012, we acquired a 50% stock ownership in SciVac (45% as of June 30, 2015) from FDS Pharma LLP (“FDS”). SciVac is a privately-held Israeli company that produces a third-generation hepatitis B-vaccine. From November 2012 until June 30, 2015, we loaned to SciVac a combined \$7.6 million for working capital purposes. We have determined that we hold variable interests in SciVac based on our assessment that SciVac does not have sufficient resources to carry out its principal activities without financial support. In order to determine the fair market value of our investment in SciVac, we have utilized a business enterprise valuation approach.

In order to determine the primary beneficiary of SciVac, we evaluated our investment to identify if we had the power to direct the activities that most significantly impact the economic performance of SciVac. We have determined that the power to direct the activities that most significantly impact the economic performance of SciVac is conveyed through SciVac’s board of directors. SciVac’s board of directors appoint and oversee SciVac’s management team who carry out the activities that most significantly impact the economic performance of SciVac. As part of the share and debt purchase agreement, SciVac’s board of directors is constituted by 5 members, of which 3 members are appointed by us, representing 60% of SciVac’s board. Based on this analysis, we determined that we have the power to direct the activities of SciVac and as such we are the primary beneficiary. As a result of this conclusion, we have consolidated the results of operations and financial position of SciVac and recorded a reduction of equity for the portion of SciVac we do not own.

Table of Contents

The following table represents the consolidated assets and non-recourse liabilities related to SciVac as of June 30, 2015 and December 31, 2014. These assets are owned by, and these liabilities are obligations of, SciVac, not us.

(In thousands)	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$21	\$393
Accounts receivable, net	304	316
Inventories, net	1,433	1,649
Prepaid expenses and other current assets	774	718
Total current assets	2,532	3,076
Property, plant and equipment, net	1,791	1,725
Intangible assets, net	843	875
Goodwill	1,602	1,553
Other assets	368	384
Total assets	\$7,136	\$7,613
Liabilities		
Current liabilities:		
Accounts payable	\$900	\$445
Accrued expenses	4,476	4,446
Notes payable	5,409	5,189
Total current liabilities	10,785	10,080
Other long-term liabilities	1,884	2,042
Total liabilities	\$12,669	\$12,122

In March 2015, SciVac entered into an agreement pursuant to which Levon Resources Ltd. ("Levon") agreed to acquire 100% of the issued and outstanding ordinary shares of SciVac by way of a court-approved plan of arrangement (the "Arrangement"). Upon closing, which occurred in July 2015, Levon changed its name to SciVac Therapeutics Inc. ("New SciVac"), and the officers and directors of SciVac became officers and directors of New SciVac. The former owners of SciVac now hold 68.4% of the outstanding shares of New SciVac, resulting in our ownership interest of approximately 24.5%.

**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 June 30, 2015:

Table of Contents

(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	—	—	1,680	1,680
Change in fair value of embedded derivative	67,950	—	—	67,950
Conversion	(60,346 )	(41,442 )	9,907	(91,881 )
Balance at June 30, 2015	\$73,551	\$46,200	\$(10,548 )	\$109,203

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. As a result, embedded derivatives are required to be separated from the host contract, the 2033 Senior Notes, and carried at fair value when: (a) the embedded derivative possesses economic characteristics that are not clearly and closely related to the economic characteristics of the host contract; and (b) a separate, stand-alone instrument with the same terms would qualify as a derivative instrument. We have concluded that the embedded derivatives within the 2033 Senior Notes meet these criteria and, as such, must be valued separate and apart from the 2033 Senior Notes and recorded at fair value each reporting period.

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

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

Table of Contents

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.

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.

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

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

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

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

	June 30, 2015
Stock price	\$16.08
Conversion Rate	141.4827
Conversion Price	\$7.07
Maturity date	February 1, 2033
Risk-free interest rate	1.19%
Estimated stock volatility	41%
Estimated credit spread	1,133 basis points

The following table sets forth the fair value of the 2033 Senior Notes with and without the embedded derivatives, and the fair value of the embedded derivatives at June 30, 2015. At June 30, 2015 the principal amount of the 2033 Senior Notes was \$46.2 million:

(In thousands)	June 30, 2015
Fair value of 2033 Senior Notes:	
With the embedded derivatives	\$107,743
Without the embedded derivatives	\$34,192

Estimated fair value of the embedded derivatives

\$73,551

24

---

Table of Contents

Changes in certain inputs into the lattice model can have a significant impact on changes in the estimated fair value of the embedded derivatives. For example, a decrease in our estimated credit spread results in an increase in the estimated value of the embedded derivatives. Conversely, a decrease in the price of our Common Stock results in a decrease in the estimated fair value of the embedded derivatives. For the six months ended June 30, 2015, we observed an increase in the market price of our Common Stock which resulted in a \$68.0 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.

We have line of credit agreements with eight financial institutions as of June 30, 2015 and twelve financial institutions as of December 31, 2014 in 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 Chilean and Spanish lines of credit:

Lender	Interest rate on borrowings at June 30, 2015	Credit line capacity	Balance Outstanding	
			June 30, 2015	December 31, 2014
Itau Bank	6.00%	\$1,800	\$1,171	\$965
Bank of Chile	5.50%	2,250	1,572	1,410
BICE Bank	6.16%	2,300	1,088	1,249
BBVA Bank	5.00%	2,300	1,552	795
Penta Bank	7.58%	1,200	631	1,008
Security Bank	6.16%	940	305	361
Estado Bank	5.30%	2,800	2,039	1,870
BBVA Bank	4.75%	277	—	—
Total		\$13,867	\$8,358	\$7,658

At June 30, 2015 and December 31, 2014, the weighted average interest rate on our lines of credit was approximately 5.7% and 6.1%, respectively.

At June 30, 2015 and December 31, 2014, we had mortgage notes and other debt related to OPKO Health Europe and EirGen as follows:

(In thousands)	June 30, 2015	December 31, 2014
Current portion of notes payable	\$832	\$608
Other long-term liabilities	2,393	2,435
Total mortgage notes and other debt	\$3,225	\$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 June 30, 2015 and December 31, 2014, was 3.2% and 3.4%, respectively. The mortgages are secured by our office space in Barcelona.

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

For the six months ended June 30, 2015, changes in Accumulated other comprehensive income (loss), net of tax, were as follows:

Table of Contents

(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	(4,547 )	(1,941 )	(6,488 )
Amounts reclassified from accumulated other comprehensive income, net of tax	—	—	—
Net other comprehensive loss	(4,547 )	(1,941 )	(6,488 )
Balance at June 30, 2015	\$(11,264 )	\$(7,616 )	\$(18,880 )

**NOTE 8 FAIR VALUE MEASUREMENTS**

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

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

As of June 30, 2015					
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Gain/(Loss) in Accumulated Deficit	Fair value
Common stock investments, available for sale	\$11,479	\$898	\$(7,119 )	\$(1,442 )	\$3,816
Common stock options/warrants	3,925	—	—	6,044	9,969
Total assets	\$15,404	\$898	\$(7,119 )	\$4,602	\$13,785
As of December 31, 2014					
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	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 June 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.

26

---

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 June 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	\$52,563	\$—	\$—	\$52,563
Common stock investments, available for sale	3,816	—	—	3,816
Common stock options/warrants	—	9,969	—	9,969
Forward contracts	—	115	—	115
Total assets	\$56,379	\$10,084	\$—	\$66,463
Liabilities:				
Embedded conversion option	\$—	\$—	\$73,551	\$73,551
Contingent consideration:				
CURNA	—	—	433	433
OPKO Diagnostics	—	—	13,342	13,342
OPKO Renal	—	—	60,090	60,090
OPKO Health Europe	—	—	464	464
Total liabilities	\$—	\$—	\$147,880	\$147,880

(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 long-term debt, as well as the applicable fair value hierarchy tiers, are contained in the table below. The fair value of the 2033 Senior Notes is determined using a binomial lattice approach in order to estimate the fair value of the embedded derivative in the 2033 Senior Notes. Refer to Note 6.

June 30, 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	\$35,652	\$34,192	\$—	\$—	\$34,192

27

---

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 June 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 June 30, 2015:

(In thousands)	June 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	4,836	67,950
Foreign currency impact	(261 )	—
Payments	(1,813 )	—
Conversion	—	(60,346 )
Balance at June 30, 2015	\$74,329	\$73,551

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 \$1.2 million. If estimated future sales were to decrease by 10%, the contingent consideration related to OPKO Renal would decrease by \$1.7 million. As of June 30, 2015, of the \$74.3 million of contingent consideration, \$41.1 million is recorded in Accrued expenses and \$33.2 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.

**NOTE 9 DERIVATIVE CONTRACTS**

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

(In thousands)	Balance Sheet Component	June 30, 2015	December 31, 2014
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	\$9,969	\$ 6,314
Embedded conversion option	2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	\$73,551	\$ 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.	\$115	\$ 36



Table of Contents

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

To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At June 30, 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 six months ended June 30, 2015 and 2014:

(In thousands)	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Derivative gain (loss):				
Common Stock options/warrants <sup>(1)</sup>	\$(2,446 )	\$(860 )	\$1,425	\$(263 )
2033 Senior Notes	(14,220 )	11,882	(67,950 )	770
Forward contracts	110	(55 )	181	87
Total	\$(16,556 )	\$10,967	\$(66,344 )	\$594

<sup>(1)</sup> Amount for 2014 includes the Pharmsynthez Note Receivable and the Purchase Option.

The outstanding forward contracts at June 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 June 30, 2015	Effect on income (loss)
Days until maturity			
0 to 30	\$1,414	\$1,466	\$52
31 to 60	324	336	12
61 to 90	939	981	42
91 to 120	180	188	8
More than 120	31	32	1
Total	\$2,888	\$3,003	\$115
(In thousands)			
Days until maturity	Contract value	Fair value at December 31, 2014	Effect on income (loss)
0 to 30	\$750	\$780	\$30
31 to 60	90	93	3
61 to 90	—	—	—
91 to 120	68	71	3
121 to 180	—	—	—
More than 180	—	—	—
Total	\$908	\$944	\$36

**NOTE 10 RELATED PARTY TRANSACTIONS**

In April 2015, we made a \$2.5 million investment in a private placement transaction with MabVax Therapeutics Holdings, Inc. pursuant to which we acquired 33,333 shares of MabVax Series E Convertible Preferred Stock and warrants to purchase 1,666,667 shares of MabVax common stock. Prior to our investment in MabVax, Dr. Frost held shares in MabVax indirectly through an entity in which he has an ownership interest. Dr. Frost, as well as non-affiliated investors, invested in the private placement transaction on the same financial terms. In connection with the OPKO investment, Steven Rubin, our Executive Vice President, Administration, was appointed as an advisor to MabVax, and we have the right to designate two board members.

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

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.

Table of Contents

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 six months ended June 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 six months ended June 30, 2015.

In 2012, we made a \$1.7 million investment in Biozone. Effective January 2, 2014, Biozone completed a merger with Cocrystal Discovery, Inc. ("Cocrystal"), another entity in which we had an equity investment. The name of the issuer was changed to Cocrystal Pharma, Inc. ("COCP"). Dr. Frost previously invested in both Biozone and Cocrystal. 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 June 30, 2015, we hold an 8% ownership interest in COCP.

We hold investments in Zebra (ownership 28%), Sevion (4%), Neovasc (5%), ChromaDex Corporation (2%) 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.

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 six months ended June 30, 2015, we recognized approximately \$167 thousand and \$293 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and six months ended June 30, 2014, we reimbursed Dr. Frost approximately \$49 thousand and \$62 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

**NOTE 11 COMMITMENTS AND CONTINGENCIES**

In connection with our acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe, and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of June 30, 2015, we recorded \$74.3 million as contingent consideration, with \$41.1 million recorded within Accrued expenses and \$33.2 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4. In addition, in connection with our asset purchase agreement with Schering Plough Corporation, now Merck & Co. ("Merck"), we are required to pay up to an additional \$25.0 million upon the achievement of certain development milestones. Future payments to be made under the agreement with Merck will be recognized when the milestones are achieved and consideration is issued or becomes issuable. Refer to Note 12.

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.

30

---

Table of Contents

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. Two of the complaints were filed in the Law Division, and two of the complaints were filed in the Chancery Division. The complaints are captioned: Naik v. Bio-Reference Laboratories, Inc., et al., Docket No. C-180-15 filed in the Chancery Division on June 11, 2015; Katcher v. Bio-Reference Laboratories, Inc., et al., Docket No. C-207-15 filed in the Chancery Division on July 16, 2015; Cohen v. Bio-Reference Laboratories, Inc., et al., Docket No. L-5697-15 filed in the Law Division on June 18, 2015; and Ertan v. Bio-Reference Laboratories, Inc., et al., Docket No. L-5701-15 filed in the Law Division on June 18, 2015. 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 seek injunctive relief enjoining Bio-Reference and OPKO from consummating the merger at the agreed upon price unless and/or until the defendants cure their breaches of fiduciary duty (or, in the event the merger is consummated, rescinding the merger or awarding rescissory damages). The complaints also seek to recover costs and disbursement from the defendants, including attorneys’ fees and experts’ fees. 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 Company denies the allegations and intends to defend the actions. It is too early to assess the probability of a favorable or unfavorable outcome or the loss or range of loss, if any.

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 the Washington University patents subject to certain exceptions. In connection with the Pfizer Transaction, we sublicensed to Pfizer the patents 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.

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.

Table of Contents

At June 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 \$19.2 million.

## 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 \$30.2 million of revenue related to the Pfizer Transaction in Revenue from transfer of

intellectual property in our Condensed Consolidated Statement of Operations during the six months ended June 30, 2015, and had deferred revenue related to the Pfizer Transaction of \$264.8 million at June 30, 2015. As of June 30, 2015, \$70.6 million of deferred revenue related to the Pfizer Transaction was classified in Accrued expenses and \$194.2 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 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

Table of Contents

million payment in Grant repayment expense in our Condensed Consolidated Statement of Operations during the six months ended June 30, 2015.

**TESARO**

In November 2009, we entered into an asset purchase agreement (the “NK-1 Agreement”) under which we acquired 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, rolapitant (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 six months ended June 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 rolapitant 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 rolapitant 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.

Under the terms of the NK-1 Agreement, we are required to pay Merck up to an additional \$25.0 million upon achievement of certain development milestones. Future payments to be made under the NK-1 Agreement will be recognized when the milestones are achieved and consideration is paid or becomes payable.

**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) pathology operations 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 six months ended June	
	June 30,		30,	
	2015	2014	2015	2014
Product revenues:				
Pharmaceuticals	\$22,848	\$21,392	\$38,334	\$41,219
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	\$22,848	\$21,392	\$38,334	\$41,219
Revenue from services:				
Pharmaceuticals	\$—	\$—	\$—	\$—
Diagnostics	1,848	2,093	3,857	4,003
Corporate	60	60	120	120
	\$1,908	\$2,153	\$3,977	\$4,123
Revenue from transfer of intellectual property:				
Pharmaceuticals	\$17,673	\$—	\$30,202	\$285
Diagnostics	—	—	—	191
Corporate	—	—	—	—
	\$17,673	\$—	\$30,202	\$476
Operating (loss) income:				
Pharmaceuticals	\$(4,660	) \$(20,368	) \$(42,584	) \$(36,941
Diagnostics	(7,098	) (6,805	) (15,575	) (13,882
Corporate	(12,905	) (7,038	) (22,882	) (13,174
Less: Operating loss attributable to noncontrolling interests	(746	) (674	) (1,281	) (1,163
	\$ (25,409	) \$ (34,885	) \$ (82,322	) \$ (65,160
Depreciation and amortization:				
Pharmaceuticals	\$2,371	\$2,287	\$4,138	\$4,135
Diagnostics	1,754	1,716	3,501	3,408
Corporate	27	24	46	48
	\$4,152	\$4,027	\$7,685	\$7,591
Net loss from investment in investees:				
Pharmaceuticals	\$(804	) \$(370	) \$(2,565	) \$(2,426
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	\$ (804	) \$ (370	) \$ (2,565	) \$ (2,426
Revenues:				
United States	\$2,525	\$2,153	\$5,019	\$4,599
Ireland	19,376	—	31,480	—
Chile	8,698	7,852	15,150	15,136
Spain	4,920	5,666	8,857	11,815
Israel	5,942	6,307	10,155	10,853
Mexico	968	1,546	1,852	3,377
Other	—	21	—	38
	\$42,429	\$23,545	\$72,513	\$45,818





Table of Contents

(In thousands)	June 30, 2015	December 31, 2014
Assets:		
Pharmaceuticals	\$1,290,366	\$1,064,498
Diagnostics	104,487	108,072
Corporate	130,638	95,094
	\$1,525,491	\$1,267,664
Goodwill:		
Pharmaceuticals	\$238,642	\$173,327
Diagnostics	50,965	50,965
Corporate	—	—
	\$289,607	\$224,292

During the three and six months ended June 30, 2015, revenue recognized under the Pfizer Transaction represented 42% of our total revenue. Refer to Note 12. During the three and six months ended June 30, 2014, one customer represented 21% and 15% of our total revenue, respectively. As of June 30, 2015 and December 31, 2014, no customer represented more than 10% of our accounts receivable balance.

**NOTE 14 SUBSEQUENT EVENTS**

On July 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 June 30, 2015. The conversion right was previously triggered during the quarter ended March 31, 2015. The 2033 Senior Notes will continue to be convertible until September 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. Pursuant to the Indenture, a holder who elects to convert the 2033 Senior Notes will receive 141.4827 shares of our Common Stock plus such number of additional shares as is applicable on the conversion date per \$1,000 principal amount of 2033 Senior Notes based on the early conversion provisions in the Indenture.

In May 2015, we submitted a New Drug Application (NDA) for oral Rayaldee to the U.S. Food and Drug Administration (FDA). The NDA requests 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. Under the terms of the agreement for our acquisition of OPKO Renal, we will pay the former owners of OPKO Renal \$20.0 million upon the acceptance of the NDA by the FDA, which is payable in either shares of our Common Stock or cash, at our option. Our NDA was accepted by the FDA in July 2015.

We have reviewed all subsequent events and transactions that occurred after the date of our June 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 multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. We are developing a range of solutions to diagnose, treat and prevent various conditions, including point-of-care tests, laboratory developed tests, and proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets.

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. We also have established pharmaceutical operations in Brazil. 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. In the U.S., we own a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, as amended ("CLIA"), with a urologic focus that generates revenue and serves as the commercial platform for the U.S. launch of the 4Kscore.

RECENT DEVELOPMENTS

On May 5, 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 \$100.2 million in cash and delivered 2,420,487 shares of our Common Stock valued at \$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 May 2015, we submitted a NDA for oral Rayaldee to the FDA. The NDA requests 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 in July 2015.

On June 3, 2015, we entered into an agreement and plan of merger pursuant to which we will acquire Bio-Reference Laboratories, Inc. (Bio-Reference). 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, which has been approved by the Boards of Directors of both companies, holders of Bio-Reference common stock will receive 2.75 shares of OPKO common stock for each share of Bio-Reference common stock. Assuming a closing price of \$16.74 per share of OPKO common stock, the transaction is valued at approximately \$1.3 billion, or \$46.04 per share of Bio-Reference common stock. We expect the transaction to be completed during the second half of 2015. Closing of the transaction is subject to approval of Bio-Reference's shareholders and other customary conditions. Although we have entered into the merger agreement, there is no guarantee that the merger will be completed.

Table of Contents

## RESULTS OF OPERATIONS

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

Revenues. Revenues for the three months ended June 30, 2015, were \$42.4 million, compared to \$23.5 million for the three months ended June 30, 2014. The increase in revenue principally reflects \$17.7 million of revenue from the transfer of intellectual property related to the Pfizer Transaction and \$2.3 million from EirGen, which we acquired in May 2015, which was partially offset by a decrease in pharmaceutical product revenue from our European and Mexican operations. Sales at OPKO Health Europe were affected by sales to a customer while we negotiated a long-term supply agreement and the weakening of the Euro against the U.S. dollar, and sales at OPKO Mexico were affected by a planned plant shutdown. 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. Costs of revenue for the three months ended June 30, 2015, were \$14.4 million, compared to \$12.6 million for the three months ended June 30, 2014. Costs of revenue for the three months ended June 30, 2015 increased principally due to cost of revenue of \$1.6 million from EirGen, which we acquired in May 2015, and was partially offset by decreased pharmaceutical product sales from our European and Mexican operations.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended June 30, 2015 and 2014, were \$20.9 million and \$14.9 million, respectively. The increase in selling, general and administrative expenses for the three months ended June 30, 2015 was primarily due to increased personnel expenses including equity based compensation as we expand our sales, marketing and administrative staff and add infrastructure, and an increase in professional fees attributable to our acquisition of EirGen and our pending merger with Bio-Reference. Selling, general and administrative expenses for the three months ended June 30, 2015 include \$0.5 million from EirGen which we acquired in May 2015. Selling, general and administrative expenses during the three months ended June 30, 2015 and 2014, include equity-based compensation expense of \$4.2 million and \$2.4 million, respectively.

Research and development expenses. Research and development expenses for the three months ended June 30, 2015 and 2014, were \$29.6 million and \$16.2 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 unallocated 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:

	For the three months ended June 30,	
	2015	2014
External expenses:		
Phase 3 clinical trials	\$ 3,707	\$ 3,399
CMC expense for biological products	7,748	718
Earlier-stage programs	1,706	1,869
Research and development employee-related expenses	6,984	5,429
Other unallocated internal research and development expenses	9,916	5,326
Third-party grants and funding from collaboration agreements	(491	) (507
Total research and development expenses	\$ 29,570	\$ 16,234

The increase in research and development expenses during the three months ended June 30, 2015, is primarily due to a \$13.1 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 clinical manufacturing costs (“CMC”), and the recognition of \$2.3 million of expense for our NDA submission to the FDA for oral Rayaldee in May 2015. This was partially offset by decreased expenses incurred by OPKO Renal related to phase 3 clinical trials for Rayaldee. In addition, during the three months ended June 30, 2015 and 2014, we recorded, as an offset to research and development expenses, \$0.5 million and \$0.5 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and

Table of Contents

development expenses for the three months ended June 30, 2015 and 2014 include equity-based compensation expense of \$2.4 million and \$1.0 million, respectively. We expect our research and development expense to increase as we continue to expand our research and development of potential future products.

**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 three months ended June 30, 2015.

**Contingent consideration.** Contingent consideration income (expense) for the three months ended June 30, 2015 and 2014, were \$(0.3) million and \$1.9 million, respectively. The decrease in contingent consideration expense was primarily attributable to a decrease in the fair value of our contingent obligations to the former stockholders of OPKO Diagnostics due to the impact of changes in the underlying assumptions during the period. The contingent consideration liabilities at June 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 June 30, 2015 and 2014, were \$3.2 million and \$2.8 million, respectively. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the three months ended June 30, 2015 include \$0.4 million from EirGen which we acquired in May 2015. 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 June 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 June 30, 2015 and 2014, was \$1.0 million and \$4.7 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 three months ended June 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 June 30, 2014 to \$46.2 million as of June 30, 2015. Interest expense for the three months ended June 30, 2015 and 2014 also reflect non-cash write-offs of deferred financing costs of \$0.1 million and \$1.5 million as interest expense related to conversion of \$5.0 million and exchange of \$70.4 million principal of 2033 Senior Notes in May 2015 and June 2014, respectively.

**Fair value changes of derivative instruments, net.** Fair value changes of derivative instruments, net for the three months ended June 30, 2015 and 2014, were \$(16.6) million of expense and \$11.0 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 \$(14.2) million and \$11.9 million for the three months ended June 30, 2015 and 2014, respectively. For the three months ended June 30, 2015, we observed an increase in the market price of our Common Stock which primarily resulted in the increase in the estimated fair value of our embedded derivatives in the 2033 Senior Notes. Expense for the three months ended June 30, 2015 also reflects expense of \$(2.4) million related to the change in the fair value of options and warrants to purchase additional shares of Neovasc and COCP.

**Other income and (expense), net.** Other income and (expense), net for the three months ended June 30, 2015 and 2014, were \$0.8 million and \$3.0 million, respectively. The decrease in other income and (expense), net for the three months ended June 30, 2015 compared to the same period in 2014 is primarily due to a \$2.7 million non-cash gain recognized in the second quarter of 2014 as a result of the exchange of \$70.4 million principal of 2033 Senior Notes compared to a \$30,000 gain recognized in the second quarter of 2015 as a result of the conversion of \$5.0 million principal of 2033 Senior Notes.

**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 \$0.8 million and \$0.4 million for the three months ended June 30, 2015 and 2014, respectively. The increase in loss from investments in investees is primarily due to an offsetting gain recognized during the three months ended June 30, 2014 from COCP.

Income taxes. Our income tax provision reflects the projected income tax payable in Ireland, Israel, Chile, Spain, Mexico, and Luxembourg. The increase in income tax expense was primarily attributable to taxable income recognized from the Pfizer Transaction during the three months ended June 30, 2015. We have recorded a full valuation allowance against our deferred tax assets in the U.S.

Table of Contents

## FOR THE SIX MONTHS ENDED JUNE 30, 2015 AND 2014

Revenues. Revenues for the six months ended June 30, 2015, were \$72.5 million, compared to \$45.8 million for the six months ended June 30, 2014. The increase in revenue principally reflects \$30.2 million of revenue from the transfer of intellectual property related to the Pfizer Transaction and \$2.3 million from EirGen, which we acquired in May 2015, which was partially offset by a decrease in pharmaceutical product revenue from our European and Mexican operations. During the 2015, sales at OPKO Health Europe were affected by sales to a customer while we negotiated a long-term supply agreement and the weakening of the Euro against the U.S. dollar, and sales at OPKO Mexico were negatively impacted by a planned plant shutdown.

Costs of revenue. Costs of revenue for the six months ended June 30, 2015, were \$24.8 million, compared to \$25.0 million for the six months ended June 30, 2014. Costs of revenue for the six months ended June 30, 2015 decreased principally due to decreased pharmaceutical product sales from our European and Mexican operations, which was partially offset by cost of revenue of \$1.6 million from EirGen which we acquired in May 2015.

Selling, general and administrative expenses. Selling, general and administrative expenses for the six months ended June 30, 2015 and 2014, were \$38.4 million and \$28.7 million, respectively. The increase in selling, general and administrative expenses for the six months ended June 30, 2015 was primarily due to increased personnel expenses including equity based compensation as we expand our sales, marketing and administrative staff and add infrastructure, and an increase in professional fees attributable to our acquisition of EirGen and our pending merger with Bio-Reference. Selling, general and administrative expenses during the six months ended June 30, 2015 and 2014, include equity-based compensation expense of \$8.1 million and \$4.4 million, respectively.

Research and development expenses. Research and development expenses for the six months ended June 30, 2015 and 2014, were \$55.1 million and \$37.2 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 unallocated 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:

	For the six months ended June 30,	
	2015	2014
External expenses:		
Phase 3 clinical trials	\$6,989	\$6,446
CMC expense for biological products	14,101	6,183
Earlier-stage programs	4,472	3,579
Research and development employee-related expenses	15,191	11,268
Other unallocated internal research and development expenses	15,276	10,763
Third-party grants and funding from collaboration agreements	(957)	(1,012)
Total research and development expenses	\$55,072	\$37,227

The increase in research and development expenses during the six months ended June 30, 2015, is primarily due to a \$16.6 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. This was partially offset by decreased expenses incurred by OPKO Renal related to phase 3 clinical trials for Rayaldee. In addition, during the six months ended June 30, 2015 and 2014, we recorded, as an offset to research and development expenses, \$1.0 million and \$1.0 million, respectively, related to research and development grants received from our collaboration and funding agreements.



Research and development expenses for the six months ended June 30, 2015 and 2014 include equity-based compensation expense of \$5.9 million and \$2.6 million, respectively. We expect our research and development expense to increase as we continue to expand our research and development of potential future products.

Table of Contents

**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 six months ended June 30, 2015.

**Contingent consideration.** Contingent consideration expenses for the six months ended June 30, 2015 and 2014, were \$4.8 million and \$4.5 million, respectively. The increase in contingent consideration expense was primarily attributable to an increase in the fair value of our contingent obligations to the former stockholders of OPKO Renal due to the time value of money. The contingent consideration liabilities at June 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 six months ended June 30, 2015 and 2014, were \$5.9 million and \$5.6 million, respectively. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the six months ended June 30, 2015 include \$0.4 million from EirGen which we acquired in May 2015. 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 six months ended June 30, 2015, we made a payment of \$25.9 million to the Office of the Chief Scientist of the Israeli Ministry of Economy (“OCS”) in connection with repayment obligations resulting from grants previously made by the OCS to OPKO Biologics to support development of hGH-CTP and the outlicense of the technology outside of Israel.

**Interest income.** Interest income for the six months ended June 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 six months ended June 30, 2015 and 2014, was \$3.6 million and \$8.2 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 six months ended June 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 June 30, 2014 to \$46.2 million as of June 30, 2015. Interest expense for the six months ended June 30, 2015 and 2014 also reflect non-cash write-offs of deferred financing costs of \$0.7 million and \$1.5 million as interest expense related to exchange or conversion of \$41.4 million and \$70.4 million principal of 2033 Senior Notes during the six months ended June 30, 2015 and 2014, respectively.

**Fair value changes of derivative instruments, net.** Fair value changes of derivative instruments, net for the six months ended June 30, 2015 and 2014, were \$(66.3) million of expense and \$0.6 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 \$(68.0) million and \$0.8 million for the six months ended June 30, 2015 and 2014, respectively. For the six months ended June 30, 2015, we observed an increase in the market price of our Common Stock which primarily resulted in the increase in the estimated fair value of our embedded derivatives in the 2033 Senior Notes. Expense for the six months ended June 30, 2015 was partially offset by income of \$1.4 million related to the change in the fair value of options and warrants to purchase additional shares of Neovasc and COCP.

**Other income and (expense), net.** Other income and (expense), net for the six months ended June 30, 2015 and 2014, were \$(0.7) million and \$4.7 million, respectively. The decrease in other income and (expense), net for the six months ended June 30, 2015 compared to the same period in 2014 is primarily due to (i) foreign currency transaction losses recognized in 2015, (ii) a \$1.3 million gain recognized in 2014 from sales of our available for sale investments and (iii) a \$2.7 million non-cash gain recognized in the 2014 as a result of the exchange of \$70.4 million principal of 2033 Senior Notes compared to a \$0.3 million loss recognized in 2015 as a result of the exchange of \$41.4 million principal of 2033 Senior Notes.

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

account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will continue to report a net loss. Loss from investments in investees was \$2.6 million and \$2.4 million for the six months ended June 30, 2015 and 2014, respectively.

Income taxes. Our income tax provision reflects the projected income tax payable in Ireland, Israel, Chile, Spain, Mexico, and Luxembourg. The increase in income tax expense was primarily attributable to taxable income recognized from the Pfizer

Table of Contents

Transaction during the six months ended June 30, 2015. We have recorded a full valuation allowance against our deferred tax assets in the U.S.

41

---

Table of Contents

## LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2015, we had cash and cash equivalents of approximately \$221.2 million. Cash provided by operations during 2015 principally reflects the \$295.0 million upfront payments recognized 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 \$30.2 million of revenue related to the \$295.0 million upfront payments during the six months ended June 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 the acquisition of EirGen of \$94.7 million. Cash provided by financing activities primarily reflects \$17.4 million received from Common Stock option and Common Stock warrant exercises. 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 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.

On June 3, 2015, we entered into an agreement and plan of merger pursuant to which we agreed to acquire Bio Reference. Under the terms of the merger agreement, which has been approved by the Boards of Directors of both companies, holders of Bio-Reference common stock will receive 2.75 shares of OPKO common stock for each share of Bio-Reference common stock. Assuming a closing price of \$16.74 per share of OPKO common stock, the transaction is valued at approximately \$1.3 billion, or \$46.04 per share of Bio-Reference common stock. We expect the transaction to be completed during the second half of 2015. Closing of the transaction is subject to approval of Bio-Reference's shareholders and other customary conditions. Although we have entered into the merger agreement, there is no guarantee that the merger will be completed. A meeting of the shareholders of Bio-Reference will be held on August 20, 2015 to vote on a proposal to approve and adopt the merger agreement and approve the merger.

On May 5, 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 New Drug Application (NDA) to the FDA for approval of oral rolapitant, an investigational neurokinin-1 receptor antagonist in development for the prevention of chemotherapy-induced nausea

and vomiting, which was accepted by the U.S. FDA in the fourth quarter 2014. 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 six months ended June 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

Table of Contents

percentage rates. TESARO assumed responsibility for clinical development and commercialization of licensed products at its expense.

If TESARO elects to develop and commercialize rolapitant 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, we are required to pay up to \$25.0 million upon the achievement of certain development milestones for rolapitant.

**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. 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 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 \$170.0 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 June 30, 2015, we have outstanding lines of credit in the aggregate amount of \$8.4 million with 8 financial institutions in Chile and Spain, of which \$5.5 million is unused. The weighted average interest rate on these lines of credit is approximately 5.7%. 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 six months ended June 30, 2015, was \$7.9 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

We expect to 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 June 30, 2015 and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements will depend on a number of factors, including our relationship with Pfizer, possible acquisitions, including the proposed merger with Bio-Reference Laboratories, Inc., 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 June 30, 2015, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining Six Months ending December 31, 2015	2016	2017	2018	2019	Thereafter	Total
Open purchase orders	\$16,911	\$676	\$676	\$485	\$199	\$298	\$19,245
Operating leases	1,673	2,728	1,774	1,346	743	1,000	9,264
2033 Senior Notes	—	—	—	—	46,200	—	46,200
Mortgages and other debts payable <sup>(1)</sup>	443	329	298	249	240	1,209	2,768
Lines of credit	8,358	—	—	—	—	—	8,358
Interest commitments	828	1,463	1,452	1,441	278	50	5,512
Total	\$28,213	\$5,196	\$4,200	\$3,521	\$47,660	\$2,557	\$91,346

<sup>(1)</sup> Excludes \$5.4 million of consolidated liabilities related to SciVac, as to which there is no recourse against us.

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 \$214.6 million.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

**Accounting estimates.** The preparation of financial statements in conformity with generally accepted accounting principles 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 sales and expenses during the reporting period. Actual results could differ from those estimates.

**Goodwill and Intangible Assets.** Goodwill and other intangible assets, including IPR&D, acquired in business combinations, licensing and other transactions was \$1.2 billion and \$1.1 billion at June 30, 2015 and December 31, 2014, respectively, representing approximately 78% and 85% of total assets, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are 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.

Table of Contents

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.

Goodwill was \$289.6 million and \$224.3 million, respectively, at June 30, 2015 and December 31, 2014. The increase in goodwill from December 31, 2014 to June 30, 2015 is due to goodwill recognized from the acquisition of EirGen in May 2015. Goodwill is tested at least annually for impairment or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, 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 \$906.7 million and \$855.8 million, including IPR&D of \$812.4 million and \$793.2 million, respectively, at June 30, 2015 and December 31, 2014. The increase in intangible assets and IPR&D from December 31, 2014 to June 30, 2015 is due to intangible assets and IPR&D recognized from the acquisition of EirGen in May 2015. Intangible assets are tested for impairment whenever events or changes in circumstances warrant a review, 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

Table of Contents

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.

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.

Revenue recognition. 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 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 certain 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 sales 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.

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.

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. 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. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of

Table of Contents

equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. We estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the "Black-Scholes Model." The Black-Scholes Model requires the use of several variables to estimate the grant-date fair value of stock options including expected term, expected volatility, expected dividends and risk-free interest rate. We perform analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model and to estimate forfeitures of equity-based awards. We are required to adjust our forfeiture estimates on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates which may have a material impact on our Condensed Consolidated Financial Statements.

**Allowance for doubtful accounts and revenue recognition.** 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 are based upon the historical patterns of products returned 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 for services is recognized on the accrual basis at the time test results are reported, which approximates when services are provided. Services are provided to certain 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 sales 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. We analyze accounts receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by management's estimate of the collectability of accounts receivable. The allowance for doubtful accounts recognized in our Condensed Consolidated Balance Sheets at June 30, 2015 and December 31, 2014 was \$2.1 million and \$1.9 million, respectively.

**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.

**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.



Table of Contents

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)," 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

## 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 \$3.0 million in foreign exchange forward contracts outstanding at June 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 June 30, 2015, we had cash and cash equivalents and marketable securities of \$221.2 million. The weighted average interest rate related to our cash and cash equivalents for the six months ended June 30, 2015 was 0%. As of June 30, 2015, the principal value of our credit lines was \$8.4 million at a weighted average interest rate of approximately 5.7%.

Our \$46.2 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 June 30, 2015.

Changes to the Company's Internal Control Over Financial Reporting

In connection with the acquisition of EirGen Pharma Limited ("EirGen") in May 2015, we began implementing standards and procedures at EirGen, 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. These changes to the Company's internal control over financial reporting that occurred during the most recent quarter ended June 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 Laboratories, Inc., four putative class action complaints challenging the merger were filed in the Superior Court of New Jersey in Bergen County. Two of the complaints were filed in the Law Division, and two of the complaints were filed in the Chancery Division. The complaints are captioned: Naik v. Bio-Reference Laboratories, Inc., et al., Docket No. C-180-15 filed in the Chancery Division on June 11, 2015; Katcher v. Bio-Reference Laboratories, Inc., et al., Docket No. C-207-15 filed in the Chancery Division on July 16, 2015; Cohen v. Bio-Reference Laboratories, Inc., et al., Docket No. L-5697-15 filed in the Law Division on June 18, 2015; and Ertan v. Bio-Reference Laboratories, Inc., et al., Docket No. L-5701-15 filed in the Law Division on June 18, 2015. 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 seek injunctive relief enjoining Bio-Reference and OPKO from consummating the merger at the agreed upon price unless and/or until the defendants cure their breaches of fiduciary duty (or, in the event the merger is consummated, rescinding the merger or awarding rescissory damages). The complaints also seek to recover costs and disbursement from the defendants, including attorneys’ fees and experts’ fees. 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 Company denies the allegations and intends to defend the actions. It is too early to assess the probability of a favorable or unfavorable outcome or the loss or range of loss, if any.

## 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. There have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2014.

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

None.

## Item 3. Defaults Upon Senior Securities

None.

## Item 4. Mine Safety Disclosures

Not Applicable.

## Item 5. Other Information

None.

Table of Contents

Item 6. Exhibits

Exhibit 2.1 <sup>+</sup>	Agreement for the Sale and Purchase of Shares in EirGen Pharma Limited, dated May 5, 2015 by and among OPKO Ireland Limited, OPKO Health, Inc. and the Sellers named therein.
Exhibit 2.2 <sup>+</sup>	Form of Additional Agreement for the Sale and Purchase of Shares in EirGen Pharma Limited, dated May 5, 2015 by and among OPKO Ireland Limited and the Sellers named therein.
Exhibit 3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation.
Exhibit 3.2 <sup>(2)</sup>	Amended and Restated By-Laws.
Exhibit 3.3 <sup>(3)</sup>	Certificate of Designation of Series D Preferred Stock.
Exhibit 4.3 <sup>(4)</sup>	Indenture, dated as of January 30, 2013, between OPKO Health, Inc. and Wells Fargo Bank, National Association.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 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 June 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 June 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 June 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

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

Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on

(1) November 12, 2013 for the Company's three month period ended September 30, 2013, and incorporated herein by reference.

(2) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008, and incorporated herein by reference.

(3) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2009, and incorporated herein by reference.

(4) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2013, and incorporated herein by reference.

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: August 5, 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 2.1 <sup>+</sup>	Agreement for the Sale and Purchase of Shares in EirGen Pharma Limited, dated May 5, 2015 by and among OPKO Ireland Limited, OPKO Health, Inc. and the Sellers named therein.
Exhibit 2.2 <sup>+</sup>	Form of Additional Agreement for the Sale and Purchase of Shares in EirGen Pharma Limited, dated May 5, 2015 by and among OPKO Ireland Limited and the Sellers named therein.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 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 June 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 June 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 June 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

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