Opko Health, Inc.
Form 10-Q
November 07, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014.

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)	75-2402409 (I.R.S. Employer Identification No.)
4400 Biscayne Blvd. Miami, FL 33137 (Address of Principal Executive Offices) (Zip Code)	
(305) 575-4100 (Registrant's Telephone Number, Including Area Code)	

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. ý 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). ý 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 x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of October 31, 2014, the registrant had 434,144,555 shares of common stock outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in "Item 1A-Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2013, 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 any 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 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.
- 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.

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- 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 Israeli 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, Brazil, 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 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.
- 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.

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- 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.
- We have reported a material weakness in our internal control over financing reporting which may cause investors and stockholders to lose confidence in our financial reporting.
- 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.

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PART I. FINANCIAL INFORMATION

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

Item 1. Financial Statements

OPKO Health, Inc. and Subsidiaries

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share and per share data)

	September 30, 2014[1]	December 31, 2013[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$118,258	$ 185,798
Accounts receivable, net	21,210	19,767
Inventory, net	16,662	18,079
Prepaid expenses and other current assets	7,018	19,084
Total current assets	163,148	242,728
Property, plant, equipment, and investment properties, net	17,036	17,027
Intangible assets, net	65,553	74,533
In-process research and development	793,214	793,341
Goodwill	224,769	226,373
Investments, net	26,849	30,653
Other assets	4,673	6,861
Total assets	$1,295,242	$ 1,391,516
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$8,841	$ 13,414
Accrued expenses	55,554	65,874
Current portion of lines of credit and notes payable	12,446	12,562
Total current liabilities	76,841	91,850
2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	114,883	211,912
Other long-term liabilities, principally contingent consideration and deferred tax liabilities	216,174	214,775
Total long-term liabilities	331,057	426,687
Total liabilities	407,898	518,537
Equity:		
Common Stock - $0.01 par value, 750,000,000 shares authorized; 432,895,788 and 414,818,195 shares issued at September 30, 2014 and December 31, 2013, respectively	4,329	4,148
Treasury Stock - 1,245,367 and 2,264,063 shares at September 30, 2014 and December 31, 2013, respectively	(4,051)	(7,362)
Additional paid-in capital	1,523,548	1,379,383
Accumulated other comprehensive income (loss)	(8,697)	3,418
Accumulated deficit	(621,872)	(503,177)
Total shareholders' equity attributable to OPKO	893,257	876,410
Noncontrolling interests	(5,913)	(3,431)

Total shareholders' equity	887,344	872,979
Total liabilities and equity	$1,295,242	$ 1,391,516

(1) As of September 30, 2014 and December 31, 2013, total assets include $7.4 million and $6.7 million, respectively, and total liabilities include $13.1 million and $10.4 million, respectively, related to SciVac Ltd ("SciVac"), previously known as SciGen (I.L.) Ltd, 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.

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2014	2013	2014	2013
Revenues:				
Products	$17,291	$16,563	$58,510	$50,708
Revenue from services	2,482	2,770	6,606	9,050
Revenue from transfer of intellectual property	—	1,308	476	16,080
Total revenues	19,773	20,641	65,592	75,838
Costs and expenses:				
Costs of revenues	11,120	11,952	36,075	36,812
Selling, general and administrative	14,010	13,572	42,697	39,875
Research and development	20,517	11,085	57,744	30,552
In process research and development	—	—	10,055	—
Contingent consideration	19,592	252	24,078	4,173
Amortization of intangible assets	2,735	2,790	8,304	8,192
Total costs and expenses	67,974	39,651	178,953	119,604
Operating loss	(48,201)	(19,010)	(113,361)	(43,766)
Other income and (expense), net:				
Interest income	402	88	450	237
Interest expense	(2,402)	(3,409)	(10,572)	(10,148)
Fair value changes of derivative instruments, net	3,305	(37,453)	3,758	(48,351)
Other income (expense), net	(2,764)	1,873	2,044	12,231
Other income and (expense), net	(1,459)	(38,901)	(4,320)	(46,031)
Loss before income taxes and investment losses	(49,660)	(57,911)	(117,681)	(89,797)
Income tax provision	(294)	(1,290)	(1,009)	(2,258)
Loss before investment losses	(49,954)	(59,201)	(118,690)	(92,055)
Loss from investments in investees	(60)	(1,600)	(2,486)	(7,861)
Net loss	(50,014)	(60,801)	(121,176)	(99,916)
Less: Net loss attributable to noncontrolling interests	(1,345)	(803)	(2,481)	(2,309)
Net loss attributable to common shareholders before preferred stock dividend	(48,669)	(59,998)	(118,695)	(97,607)
Preferred stock dividend	—	—	—	(420)
Net loss attributable to common shareholders	$(48,669)	$(59,998)	$(118,695)	$(98,027)
Loss per share, basic and diluted:				
Net loss per share	$(0.11)	$(0.17)	$(0.28)	$(0.29)
Weighted average number of common shares outstanding, basic and diluted	427,577,102	360,638,527	418,649,421	336,942,515

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

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2014	2013	2014	2013
Net loss attributable to common shareholders	$(48,669)	$(59,998)	$(118,695)	$(98,027)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation & OCI from Equity Investments	(3,169)	367	(4,781)	(1,395)
Available for sale investments:				
Change in other unrealized gains (loss), net	(5,834)	40	(6,781)	1,869
Less: reclassification adjustments for gains included in net loss, net of tax	—	—	(553)	(4,593)
Comprehensive loss	$(57,672)	$(59,591)	$(130,810)	$(102,146)

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.
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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	For the nine months ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	$(121,176)	$(99,916)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11,269	10,648
Non-cash interest on 2033 Senior Notes	4,596	4,250
Amortization of deferred financing costs	1,907	993
Losses from investments in investees	2,486	7,861
Equity-based compensation – employees and non-employees	10,088	7,411
(Recovery of) provision for bad debts	(20)	810
Provision for inventory obsolescence	773	1,529
Revenue from receipt of equity	(180)	(12,680)
Realized gain on sale of equity securities	(1,273)	(10,953)
Gain on conversion of 3.00% convertible senior notes	(2,668)	(972)
Loss on sale of property, plant and equipment	—	56
Change in fair value of derivative instruments	(3,758)	48,351
In-process research and development	10,055	—
Change in fair value of contingent consideration	24,078	4,173
Deferred income tax benefit	—	(197)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable	(4,140)	(724)
Inventory	(1,099)	952
Prepaid expenses and other current assets	3,487	(2,081)
Other assets	4,465	525
Accounts payable	(3,850)	2,303
Foreign currency measurement	1,008	(1,409)
Accrued expenses	(1,666)	9,467
Net cash used in operating activities	(65,618)	(29,603)
Cash flows from investing activities:		
Investments in investees	(589)	(13,341)
Proceeds from sale of equity securities	1,331	11,628
Acquisition of businesses, net of cash	(1,683)	20,528
Purchase of marketable securities	—	(50,027)
Maturities of short-term marketable securities	—	25,016
Proceeds from the sale of property, plant and equipment	—	631
Capital expenditures	(3,935)	(2,991)
Net cash used in investing activities	(4,876)	(8,556)
Cash flows from financing activities:		
Issuance of 2033 Senior Notes, net, including related parties	—	170,184
Payment of Series D dividends, including related parties	—	(3,015)
Proceeds from the exercise of Common Stock options and warrants	12,066	5,061
Contingent consideration payments	(6,435)	(2,539)

Borrowings on lines of credit	19,326	24,613
Repayments of lines of credit	(21,823)	(27,706)
Net cash provided by financing activities	3,134	166,598
Effect of exchange rate on cash and cash equivalents	(180)	34
Net (decrease) increase in cash and cash equivalents	(67,540)	128,473
Cash and cash equivalents at beginning of period	185,798	27,361
Cash and cash equivalents at end of period	$118,258	$155,834
SUPPLEMENTAL INFORMATION:		
Interest paid	$5,222	$3,126
Income taxes paid, net	$566	$316
RXi common stock received	$—	$12,500
Pharmsynthez common stock received	$6,264	$—
Non-cash financing:		
Shares issued upon the conversion of:		
Series D Preferred Stock	$—	$24,386
2033 Senior Notes	$95,665	$20,839
Common Stock options and warrants, surrendered in net exercise	$3,494	$815
Issuance of Common Stock to acquire:		
OPKO Biologics	$—	$586,643
OPKO Renal	$21,155	$146,902
OPKO Brazil	$—	$436
OPKO Health Europe	$—	$4,404
Arama Uruguay	$159	$—
Inspiro	$8,566	$—

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

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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.

We own established pharmaceutical platforms in Chile, Spain, Mexico, and Uruguay, which are generating revenue and which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. In addition, we have also established pharmaceutical operations in Brazil. 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 our next generation prostate cancer 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 Nesher, Israel for our API business. We lease laboratory and office space in Nashville, Tennessee and Burlingame, California for our CLIA-certified laboratory business, and we lease office space in Bannockburn, Illinois, and Markham, Ontario for our pharmaceutical business directed to chronic kidney disease ("CKD"). 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.

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 nine months ended September 30, 2014, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2014 or for 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, 2013.

Reclassifications and correction of immaterial errors. During 2013 and the first quarter of 2014, we reported payments for contingent consideration and some deferred payments as cash outflows from operating activities. Amounts paid pertaining to the initial purchase accounting contingent liabilities should have been classified as cash outflows from financing activities. Amounts paid in excess of the initial purchase accounting contingent liabilities have been classified as cash outflows from operating activities. We have corrected the amounts previously reported in our Form 10-Q for the nine months ended September 30, 2013 in conjunction with the filing of this Form10-Q and the nine months ended September 30, 2014 by reducing cash outflows from operating activities and increasing cash outflows

from financing activities by $2.5 million and $6.4 million for 2013 and 2014, respectively.

During the nine months ended September 30, 2013, we reported an $8.7 million loss on early conversion of our 2033 Senior Notes (defined in Note 6) in Other income (expense), net and expense of $41.8 million for the change in the fair value of the 2033 Senior Notes' embedded derivative in Fair value changes of derivative instruments, net in our Condensed Consolidated Statement of Operations. The loss on early conversion was overstated by $9.7 million while the change in the fair

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value of the embedded derivative was understated by the same amount. We have corrected the amounts previously reported in our Condensed Consolidated Statement of Operations in our Form 10-Q for the three and nine months ended September 30, 2013 in conjunction with the filing of this Form10-Q by increasing the expense related to the embedded derivative in the 2033 Senior Notes in Fair value changes of derivative instruments, net and reducing the early conversion of the 2033 Senior Notes in Other income (expense), net by $9.7 million. This adjustment also increased Change in fair value of derivative instruments and reduced Gain on conversion of 3.00% convertible senior notes by $9.7 million in our Condensed Consolidated Statement of Cash Flows. The adjustment only affects the components of Other income and expense in our Condensed Consolidated Statement of Operations and the components of Cash flows from operating activities in our Condensed Consolidated Statement of Cash Flows and does not affect Net loss, Net loss per share, net cash flows or income taxes for the period. See further discussion of the 2033 Senior Notes in Note 6.

Principles of consolidation. The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of OPKO Health, Inc. and of our wholly-owned subsidiaries and variable interest entities ("VIEs") 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 from those 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 September 30, 2014 and December 31, 2013, 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") and PROLOR Biotech, Inc. ("OPKO Biologics"). Goodwill, in-process research and development ("IPR&D") and other intangible assets acquired in business combinations, licensing and other transactions at September 30, 2014 and December 31, 2013 were $1.1 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. We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, currently ranging from 3 to 10 years, and review for impairment at least annually, or when events or changes in circumstances indicate

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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 from continuing operations was $8.3 million and $8.2 million for the nine months ended September 30, 2014 and 2013, 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 September 30, 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 the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts. Accordingly, the estimates of fair value presented herein may not be indicative of the amounts that could be realized in a current market exchange. Refer to Note 8.

Contingent consideration. Each period we revalue the contingent consideration obligations associated with certain 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 strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2014 and December 31, 2013, our forward contracts for inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in the fair values of our derivatives instruments, net, in our Condensed Consolidated Statement of Operations. Refer to Note 9.

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.

For the three and nine months ended September 30, 2014 and 2013, revenue from services also includes $0.2 million and $0.6 million, respectively, of revenue related to our consulting agreement with Neovasc and to revenue related to molecular diagnostics collaboration agreements. We recognize this revenue on a straight-line basis over the contractual term of the agreements.

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

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and the fair value of our undelivered obligations, if any, can be determined. If the license is considered to have standalone value but the fair value of any of the undelivered items cannot be determined, the license payments are recognized as revenue over the period of our performance for such undelivered items or services. License fees with ongoing involvement or performance obligations 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 obligation only after both the license period has commenced and we have delivered the technology.

The assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the relevant time period of research and development on a quarterly basis. For the nine months ended September 30, 2014, we recorded $0.5 million of revenue from the transfer of intellectual property. Refer to Note 5.

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 $7.7 million and $8.3 million at September 30, 2014 and December 31, 2013, respectively.

Allowance for doubtful accounts. 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 our estimate of the collectability of accounts receivable. The amount of the allowance for doubtful accounts was $1.4 million and $1.9 million at September 30, 2014 and December 31, 2013, 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 rather than 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 is subject to periodic adjustment as the underlying equity instruments vest. During the three months ended September 30, 2014 and 2013, we recorded $3.1 million and $0.4 million, respectively, of equity-based compensation expense. During the nine months ended September 30, 2014 and 2013, we recorded $10.1 million and $7.4 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.

Segment reporting. Our chief operating decision-maker ("CODM") is comprised of our executive management with the oversight of our Board of Directors. 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, Israel, Spain, Uruguay and Brazil. The diagnostics segment consists of two operating segments, our (i) pathology operations we acquired through the acquisition of

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OPKO Lab and (ii) point-of-care and molecular diagnostics operations. There are no 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. 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 loss based on their closing price per share at the end of each reporting period. Refer to Note 5.

Recent accounting pronouncements. In July 2013, the FASB issued an Accounting Standards Update ("ASU"), ASU 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. ASU 2013-11 is intended to eliminate inconsistent practices regarding the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is available to reduce the taxable income or tax payable that would result from the disallowance of a tax position. ASU 2013-11 is effective for our fiscal year beginning January 1, 2014 and subsequent interim periods. The adoption of ASU 2013-11 does not have a material effect on our Condensed Consolidated Financial Statements.

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

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

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 with early adoption permitted. We do

not believe the impact of our pending adoption of ASU 2014-15 on our condensed consolidated financial statements will be material.

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)

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were not included in the computation of net loss per share for the three and nine months ended September 30, 2014, because their inclusion would be antidilutive.

Also, a total of 29,874,112 and 35,157,966 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for the three months ended September 30, 2014 and 2013, respectively, because their inclusion would be antidilutive. A total of 29,231,538 and 31,659,650 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2014 and 2013, respectively, because their inclusion would be antidilutive.

During the three months ended September 30, 2014, 3,556,688 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 3,556,602 shares of Common Stock. Of the 3,556,688 Common Stock options exercised, 86 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

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

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NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	September 30, 2014	December 31, 2013
Accounts receivable, net		
Accounts receivable	$22,642	$21,652
Less: allowance for doubtful accounts	(1,432)	(1,885)
	$21,210	$19,767
Inventories, net		
Finished products	$11,355	$13,374
Work in-process	1,040	1,350
Raw materials	4,859	4,132
Less: inventory reserve	(592)	(777)
	$16,662	$18,079
Prepaid expenses and other current assets		
Prepaid supplies	$1,626	$945
Prepaid insurance	944	892
Pharmsynthez notes receivable	—	6,151
Other receivables	565	1,985
Taxes recoverable	1,292	3,458
Other	2,591	5,653
	$7,018	$19,084
Intangible assets, net:		
Technologies	$52,694	$51,660
Customer relationships	22,153	22,725
Product registrations	8,941	9,692
Trade names	3,509	3,669
Covenants not to compete	8,652	8,671
Other	1,131	2,519
Less: accumulated amortization	(31,527)	(24,403)
	$65,553	$74,533
Accrued expenses:		
Taxes payable	$325	$702
Deferred revenue	5,147	7,639
Clinical trials	5,524	3,342
Professional fees	766	402
Employee benefits	5,614	4,399
Deferred acquisition payments, net of discount	—	5,465
Contingent consideration	25,857	28,047
Other	12,321	15,878
	$55,554	$65,874

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(In thousands)	September 30, 2014	December 31, 2013
Other long-term liabilities:		
Contingent consideration – OPKO Renal	$35,425	$34,401
Contingent consideration – OPKO Health Europe	292	504
Contingent consideration – OPKO Diagnostics	9,237	8,340
Contingent consideration – CURNA	423	316
Mortgages and other debts payable	2,627	3,270
Deferred tax liabilities	164,512	166,435
Other, including deferred revenue	3,658	1,509
	$216,174	$214,775

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 Renal, OPKO Biologics and SciVac, a consolidated VIE. The pharmaceutical, nutraceutical and veterinary products from ALS and OPKO Health Europe do not require ongoing product renewals. 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, or Israel.

At September 30, 2014, the changes in value of the intangible assets and goodwill are primarily due to foreign currency fluctuations between the Chilean and Mexican pesos, the Euro and the Shekel against the U.S. dollar.

The following table summarizes the changes in Goodwill during the nine months ended September 30, 2014.

	2014			
(In thousands)	Balance at January 1st	Acquisitions	Foreign exchange	Balance at September 30th
Pharmaceuticals				
CURNA	$4,827	$—	$—	$4,827
OPKO Mexico	113	—	(3)	110
OPKO Chile	6,102	—	(784)	5,318
OPKO Health Europe	9,075	—	(712)	8,363
FineTech	11,698	—	—	11,698
SciVac	1,740	—	(105)	1,635
OPKO Renal	2,069	—	—	2,069
OPKO Biologics	139,784	—	—	139,784
Diagnostics				
OPKO Diagnostics	17,977	—	—	17,977
OPKO Lab	32,988	—	—	32,988
	$226,373	$—	$(1,604)	$224,769

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NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

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 based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or $8.57 per share. The transaction closed on May 22, 2014. The number of shares issued was based upon our trading price as reported by the NYSE for the ten trading days immediately preceding the execution date of the purchase agreement, or $9.00 per share.

Inspiro's Inspiromatic™ is a "smart" easy-to-use dry powder inhaler with several advantages over existing devices. We anticipate that this innovative device will play a valuable role in the improvement of therapy for asthma, chronic obstructive pulmonary disease, cystic fibrosis and other respiratory diseases. We recorded the transaction as an asset acquisition and recorded the assets and liabilities at fair value, and as a result, we recorded $10.1 million of acquired in-process research and development expenses.

OPKO Biologics acquisition

In August 2013, we acquired OPKO Biologics (formerly PROLOR) pursuant to an agreement and plan of merger dated April 23, 2013 (the "Merger Agreement") in an all-stock transaction. OPKO Biologics is an Israeli-based biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins.

Under the terms of the Merger Agreement, holders of PROLOR common stock received 0.9951 shares of our Common Stock for each share of PROLOR common stock. At closing, we delivered 63,670,805 shares of our Common Stock valued at $540.6 million based on the closing price per share of our Common Stock as reported by the NYSE on the closing date of the acquisition, or $8.49 per share. In addition, each outstanding option and warrant to purchase shares of PROLOR common stock that was outstanding and unexercised immediately prior to the closing date, whether vested or not vested, was converted into 7,889,265 options and warrants to purchase OPKO Common Stock at a fair value of $46.1 million.

Until completion of the acquisition, Dr. Phillip Frost, our Chairman and Chief Executive Officer, was PROLOR's Chairman of the Board and owned greater than 5% of its stock. Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer, and Mr. Steven Rubin, our Executive Vice President, Administration, were both directors of PROLOR and owned less than 5% of its stock.

OPKO Renal acquisition

In March 2013, we acquired OPKO Renal (formerly Cytochroma, Inc.), whose lead products, both in Phase 3 development, are Rayaldee™ (CTAP101), a vitamin D prohormone to treat secondary hyperparathyroidism in patients with stage 3 or 4 CKD and vitamin D insufficiency, and Alpharen™ (Fermagate Tablets), a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients (the "OPKO Renal Acquisition").

In connection with the OPKO Renal Acquisition, we delivered 20,517,030 of shares of our Common Stock valued at $146.9 million based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or $7.16 per share. The number of shares issued was based on the volume-weighted average price per share of our Common Stock as reported on the NYSE for the 10 trading days immediately preceding the date of the purchase agreement for the OPKO Renal Acquisition, or $4.87 per share.

In addition, the OPKO Renal Acquisition requires payments of up to an additional $190.0 million in cash or additional shares of our Common Stock, at our election, upon the achievement of certain milestones relating to development and annual revenue. As a result, we recorded $47.7 million as contingent consideration at acquisition. We evaluate the contingent consideration on an ongoing basis and the changes in the fair value are recognized in earnings until the milestones are achieved. Refer to Note 8.

Upon the achievement of a development milestone in September 2014, we delivered 2,236,210 shares of our Common Stock valued at $21.2 million based on the $9.46 closing price per share of our Common Stock on August 8, 2014, the date the milestone was achieved.

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The following table summarizes the purchase price allocation and the fair value of the net assets acquired and liabilities assumed in the acquisitions of OPKO Renal and OPKO Biologics:

(In thousands)	OPKO Renal	OPKO Biologics
Current assets [1]	$1,224	$21,500
Intangible assets:		
In-process research and development	191,530	590,200
Patents	210	—
Total intangible assets	191,740	590,200
Goodwill	2,411	139,784
Property, plant and equipment	306	1,057
Other assets	—	371
Accounts payable and accrued expenses	(1,069)	(9,866)
Deferred tax liability	—	(156,403)
Total purchase price	$194,612	$586,643

(1)Current assets include cash of $0.4 million and $20.5 million related to the OPKO Renal and OPKO Biologics acquisitions, respectively.

Goodwill from the acquisition of OPKO Biologics principally relates to the deferred tax liability generated as a result of this being a stock transaction and the assembled workforce. Goodwill from the acquisition of OPKO Renal principally relates to the assembled workforce. Goodwill is not tax deductible for income tax purposes.

Pro forma disclosure for acquisitions

The following table includes the pro forma results for the three and nine months ended September 30, 2014 and 2013 of the combined companies as though the acquisition of OPKO Biologics and OPKO Renal had been completed as of the beginning of the period presented.

	For the three months ended September 30,		For the nine months ended September 30,	
(In thousands)	2014	2013	2014	2013
Revenues	$19,773	$20,641	$65,592	$75,838
Net loss	(50,014)	(75,858)	(121,176)	130,118
Net loss attributable to common shareholders	(48,669)	(75,055)	(118,695)	(128,229)
Basic and diluted loss per share	$(0.11)	$(0.19)	$(0.28)	$(0.32)

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 each company as of the beginning of the period presented.

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Investments

The total assets, liabilities, and net losses of our equity method investees for nine months ended September 30, 2014 were $127.8 million, $18.8 million, and $31.3 million, respectively. The following table reflects our maximum exposure, accounting method, ownership interest and underlying equity in net assets of each of our unconsolidated investments as of September 30, 2014:

(Dollars in thousands, except per share prices) Investee name	Year invested	Accounting method	Ownership at September 30, 2014	Investment	Underlying equity in net assets	Closing share price at September 30, 2014 for investments available for sale
Neovasc	2011	Equity method	6 %	$ 3,798	$ 1,470	
Sevion	2014	Equity method	4 %	750	1,026	
Pharmsynthez	2013	Equity method	17 %	11,300	8,123	
Zebra	2013	VIE, equity method	19 %	2,000	837	
Cocrystal Pharma	2009	Equity method	15 %	5,476	637	
NIMS	2014	Equity method	1 %	89	—	
RXi	2013	Investment available for sale	11 %	8,159		$ 2.00
Neovasc options	2011	Investment available for sale	N/A	925		$ 5.88
ChromaDex	2012	Investment available for sale	2 %	1,320		$ 1.08
ARNO	2013	Investment available for sale	4 %	2,000		$ 1.35
Cocrystal 10 yr warrants	2014	Investment available for sale	N/A	500		$ 0.36
Plus unrealized gains on investments, options and warrants, net				387		
Less accumulated losses in investees				(9,855)		
Total carrying value of equity method investees and investments, available for sale				$ 26,849		

Cocrystal Pharma, Inc.

We previously made investments in Biozone Pharmaceuticals, Inc. (“Biozone”) and Cocrystal Discovery, Inc. (“Cocrystal”). Effective January 2, 2014, Biozone and Cocrystal completed a merger transaction pursuant to which Cocrystal was the surviving entity, and the name of the issuer was changed to Cocrystal Pharma, Inc. (“CPI”). In connection with the transaction, CPI issued to Cocrystal’s former security holders 1,000,000 shares of the CPI’s Series B Convertible Preferred Stock (“Series B”). The Series B shares: (i) automatically convert into shares of the CPI’s common stock at a rate of 205.08 shares for each share of Series B at such time that CPI has sufficient authorized capital, (ii) are entitled to vote on all matters submitted to shareholders of CPI and vote on an as converted basis and (iii) have a nominal liquidation preference. The merger was being treated as a reverse merger and recapitalization effected by a share exchange for financial accounting and reporting purposes since substantially all of the former Biozone’s operations were disposed of immediately prior to the consummation of the merger as reported on a Form 8-K filed on January 8, 2014. Cocrystal is treated as the accounting acquirer as its shareholders control CPI after the Merger. Effective January 16, 2014, we invested an additional $0.5 million in CPI as part of a $2.75 million private placement and received 1.0 million shares of common stock of CPI and 1.0 million 10-year warrants to purchase common stock of CPI exercisable at $0.50 per share.

We have determined that we and our related parties can significantly influence the success of CPI through our board representation and voting power. Accordingly, as we and our related parties have the ability to exercise significant influence over CPI’s operations, we account for our investment in CPI under the equity method.

ARNO

In October 2013, we made an investment in ARNO Therapeutics, Inc. (“ARNO”), a clinical stage company focused on the development of oncology drugs. We invested $2.0 million and received 833,333 ARNO common shares, one year warrants to purchase 833,333 ARNO common shares for $2.40 a share and five year warrants to purchase an additional 833,333 ARNO common shares for $4.00 a share. Our investment was part of a private placement by ARNO. Other investors participating in the private financing included certain related parties. Refer to Note 10. We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of ARNO and as a result, we account for ARNO as an investment, available for sale, and we record changes in the fair value of ARNO as an unrealized gain or loss in Other comprehensive loss each reporting period. We record changes in fair value of ARNO warrants in Other income (expense), net in our Condensed Consolidated Statement of Operations.

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Neovasc

In 2011, we made an investment in Neovasc, a medical technology company based in Vancouver, Canada. We invested $2.0 million and received two million Neovasc common shares, and two-year warrants to purchase an additional one million shares for $1.25 a share. During the year ended December 31, 2013 we exercised the warrants and paid $1.2 million. We accounted for the warrants as an investment, available for sale and recorded the warrants at fair value on the date of acquisition. We recorded the changes in the fair value of the warrants in Fair value changes of derivatives instruments, net in our Condensed Consolidated Statements of Operations. We have determined that our related parties can significantly influence the success of Neovasc through our board representation and voting power. Accordingly, as we and our related parties have the ability to exercise significant influence over Neovasc's operations, we account for our investment in Neovasc under the equity method.

2013 licensing agreements

An element of our growth strategy is to leverage our proprietary technology through a combination of internal development, acquisition, and external partnerships to maximize the commercial opportunities for our portfolio of proprietary pharmaceutical and diagnostic products and as such during 2013, we have entered into licensing agreements with Pharmsynthez and RXi.

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 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) 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 pays 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 royalty 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 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 receivable from Pharmsynthez for its common stock or RUR, with the embedded derivative, and the Purchase Option are 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 will 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 will record revenue in connection with the grant of rights to the technologies proportionately as the payments are received.

During the nine months ended September 30, 2014, we received $1.7 million related to the Collaboration Payments of which we recorded $0.5 million in Revenue from transfer of intellectual property and $1.2 million as an offset to Research and development expenses.

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RXi transactions

In March 2013, we completed the sale to RXi Pharmaceuticals, Inc. ("RXi") of substantially all of our assets in the field of RNA interference (the "RNAi Assets") (collectively, the "Asset Purchase Agreement"). As consideration for the RNAi Assets, at the closing of the Asset Purchase Agreement, RXi issued to us 50 million shares of its common stock (the "APA Shares").

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.

In addition to the Asset Purchase Agreement, we purchased 17,241,380 shares of RXi, for $2.5 million, as part of a $16.4 million financing for RXi, which included other related parties. Prior to the third quarter of 2014, we had determined that our ownership, along with that of our related parties, provided us the ability to exercise significant influence over RXi operations, and as such, we accounted for our investment in RXi under the equity method. During the third quarter of 2014, we determined we no longer have a significant influence over RXi. As a result, we discontinued applying the equity method of accounting for RXi and account for our investment in RXi as an available for sale investment.

Sevion Therapeutics, Inc.

We previously held a variable interest in Fabrus, Inc ("Fabrus"). Effective May 16, 2014 Senesco Technologies, Inc. ("Senesco") acquired Fabrus through a merger, with Fabrus surviving the merger as a wholly-owned subsidiary of Senesco. On September 29, 2014, Senesco changed its name to Sevion Therapeutics, Inc. ("Sevion").

Immediately prior to the effective time of the Merger, any unpaid indebtedness pursuant to all outstanding Fabrus convertible promissory notes was canceled and converted into Fabrus common stock. As a part of the Merger consideration, Sevion issued to the Fabrus investors Common Stock Purchase Warrants to purchase shares of Sevion's common stock.

OPKO's convertible promissory notes in Fabrus were canceled and converted into 80,000 shares of Sevion common stock, and OPKO's 1,159,380 shares of Fabrus common stock were replaced with 437,016 shares of Sevion common stock. OPKO received a total of 517,016 shares of Sevion common stock and warrants to purchase an additional 267,927 shares of Sevion common stock.

We have determined that we and our related parties can significantly influence the success of Sevion through our board representation and voting power. Accordingly, as we and our related parties have the ability to exercise significant influence over Sevion's operations, we account for our investment in Sevion under the equity method. Based on our review of the applicable accounting literature, we believe the transaction qualifies for carryover basis.

Investments in variable interest entities

We have determined that we hold variable interests in SciVac Ltd ("SciVac"), previously known as SciGen (I.L.) Ltd, 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.

In October 2013, we acquired 840,000 shares of Zebra Series A-2 Preferred Stock for $2.0 million. In connection with the transactions, Dr. Frost also gifted to OPKO 900,000 shares of Zebra restricted common stock which he had received as a founding member of Zebra. 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

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influence the success of Zebra through our board representation and voting power. Accordingly, as we have the ability to exercise significant influence over Zebra's operations, we account for our investment in Zebra under the equity method.

Consolidated variable interest entities

In June 2012, we entered into a share and debt purchase agreement whereby in exchange for $0.7 million we acquired shares representing a 50% stock ownership in SciVac from FDS Pharma LLP ("FDS"). SciVac is a privately-held Israeli company that produces a third-generation hepatitis B-vaccine. From November 2012 until September 30, 2014, we loaned to SciVac a combined $4.4 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 will be 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.

The following table represents the consolidated assets and non-recourse liabilities related to SciVac as of September 30, 2014 and December 31, 2013. These assets are owned by, and these liabilities are obligations of, SciVac, not us.

(In thousands)	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$57	$2
Accounts receivable, net	422	283
Inventories, net	1,650	1,696
Prepaid expenses and other current assets	599	218
Total current assets	2,728	2,199
Property, plant and equipment, net	1,828	1,374
Intangible assets, net	951	1,111
Goodwill	1,634	1,821
Other assets	255	261
Total assets	$7,396	$6,766
Liabilities		
Current liabilities:		
Accounts payable	$843	$1,136
Accrued expenses	5,481	6,498
Notes payable	4,193	1,537
Total current liabilities	10,517	9,171
Other long-term liabilities	2,568	1,240
Total liabilities	$13,085	$10,411

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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. Hsiao. 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:

(In thousands)	Embedded conversion option	2033 Senior Notes	Discount	Total
Balance at December 31, 2013	$101,087	$158,064	$(47,239)	$211,912
Amortization of debt discount	—	—	4,596	4,596
Change in fair value of embedded derivative	(3,291)	—	—	(3,291)
Conversion	(47,353)	(70,422)	19,441	(98,334)
Balance at September 30, 2014	$50,443	$87,642	$(23,202)	$114,883

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

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

The terms of the 2033 Senior Notes, include, among others: (i) rights to convert into shares of our Common Stock, including upon a fundamental change; and (ii) a coupon make-whole payment in the event of a conversion by the holders of the 2033 Senior Notes on or after February 1, 2017 but prior to February 1, 2019. We have determined that these specific terms are considered to be embedded derivatives. 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

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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 141.48 shares of Common Stock per $1,000 principal amount of 2033 Senior Notes. We recorded a $1.0 million non-cash gain related to the exchange. The gain on exchange is included within Other income (expense) on our Condensed Consolidated Statement of Operations.

In June 2014, we entered into an exchange agreement with a holder of the Company's Notes pursuant to which such holder exchanged $70.4 million in aggregate principal amount of 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. We recorded a $2.7 million non-cash gain related to the exchange. The gain on exchange is included within Other income (expense) on 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:

	September 30, 2014
Stock price	$8.51
Conversion Rate	141.4827
Conversion Price	$7.07
Maturity date	February 1, 2033
Risk-free interest rate	1.55%
Estimated stock volatility	45%
Estimated credit spread	883 basis points

The following table sets forth the fair value of the 2033 Senior Notes with and without the embedded derivatives, and the fair value of the embedded derivatives at September 30, 2014. At September 30, 2014 the principal amount of the 2033 Senior Notes was $87.6 million:

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(In thousands)	September 30, 2014
Fair value of 2033 Senior Notes:	
With the embedded derivatives	$116,597
Without the embedded derivatives	$66,154
Estimated fair value of the embedded derivatives	$50,443

Changes in certain inputs into the lattice model can have a significant impact on changes in the estimated fair value of the embedded derivatives. For example, a decrease in our estimated credit spread results in an increase in the estimated value of the embedded derivatives. Conversely, a decrease in the price of our Common Stock results in a decrease in the estimated fair value of the embedded derivatives. For the nine months ended September 30, 2014, we observed a decrease in the volatility and risk free rate which primarily resulted in a $3.3 million decrease in the estimated fair value of our embedded derivatives recorded in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations.

We have line of credit agreements with ten financial institutions as of September 30, 2014 and twelve financial institutions as of December 31, 2013 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:

(Dollars in thousands)			Balance Outstanding	
Lender	Interest rate on borrowings at September 30, 2014	Credit line capacity	September 30, 2014	December 31, 2013
Itau Bank	6.52%	$1,800	$927	$1,999
Bank of Chile	6.34%	2,250	1,386	2,079
BICE Bank	6.16%	1,700	887	516
Corp Banca	—%	—	—	(47)
BBVA Bank	5.00%	2,000	1,241	523
Penta Bank	7.34%	1,200	1,007	946
Security Bank	6.16%	640	806	1,075
BCI	—%	—	—	198
Estado Bank	5.30%	2,800	1,507	1,772
Sabadell Bank	4.50%	190	—	—
Bilbao Vizcaya Bank	4.72%	317	—	—
Santander Bank	4.50%	254	—	—
Total		$13,151	$7,761	$9,061

At September 30, 2014 and December 31, 2013, the weighted average interest rate on our lines of credit was approximately 6.0% and 7.7%, respectively.

At September 30, 2014 and December 31, 2013, we had mortgage notes and other debt related to OPKO Health Europe as follows:

(In thousands)	September 30, 2014	December 31, 2013
Current portion of notes payable	$492	$1,964
Other long-term liabilities	2,627	3,270
Total mortgage notes and other debt	$3,119	$5,234

The mortgages and other debts mature at various dates ranging from 2015 through 2024 bearing variable interest rates from 2.7% up to 6.3%. The weighted average interest rate on the mortgage notes and other debt at September 30, 2014 and December 31, 2013, was 3.3% and 3.9%, respectively. The mortgages are secured by our office space in Barcelona.

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NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

For the nine months ended September 30, 2014, changes in Accumulated other comprehensive income (loss), net of tax, were as follows:

(In thousands)	Foreign currency	Unrealized gain (loss) in Accumulated OCI	Total
Balance at December 31, 2013	$1,371	$2,047	$3,418
Other comprehensive income before reclassifications, net of tax [1]	(4,781)	(6,781)	(11,562)
Amounts reclassified from accumulated other comprehensive income, net of tax [1]	—	(553)	(553)
Net other comprehensive loss	(4,781)	(7,334)	(12,115)
Balance at September 30, 2014	$(3,410)	$(5,287)	$(8,697)

(1) Effective tax rate of 38.47%.

Amounts reclassified from Accumulated other comprehensive income (loss) for the nine months ended September 30, 2014 related to $1.3 million realized gain on the sales of certain of our investments available for sale. Of the $1.3 million gain on the sales of our investments available for sale, a $0.9 million gain was reclassified from unrealized gains in Accumulated other comprehensive income (loss) to Other income (expense), net for the nine months ended September 30, 2014. Amounts reclassified for our available for sale investments were based on the specific identification method.

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 as of September 30, 2014, classified as available for sale and carried at fair value, is as follows:

	As of September 30, 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	$660	$(4,551)	$—	$7,588
Common stock options/warrants	1,425	216	—	4,062	5,703
Total assets	$12,904	$876	$(4,551)	$4,062	$13,291

A summary of our investments as of December 31, 2013, classified as available for sale and carried at fair value is as follows:

	As of December 31, 2013				
(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	$3,376	$2,698	$—	$—	$6,074
Common stock options/warrants	925	1,041	—	4,022	5,988
Total assets	$4,301	$3,739	$—	$4,022	$12,062

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Any future fluctuation in fair value related to these instruments that is judged to be temporary, including 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.

As of September 30, 2014, 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 Cocrystal, ARNO and Sevion.

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

	Fair value measurements as of September 30, 2014			
(In thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$97,694	$—	$—	$97,694
Certificates of deposit	—	—	—	—
Common stock investments, available for sale	7,588	—	—	7,588
Common stock options/warrants	—	5,703	—	5,703
Forward contracts	—	79	—	79
Total assets	$105,282	$5,782	$—	$111,064
Liabilities:				
Embedded conversion option	$—	$—	$50,443	$50,443
Contingent consideration:				
CURNA	—	—	423	423
OPKO Diagnostics	—	—	14,493	14,493
OPKO Renal	—	—	54,720	54,720
OPKO Health Europe	—	—	1,598	1,598
Total liabilities	$—	$—	$121,677	$121,677

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	Fair value measurements as of December 31, 2013			
(In thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$168,418	$—	$—	$168,418
Certificates of deposit	—	827	—	827
Pharmsynthez Notes Receivable & Purchase Option	—	6,151	—	6,151
Common stock investments, available for sale	6,074	—	—	6,074
Common stock options/warrants	—	5,988	—	5,988
Forward contracts	—	49	—	49
Total assets	$174,492	$13,015	$—	$187,507
Liabilities:				
Embedded conversion option	$—	$—	$101,087	$101,087
Deferred acquisition payments, net of discount	—	—	5,465	5,465
Contingent consideration:				
CURNA	—	—	573	573
OPKO Diagnostics	—	—	13,776	13,776
FineTech	—	—	3,124	3,124
OPKO Renal	—	—	53,092	53,092
OPKO Health Europe	—	—	1,043	1,043
Total liabilities	$—	$—	$178,160	$178,160

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.

	September 30, 2014				
(In thousands)	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2033 Senior Notes	$64,440	$66,154	$—	$—	$66,154

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

As of September 30, 2014 and December 31, 2013, the carrying value of our other assets and liabilities approximates their fair value due to their short-term nature.

The following tables reconcile the beginning and ending balances of our Level 3 assets and liabilities as of September 30, 2014:

	September 30, 2014		
(In thousands)	Contingent consideration	Deferred acquisition payments, net of discount	Embedded conversion option
Balance at December 31, 2013	$71,620	$5,465	$101,087
Additions	—	—	—
Total losses (gains) for the period:			
Included in results of operations	24,078	(735)	(3,291)
Payments	(24,464)	(4,730)	—

Conversion	—	—	(47,353)
Balance at September 30, 2014	$71,234	$—	$50,443

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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 $1.3 million. If estimated future sales were to decrease by 10%, the contingent consideration related to OPKO Renal would decrease by $1.3 million. As of September 30, 2014, of the $71.2 million of contingent consideration, $25.9 million is recorded in Accrued expenses and $45.4 million is recorded in Other long-term liabilities. As of December 31, 2013, of the $71.6 million of contingent consideration, $28.0 million is recorded in Accrued expenses and $43.6 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.

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NOTE 9 DERIVATIVE CONTRACTS

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

(In thousands)	Balance Sheet Component	September 30, 2014	December 31, 2013
Derivative financial instruments:			
Pharmsynthez Note Receivable and Purchase Option	Prepaid expenses and other current assets	$ —	$ 6,151
Common stock options/warrants	Investments, net	$ 5,703	$ 5,988
Embedded conversion option	2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	$ 50,443	$ 101,087
Forward contracts [1]	Current portion of lines of credit and notes payable	$ 2,914	$ 1,585

[1] Gains on forward contracts are recorded in Prepaid expenses and other current assets. Losses on forward contracts are recorded in Accrued expenses.

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

To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2014 and December 31, 2013, 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 during the three and nine months ended September 30, 2014 and 2013:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	2014	2013	2014	2013
Derivative gain (loss):				
Common stock options/warrants	$651	$(692)	$388	$3,152
2033 Senior Notes	2,521	(36,603)	3,291	(51,478)
Forward contracts	133	(158)	79	(25)
Total	$3,305	$(37,453)	$3,758	$(48,351)

The outstanding forward contracts at September 30, 2014 and December 31, 2013, have been recorded at fair value, and their maturity details are as follows:

(In thousands) Days until maturity	Contract value	Fair value at September 30, 2014	Effect on income (loss)
0 to 30	$535	$568	$33
31 to 60	1,217	1,245	28
61 to 90	735	748	13
91 to 120	348	353	5
121 to 180	—	—	—
Total	$2,835	$2,914	$79

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(In thousands) Days until maturity	Contract value	Fair value at December 31, 2013	Effect on income (loss)
0 to 30	$472	$489	$17
31 to 60	561	579	18
61 to 90	503	517	14
91 to 120	—	—	—
121 to 180	—	—	—
More than 180	—	—	—
Total	$1,536	$1,585	$49

NOTE 10 RELATED PARTY TRANSACTIONS

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

In October, 2013, we paid the $170,000 filing fee to the FTC in connection with filings made by us and Dr. Hsiao, our Vice Chairman of the Board and Chief Technical Officer, under the HSR Act.

In October 2013, we entered into an agreement with ARNO pursuant to which we invested $2.0 million as part of an approximate $30 million financing. In exchange for our investment, we received 833,333 shares of ARNO common stock, one-year warrants to purchase 833,333 shares of ARNO common stock, for $2.40 a share and five-year warrants to purchase an additional 833,333 shares of ARNO common stock for $4.00 a share. Other investors participating in the private financing included Frost Gamma Investments Trust, a trust affiliated with Dr. Frost (the “Gamma Trust”), Hsu Gamma Investment, L.P., an entity affiliated with Dr. Hsiao (the “Hsu Gamma”), and other members of our board of directors and management. In connection with the transaction, ARNO agreed that for so long as we continue to hold at least 3% of the total number of outstanding shares of ARNO’s common stock on a fully-diluted basis, we will have the right to appoint a non-voting observer to attend all meetings of ARNO’s board of directors and we shall have a right of first negotiation that provides us with exclusive rights to negotiate with ARNO for a 45-day period regarding any potential strategic transactions that ARNO’s board of directors elects to pursue.

In October 2013, we made an investment in Zebra pursuant to which we acquired 840,000 shares of Zebra’s Series A-2 Preferred stock for $2.0 million. Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Zebra’s patented platform is an advanced version of a core technology developed at The Scripps Research Institute (“TSRI”) by Dr. Lerner (the “TSRI Technology”). Zebra acquired the license to the TSRI Technology from a third party who had licensed such rights from TSRI. In connection with its acquisition of rights to the TSRI Technology, Zebra agreed to make certain research funding payments to Dr. Lerner’s laboratory at TSRI to further support development of the TSRI Technology. Dr. Lerner also participated in the Series A-2 Preferred Stock financing on the same financial terms as the Company. Each of Drs. Frost and Lerner serve as members of the board of directors and scientific consultants to Zebra. After the closing, we own 23.5% of the Series A-2 Preferred stock issued and outstanding by Zebra. Each of Drs. Frost and Lerner received 900,000 restricted shares of Zebra common stock in connection with their roles as founders and scientific consultants to Zebra. Dr. Frost gifted his 900,000 shares of Zebra restricted common stock to OPKO.

Effective May 1, 2013, we entered into an agreement with Dr. Hsiao pursuant to which we have the right to utilize approximately 5,000 square feet of laboratory space in Taiwan, inclusive of any and all utility costs, taxes and building maintenance fees. In addition, Dr. Hsiao provides certain other services to us relating to government grant work in Taiwan, as well as the coordination of work flow between our U.S. and Taiwanese operations. The term of the agreement is for five years and obligates us to pay Dr. Hsiao approximately $60,000 annually.

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.

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In December 2012, we entered into a five-year lease agreement with AVI Properties, LLC (“AVI”), an entity affiliated with Dr. Jonathan Oppenheimer, who previously served as OPKO Lab’s Chief Executive Officer and currently serves as Strategic Director. The lease is for approximately 44,000 square feet of laboratory and office space in Nashville, Tennessee, where OPKO Lab is based. The lease provides for payments of approximately $18 thousand per month in the first year, increasing annually if the consumer price index exceeds 5%, plus applicable sales tax. In addition to the rent, we pay a portion of operating expenses, property taxes and parking.

During the nine months ended September 30, 2014 and the year ended December 31, 2013, FineTech recorded revenue of $0.3 million and $0.3 million, respectively, for the sale of APIs to Teva Pharmaceutical Industries, Limited (“Teva”). Dr. Frost serves as the Chairman of the Board of Directors of Teva.

In February 2012, we entered into a cooperative research funding and option agreement with TSRI to support research for the development of novel oligomeric compounds relating to our molecular diagnostics technology (the “Research Agreement”). Pursuant to the Research Agreement, we agreed to provide funding of approximately $0.9 million annually over a five year period. In conjunction with entering into the Research Agreement, we also entered into a license agreement with TSRI for technology relating to libraries of peptide tertiary amides. In addition, we entered into a second license with TSRI for technology relating to highly selective inhibitors of c-Jun-N-Terminal Kinases that may be useful for the treatment of various diseases, including Parkinson’s disease. We also entered into a research funding and option agreement to provide funding of approximately $0.2 million annually over three years to support further development of the technology. Dr. Frost served as a Trustee for TSRI until November 2012 and Dr. Lerner, a member of our Board of Directors, served as its President until December 2011.

In February 2012, we made a $1.0 million investment in ChromaDex. Other investors participating in the private financing included the Gamma Trust, Hsu Gamma, and Dr. Lerner. Following our investment, we own 1.5% of ChromaDex, the Gamma Trust owns approximately 16% of ChromaDex; Hsu Gamma owns approximately 1%; and certain of our directors own less than 1% of ChromaDex.

In February 2012, we purchased from Biozone, now known as CPI, $1.7 million of 10% secured convertible promissory notes (the “Biozone Notes”), convertible into Biozone common stock at a price equal to $0.20 per common share, which Biozone Notes are due and payable on February 24, 2014 and ten year warrants to purchase 8.5 million shares of Biozone common stock at an exercise price of $0.40 per share. In December 2013, we converted the Biozone Notes into approximately 10 million shares of Biozone common stock. In July 2012, we exercised the Biozone Warrants utilizing the net exercise feature and received approximately 7,700,000 shares of Biozone common stock. We also entered into a license agreement pursuant to which we acquired a world-wide license for the development and commercialization of products utilizing Biozone’s proprietary drug delivery technology, including a technology called QuSomes, exclusively for OPKO in the field of ophthalmology and non-exclusive for all other therapeutic fields, subject in each case to certain excluded products.

On January 2, 2014, Biozone sold substantially all of its operating assets, including its QuSomes technology, to MusclePharm Corporation (OTCQB: MSLP), an international, award-winning sports nutrition company (“Musclepharm”)
in exchange for 1.2 million shares of Musclepharm’s common stock. Effective January 2, 2014, Biozone completed a merger with Cocrystal, another entity in which we have an equity investment, to which Cocrystal was the surviving entity, and the name of the issuer was changed to Cocrystal Pharma, Inc. ("CPI"). In connection with the merger, CPI issued to Cocrystal’s former security holders 1,000,000 shares of CPI's Series B Convertible Preferred Stock (“Series B”). The Series B shares: (i) automatically convert into shares of CPI's common stock at a rate of 205.08 shares for each share of Series B at such time that CPI has sufficient authorized capital, (ii) are entitled to vote on all matters submitted to shareholders of CPI and vote on an as converted basis and (iii) have a nominal liquidation preference. 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.

In August 2011, we made an investment in Neovasc. Dr. Frost and other members of our management are shareholders of Neovasc. Prior to the investment, Dr. Frost beneficially owned approximately 36% of Neovasc,

Dr. Hsiao owned approximately 6%, and Mr. Rubin owned less than 1%. Dr. Hsiao and Mr. Rubin also serve on the board of directors of Neovasc.

In November 2010, we made an investment in Fabrus. In exchange for the investment, we acquired approximately 13% of Fabrus on a fully diluted basis. Our investment was part of a $2.1 million financing for Fabrus. In October 2013, we made loans totaling $0.1 million to Fabrus, which loans are due and payable in January, 2014 and accrue interest as a rate of 7% per annum. No payments have been made to date. On May 16, 2014, Senesco Technologies, Inc. (OTCBB: SNTI) acquired Fabrus pursuant to an agreement and plan of merger. On September 29, 2014, Senesco changed its name to Sevion Therapeutics, Inc. Dr. Frost and Steven Rubin serve on the Sevion board of directors.

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In June 2010, we entered into a cooperative research and development agreement with Academia Sinica, Taipei, Taiwan ("Academia Sinica"), for pre-clinical work for a compound against various forms of cancer. Dr. Alice Yu, a member of our Board of Directors, previously served as a Distinguished Research Fellow and Associate Director at the Genomics Research Center, Academia Sinica ("Genomics Research Center"). In connection with the Academia Sinica Agreement, we are required to pay Academia Sinica approximately $0.2 million over the term of the agreement.

Effective in September 2009, we entered into an agreement pursuant to which we invested $2.5 million in Cocrystal (now CPI) in exchange for 1,701,723 shares of Cocrystal's Convertible Series A Preferred Stock. A group of investors, led by the Frost Group LLC, which is an entity controlled by Dr. Frost, Dr. Hsiao and Mr. Rubin, (the "Cocrystal Investors"), previously invested $5.0 million in Cocrystal, and agreed to invest an additional $5.0 million payable in two equal installments in September 2009 and March 2010. As a result of an amendment to the Cocrystal Investors' agreements dated June 9, 2009, we, rather than the Cocrystal Investors, made the first installment investment ($2.5 million) on September 21, 2009. As discussed above, effective January 2014, Cocrystal completed a merger with Biozone and is now known as Cocrystal Pharma, Inc.

In June 2009, we entered into a stock purchase agreement with Sorrento, pursuant to which we invested $2.3 million in Sorrento Therapeutics, Inc. ("Sorrento"). In exchange for the investment, we acquired approximately one-third of the outstanding common shares of Sorrento and received a fully-paid, exclusive license to the Sorrento antibody library for the discovery and development of therapeutic antibodies in the field of ophthalmology. On September 21, 2009, Sorrento entered into a merger transaction with Quikbyte Software, Inc. ("Quikbyte"). Prior to the merger transaction, certain investors, including Dr. Frost and other members of our management group, made an investment in Quikbyte. Dr. Lerner serves as a consultant and scientific advisory board member to Sorrento and owns less than one percent of its shares. In December 2013, we completed the sale of our stake in Sorrento and recorded a gain on the sale of $17.2 million and other income of $2.7 million related to an early termination fee under a license agreement with Sorrento.

In November 2007, we entered into an office lease with Frost Real Estate Holdings, LLC ("Frost Holdings"), an entity affiliated with Dr. Frost. The lease was for approximately 8,300 square feet of space in an office building in Miami, Florida, where our principal executive offices are located. The lease provided for payments of approximately $18 thousand per month in the first year increasing annually to $24 thousand per month in the fifth year, plus applicable sales tax. The rent was inclusive of operating expenses, property taxes and parking. The rent for the first year was reduced to reflect a $30 thousand credit for the costs of tenant improvements. In August 2012, we entered into a six-month extension on the same terms as the 2007 expiring lease and in February 2013, we agreed to extend the lease on a month-to-month basis. Effective January 1, 2014, we entered into a new lease agreement with Frost Holdings. The lease, as amended on July 28, 2014, was for approximately 22,000 square feet of space. The lease provides for payments of approximately $57 thousand per month in the first year increasing annually to $65 thousand per month in the fifth year, plus applicable sales tax. As in the original lease, the rent is inclusive of operating expenses, property taxes and parking. The rent will be reduced by $216 thousand for the cost of tenant improvements, of which approximately $113 thousand and $103 thousand will be credited against rent payments in 2014 and 2015, respectively.

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost 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. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive; nor do we pay for any other fixed or variable operating costs of the airplane. For the three and nine months ended September 30, 2014, we reimbursed Dr. Frost approximately $110 thousand and $118 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2013, we reimbursed Dr. Frost approximately $19 thousand and $37 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 September

30, 2014, we recorded $71.2 million as contingent consideration, with $25.9 million recorded within Accrued expenses and $45.4 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

On April 29, 2013, we were named in a putative class action filed in the Eighth Judicial District Court in and for Clark County, Nevada against PROLOR (now known as OPKO Biologics), the members of the PROLOR Board of Directors, individually (including Drs. Frost and Hsiao and Steven Rubin), and the Company. From May 1, 2013 through May 6, 2013, we were named in an additional five putative class actions suits filed in the Eighth Judicial District Court in and for Clark County, Nevada against the same defendants. On July 17, 2013, these suits were consolidated, for all purposes, into an amended class action complaint. The lawsuit is brought by purported holders of PROLOR’s common stock, both individually

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and on behalf of a putative class of PROLOR's stockholders, asserting claims that PROLOR's Board of Directors breached its fiduciary duties in connection with the merger by purportedly failing to maximize stockholder value, that PROLOR and its Board of Directors failed to disclose material information to PROLOR's stockholders, and that the Company aided and abetted the alleged breaches of fiduciary duty. The lawsuit seeks monetary damages, including increased consideration to PROLOR's stockholders, equitable relief, including, among other things, rescission of the Merger Agreement along with recissionary damages, and an award of all costs, including reasonable attorneys' fees. On May 5, 2014, the court issued an order dismissing all claims as to all defendants without prejudice, and the plaintiffs did not appeal the dismissal or file an amended complaint.

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

On or around October 21, 2014, we received a Civil Investigative Demand ("Demand") from the United States 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.

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, or results of operations.

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.

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NOTE 12 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, Israel, Spain, Brazil, and Uruguay. The diagnostics segment 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 inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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

	For the three months ended September 30,		For the nine months ended September 30,	
(In thousands)	2014	2013	2014	2013
Product revenues:				
Pharmaceuticals	$17,291	$16,563	$58,510	$50,708
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$17,291	$16,563	$58,510	$50,708
Revenue from services:				
Pharmaceuticals	$—	$—	$—	$—
Diagnostics	2,422	2,710	6,426	8,870
Corporate	60	60	180	180
	$2,482	$2,770	$6,606	$9,050
Revenue from transfer of intellectual property:				
Pharmaceuticals	$—	$913	$285	$14,720
Diagnostics	—	395	191	1,360
Corporate	—	—	—	—
	$—	$1,308	$476	$16,080
Operating (loss) income:				
Pharmaceuticals	$(34,480)	$(11,126)	$(71,421)	$(7,171)
Diagnostics	(6,738)	(399)	(20,621)	(16,783)
Corporate	(6,384)	(6,606)	(19,557)	(17,393)
Less: Operating loss attributable to noncontrolling interests	(599)	(879)	(1,762)	(2,419)
	$(48,201)	$(19,010)	$(113,361)	$(43,766)
Depreciation and amortization:				
Pharmaceuticals	$1,925	$2,020	$6,061	$5,417
Diagnostics	1,729	1,717	5,136	5,110
Corporate	24	31	72	121
	$3,678	$3,768	$11,269	$10,648
Revenues:				
United States	$2,482	$4,078	$7,082	$25,130
Chile	7,622	7,993	22,758	24,216
Spain	4,414	4,026	16,230	13,503
Israel	3,710	3,099	14,563	9,666
Mexico	1,528	1,445	4,905	3,323
Other	17	—	54	—
	$19,773	$20,641	$65,592	$75,838

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(In thousands)	September 30, 2014	December 31, 2013
Assets:		
Pharmaceuticals	$1,061,168	$1,065,033
Diagnostics	109,048	116,944
Corporate	125,026	209,539
	$1,295,242	$1,391,516
Goodwill:		
Pharmaceuticals	$173,804	$175,408
Diagnostics	50,965	50,965
Corporate	—	—
	$224,769	$226,373

During the three months ended September 30, 2014, no customer represented more than 10% of our total revenue and during the nine months ended September 30, 2014, one customer represented 13% of our total revenue. During the three and nine months ended September 30, 2013, no customer represented more than 10% of our total revenue. As of September 30, 2014, no customer represented more than 10% of our accounts receivable balance. As of December 31, 2013, no customer represented more than 10% of our accounts receivable balance.

NOTE 13 SUBSEQUENT EVENTS

We have reviewed all subsequent events and transactions that occurred after the date of our September 30, 2014 condensed consolidated balance sheet date, through the time of filing this Quarterly Report on Form 10-Q.

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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, 2013 (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, 2013, 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, molecular diagnostics 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, 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 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™.

RECENT DEVELOPMENTS

In January 2014, we completed the acquisition of Laboratorio Arama de Uruguay Limitada ("Arama Uruguay"), a privately-owned company located in Montevideo, Uruguay. Arama Uruguay will expand our presence in Latin America and complement the business activities of our operations in Chile and Mexico, as well as permit commercialization of OPKO's products currently commercialized and those in development.

In March 2014, we began selling the 4Kscore test domestically through our CLIA-accredited laboratory in Nashville, TN and in September 2014, we commercially launched the 4Kscore test in Europe through our wholly owned subsidiary in Spain. The laboratory developed test is designed to enhance the prostate biopsy decision making process that, in the United States, leads to approximately 1 million biopsies being performed annually, with 80% of the results indicating no cancer or a low-grade cancer. We believe the 4Kscore test will help to reduce unnecessary prostate biopsies by providing information on the risk (probability) of having high-grade prostate cancer. The test was developed by OPKO Lab and tested in collaboration with 26 urology centers across the United States from October 2013 to March 2014. Results showed that the 4Kscore test was highly accurate for predicting the presence of high-grade cancer (Gleason score 7 or higher) prior to prostate biopsy. The full data from the blinded, prospective U.S. clinical validation study was presented at the AUA Annual Meeting in Orlando, FL on May 18th at Plenary Session.

In May 2014, we acquired Inspiro Medical Ltd. ("Inspiro"), an Israeli medical device company developing a new platform to deliver small molecule drugs such as corticosteroids and beta agonists or larger molecules to treat respiratory diseases. Inspiro's Inspiromatic™ is a "smart" easy-to-use dry powder inhaler with several advantages over existing devices. We anticipate that this innovative device will play a valuable role in the improvement of therapy for asthma, chronic obstructive pulmonary disease, cystic fibrosis and other respiratory diseases.

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 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 June 2014, we announced positive interim 6 month results from our Phase 2 dose-finding study evaluating the safety and efficacy of hGH-CTP, a long-acting form of human growth hormone, to treat growth hormone deficiency in children. All three hGH-CTP once-weekly doses resulted in strong catch-up growth during the six month treatment period, with annualized increases in height of more than 12 cm. The results indicated excellent dose dependent pharmacokinetic and pharmacodynamic profiles. In June 2014, we initiated a multi-center worldwide pivotal Phase 3 clinical trial in adults for hGH-CTP.

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In the third quarter of 2014, we announced successful top-line results from two pivotal phase 3 trials of Rayaldee™. These trials were two identical randomized, double-blind, placebo-controlled, multi-site studies intended to establish the safety and efficacy of Rayaldee as a new treatment for secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency. Patients completing the two pivotal trials are being treated, at their election, for an additional six months with Rayaldee during an open-label extension study. A New Drug Application submission to the U.S. FDA is planned for the end of 2014.

In August 2014, we announced the submission of an Investigational New Drug Application to the U.S. FDA to evaluate Rayaldee as an adjunctive therapy for the prevention of skeletal-related events in patients with bone metastases undergoing anti-resorptive therapy.

RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2014 AND 2013

Revenues. Revenues for the three months ended September 30, 2014, were $19.8 million, compared to $20.6 million for the three months ended September 30, 2013. During the three months ended September 30, 2014, pharmaceutical product revenue increased $0.7 million to $17.3 million. The increase in pharmaceutical product revenue was the result of increased demand for one product at our active pharmaceutical ingredient subsidiary FineTech resulting in an increase of $0.5 million. Offsetting the increase in pharmaceutical product revenue was decreased service revenue at OPKO Lab and revenue from the transfer of intellectual property of $0.3 million and $1.3 million, respectively. The three months ended September 30, 2013 included revenue related to our Pharmsynthez transaction which we did not have during the three months ended September 30, 2014. In addition, revenue from services decreased at OPKO Lab principally as a result of decreased specimen volume and decreased reimbursement from government payors in comparison to the three months ended September 30, 2013. Partially offsetting those decreases were sales of our 4Kscore test and price increases for certain of our laboratory services to non-government payors.

Costs of revenue. Costs of revenue for the three months ended September 30, 2014, were $11.1 million, compared to $12.0 million for the three months ended September 30, 2013. Costs of revenue for the three months ended September 30, 2014 decreased principally due to lower service cost of revenue as a result of decreased specimen volume at OPKO Lab, and to decreased costs of revenues at OPKO Chile primarily due to foreign currency fluctuations and lower inventory obsolescence charges for the three months ended September 30, 2014 compared to the same period in 2013.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2014 were $14.0 million, compared to $13.6 million for the three months ended September 30, 2013. The increase in selling, general and administrative expenses for the three months ended September 30, 2014 was a result of increased sales and marketing activities related to the launch of the 4Kscore test in the U.S. in March 2014 and Europe in September 2014, as well as increased personnel expenses. Partially offsetting the increase were decreased professional fees as the 2013 period included professional fees related to the acquisition of OPKO Biologics in August 2013. Selling, general and administrative expenses during the three months ended September 30, 2014 and the three months ended September 30, 2013, include equity-based compensation expense of $2.3 million and $2.1 million, respectively.

Research and development expenses. Research and development expenses for the three months ended September 30, 2014 and three months ended September 30, 2013, were $20.5 million and $11.1 million, respectively. Research and development costs include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and PMA's 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.

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

	For the three months ended September 30,	
	2014	2013
External expenses:		
Phase 3 clinical trials	$3,898	$3,137
Earlier-stage programs	7,244	1,845
Research and development employee-related expenses	4,800	1,748
Other unallocated internal research and development expenses	5,188	5,195
Third-party grants and funding from collaboration agreements	(613)	(840)
Total research and development expenses	$20,517	$11,085

The increase in research and development expenses during the three months ended September 30, 2014, as compared to the three months ended September 30, 2013, principally resulted from the development programs we acquired from OPKO Biologics, including clinical manufacturing costs, our ongoing phase 3 clinical trial in adults and pediatric Phase 2 clinical trial for hGH-CTP, a long acting human growth hormone, and the phase 3 clinical trials for Rayaldee (CTAP101) which were completed in the third quarter of 2014. In addition, during the three months ended September 30, 2014 and three months ended September 30, 2013, we recorded, as an offset to research and development expenses, $0.6 million and $0.8 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the three months ended September 30, 2014 and three months ended September 30, 2013 include equity-based compensation expense of $0.7 million and $(1.7) million, respectively. The three months ended September 30, 2013 includes an offset to research and development expenses of $2.7 million related to the correction of an error related to equity awards granted to non-employees with performance based vesting.

Contingent consideration. Contingent consideration expenses for the three months ended September 30, 2014 and three months ended September 30, 2013, were $19.6 million and $0.3 million, respectively. The increase in contingent consideration expense was attributable to OPKO Renal resulting from an increase in the fair value of our contingent obligations to OPKO Renal due to changes in assumptions regarding probabilities of successful achievement of future milestones driven by the two successful phase 3 trials of Rayaldee in the third quarter of 2014. The contingent consideration liabilities at September 30, 2014 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $2.7 million and $2.8 million, respectively, for the three months ended September 30, 2014 and 2013. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. The acquisitions of OPKO Renal and OPKO Biologics resulted in acquiring IPR&D which will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, 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.

Other income and (expense), net. Other income and (expense), net for the three months ended September 30, 2014 and 2013 was $(1.5) million and $(38.9) million, respectively. During the three months ended September 30, 2014, we recorded $2.5 million non-cash other income related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes. Other income and (expense), net, for the three months ended September 30, 2014, also included $2.4 million of interest expense principally related to interest incurred on the 2033 Senior Notes and by the amortization of related deferred financing costs and $1.3 million of expense from our consolidated variable interest entity SciVac. For the three months ended September 30, 2013, we recorded a $36.6 million non-cash other expense related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes and a $1.0 million gain on early partial conversion of the 2033 Senior Notes. Other income and (expense), net, for the three months ended September 30, 2013, also included $3.4 million of interest expense 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 September 30, 2014 compared to the same period in 2014 is due to a decrease in the principal amount of 2033 Senior Notes outstanding from $158.1 million at September 30, 2013 to $87.6 million as of September 30, 2014. 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.

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. We account for these

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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 $0.1 million and $1.6 million for the three months ended September 30, 2014 and 2013, respectively. The decrease in loss from investments in investees is primarily due to decreased losses from our portfolio companies, principally RXi. During the third quarter of 2014, we began accounting for RXi as an available for sale investment with changes in fair value reported in other comprehensive income (loss) due to our decreased ownership percentage during the quarter. Previously, we accounted for RXi under the equity method of accounting.

Income taxes. Our income tax provision reflects the projected income tax payable in Israel, Chile, Spain, Mexico and Canada. We have recorded a full valuation allowance against our deferred tax assets in the U.S.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2014 AND 2013

Revenues. Revenues for the nine months ended September 30, 2014, were $65.6 million, compared to $75.8 million for the nine months ended September 30, 2013. The decrease in revenue principally reflects non-recurring, non–cash revenue related to the transfer of technology under the RXi Asset Purchase Agreement of $12.5 million in the first nine months of 2013. Partially offsetting the non-cash revenue decrease was a 15% increase in pharmaceutical product revenue principally from FineTech of $4.4 million during the nine months ended September 30, 2014. In addition, pharmaceutical product revenue from our Spanish and Mexican operations increased by $2.7 million and $2.1 million, respectively, during the nine months ended September 30, 2014, primarily due to increased sales by OPKO Health Europe throughout Europe and an increase in government tenders in Mexico. Revenue related to OPKO Lab decreased $2.4 million during the nine months ended September 30, 2014, compared to the nine months ended September 30, 2013, primarily related to decreased reimbursement rates from government payors and decreased specimen volume, partially offset by revenue after the launch of our 4Kscore test and a price increase to non-government payors initiated in June 2014.

Costs of revenue. Costs of revenue for the nine months ended September 30, 2014, were $36.1 million, compared to $36.8 million for the nine months ended September 30, 2013. Costs of revenue for the nine months ended September 30, 2014 decreased principally due to decreased revenue at OPKO Lab, which has a lower margin than pharmaceutical product sales. This was partially offset by increased pharmaceutical product sales.

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2014 were $42.7 million, compared to $39.9 million for the nine months ended September 30, 2013. The increase in selling, general and administrative expenses for the nine months ended September 30, 2014 was a result of increased personnel expenses including equity based compensation as well as sales and marketing activities related to the launch of our 4Kscore test in the U.S. in March 2014 and Europe in September 2014. These increases were partially offset by decreased professional fees as the 2013 period included expenses related to the acquisitions of OPKO Renal and OPKO Biologics. Selling, general and administrative expenses during the nine months ended September 30, 2014 and the nine months ended September 30, 2013, include equity-based compensation expense of $6.7 million and $4.7 million, respectively.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2014 were $57.7 million, compared to $30.6 million for the nine months ended September 30, 2013. 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 for diagnostics tests, if any. Internal expenses include 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.

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

	For the nine months ended September 30,	
	2014	2013
External expenses:		
Phase 3 clinical trials	$10,344	$6,059
Earlier-stage programs	17,006	2,002
Research and development employee-related expenses	15,778	11,718
Other unallocated internal research and development expenses	16,029	12,597
Third-party grants and funding from collaboration agreements	(1,413)	(1,824)
Total research and development expenses	$57,744	$30,552

The increase in research and development expenses during the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013, principally resulted from an increase related to research and development expenses incurred by OPKO Renal related to the external costs of Phase 3 clinical trials for Rayaldee (CTAP101) which were completed in the third quarter of 2014 and $23.9 million of costs related to OPKO Biologics which was acquired in August 2013. OPKO Biologics principally incurred development and clinical manufacturing costs related to hGH-CTP, a long acting human growth hormone. Research and development expenses for the nine months ended September 30, 2014 and nine months ended September 30, 2013 include equity-based compensation expense of $3.3 million and $2.7 million, respectively. The nine months ended September 30, 2013 includes an offset to research and development expenses of $2.7 million related to the correction of an error related to equity awards granted to non-employees with performance based vesting.

Contingent consideration. Contingent consideration expenses for the nine months ended September 30, 2014 and nine months ended September 30, 2013, were $24.1 million and $4.2 million, respectively. The increase in contingent consideration expense was attributable to OPKO Renal resulting from an increase in the fair value of our contingent obligations to OPKO Renal due to changes in assumptions regarding probabilities of successful achievement of future milestones driven by the two successful phase 3 trials of Rayaldee in the third quarter of 2014. The contingent consideration liabilities at September 30, 2014 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $8.3 million and $8.2 million, respectively, for the nine months ended September 30, 2014 and 2013. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. The acquisitions of OPKO Renal and OPKO Biologics resulted in principally acquiring IPR&D assets which will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, the IPR&D asset will then be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. The increase in amortization reflects the amortization of the finite-lived intangible assets acquired from OPKO Renal.

Write-off of Acquired In-Process Research and Development. In May 2014, we acquired Inspiro, a privately held company that is developing the Inspiromatic, a “smart” easy-to-use dry powder inhaler with several advantages over existing devices in a stock for stock transaction. We recorded the transaction as an asset acquisition and recorded the assets and liabilities at fair value, and as a result, we recorded $10.1 million of acquired in-process research and development expense. We did not have any such activity during the nine months ended September 30, 2013.

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. The Inspiromatic has not reached a stage of technological feasibility and has no alternative future use.

Other income and (expense), net. Other income and (expense), net for the nine months ended September 30, 2014 and 2013 was $(4.3) million and $(46.0) million, respectively. During the nine months ended September 30, 2014, we recorded $3.3 million non-cash other income, net, related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes, and a $2.7 million gain as the result of the exchange of $70.4 million principal of 2033 Senior Notes in June 2014. Other income and (expense), net, for the nine months ended September 30, 2014, also included $10.6 million of interest expense principally related to interest incurred on the 2033 Senior Notes and by the amortization of related deferred financing costs. For the nine months ended September 30, 2013, we recorded a $51.5 million non-cash charge, net, related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes, partially offset by a $1.0 million gain on early partial conversion of the 2033 Senior Notes and a gain of $10.8 million on the sale of certain of our investments available for sale. Other income

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and (expense), net, for the nine months ended September 30, 2013, also included $10.1 million of interest expense primarily related to interest expense incurred by the 2033 Senior Notes and by the amortization of related deferred financing costs. The increase in interest expense for the nine months ended September 30, 2014 compared to the same period in 2013 is due to a non-cash write-off of deferred financing costs of $1.5 million as interest expense related to exchange of $70.4 million principal of 2033 Senior Notes in June 2014.

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. 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 $2.5 million and $7.9 million for the nine months ended September 30, 2014 and 2013, respectively. The decrease in loss from investments in investees is primarily due to decreased losses at RXi and Pharmsynthez.

Income taxes. Our income tax provision reflects the projected income tax payable in Israel, Chile, Spain, Mexico and Canada. We have recorded a full valuation allowance against our deferred tax assets in the U.S.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2014, we had cash and cash equivalents of approximately $118.3 million. Cash used in operations during 2014 principally reflects 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, OPKO Diagnostics, OPKO Lab, SciVac, OPKO Mexico, OPKO Chile and OPKO Brazil, partially offset by cash provided from our operations at FineTech and OPKO Health Europe. Cash used in investing activities includes net cash used in business combinations of $1.7 million, capital expenditures of $3.9 million and investments in investees of $0.6 million, which was partially offset by the disposition of investments available for sale. Cash provided by financing activities primarily reflects $12.1 million received from Common Stock option and Common Stock warrant exercises, which was partially offset by $6.4 million of deferred and contingent consideration payments related to our acquisitions of OPKO Health Europe and Finetech. In addition to cash contingent consideration payments made during the nine months ended September 30, 2014, we also satisfied a $20.0 million contingent payment to the former owners of OPKO Renal through the issuance of 2,236,210 shares of our common stock in September 2014. 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 and credit facilities available to us.

In September 2014, our licensee, TESARO, Inc. submitted a New Drug Application (NDA) to the U.S. FDA for approval of oral rolapitant, an investigational neurokinin-1 receptor antagonist in development for the prevention of chemotherapy-induced nausea and vomiting. Under the terms of our agreement with TESARO, TESARO will pay us a milestone payment of $5.0 million upon acceptance by the U.S. FDA of a NDA. TESARO's NDA was accepted by the U.S. FDA in the fourth quarter 2014. We will also receive double digit tiered-royalties on sales of rolapitant. In addition, TESARO and OPKO will share future profits from the commercialization of rolapitant in Japan, and we will have an option to market the products in Latin America.

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 Notes for 10,974,431 shares of the Company's Common stock, par value $0.01 per share and approximately $0.8 million in cash representing accrued interest through the date of completion of the exchange. We recorded a $2.7 million non-cash gain related to the exchange. The gain on exchange is included within Other income (expense), net on our Condensed Consolidated Statement of Operations.

In May 2014, we acquired 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 an aggregate of $10.1 million, of which $1.5 million was paid in cash and $8.6 million was paid in 999,556 shares of the Company's Common Stock based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or $8.57 per share. The number of shares issued was based upon our trading price as reported by the NYSE for the ten trading days immediately preceding the execution date of the purchase agreement, or $9.00 per share.

In April 2013, we invested $9.6 million in exchange for approximately 13.6 million shares of Pharmsynthez common stock. Concurrent with our investment, Pharmsynthez also agreed, at its option, to issue approximately 12.0 million shares of its common stock or pay us Russian Rubles (“RUR”) 265.0 million ($8.1 million) on or before December 31, 2013. We had a right to purchase additional shares in Pharmsynthez at a fixed price if Pharmsynthez paid us in cash rather than the 12.0 million

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shares of Pharmsynthez common stock. Pharmsynthez delivered approximately 12.0 million shares of its common stock to us in January 2014.

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.

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 141.48 shares of Common Stock per $1,000 principal amount of 2033 Senior Notes. We recorded a $1.0 million non-cash gain related to the exchange. The gain on exchange is included within Other income (expense), net on our Condensed Consolidated Statement of Operations.

In August 2012, we entered into a stock purchase agreement pursuant to which we acquired all of the outstanding stock of OPKO Health Europe (previously Farmadiet Group Holding, S.L.), a Spanish company engaged in the development, manufacture, marketing, and sale of pharmaceutical, nutraceutical, and veterinary products in Europe (the “OPKO Health Europe Transaction”). In connection with the OPKO Health Europe Transaction, we agreed to pay an aggregate purchase price of €13.5 million (approximately $16.0 million), of which (i) 50% ($8.4 million) was paid in cash at closing, and (ii) 50% (the “Deferred Payments”) was paid, at our option, in cash or shares of our Common Stock as follows: (x) 25% to be paid on the first anniversary of the closing date; and (y) 25% to be paid 18 months after the closing date. In the event we elected to pay the Deferred Payments in shares of our Common Stock, the number of shares issuable shall be calculated using the average closing price per share of our Common Stock as reported on the NYSE for the 10 trading days immediately preceding the applicable payment date. On August 2, 2013, we issued 585,703 shares of our Common Stock, in accordance with the first Deferred Payment. The number of shares issued was based on the average closing price per share of our Common Stock as reported on the NYSE for the 10 trading days up to and including August 1, 2013, or $7.61 per share. On February 14, 2014, we delivered approximately €3.4 million in cash in accordance with the second Deferred Payment.

In connection with our acquisitions of CURNA, OPKO Diagnostics, FineTech and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events, including minimum cash payments of $5.0 million to the former stockholder of FineTech upon the achievement of certain sales milestones, of which $2.7 million and $3.2 million were paid in March 2013 and 2014, respectively; 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 $190.0 million in either shares of our Common Stock or cash, at our option subject to the achievement of certain milestones, to the former shareholders of OPKO Renal. In September 2014, we satisfied a $20.0 million contingent payment to the former owners of OPKO Renal through the issuance of 2,236,210 shares of our common stock.

As of September 30, 2014, we have outstanding lines of credit in the aggregate amount of $7.8 million with 10 financial institutions in Chile and Spain, of which $5.4 million is unused. The weighted average interest rate on these lines of credit is approximately 6.0%. These lines of credit are short-term and are generally due within three months. These lines of credit are used primarily as a source of working capital for inventory purchases. The highest balance at any time during the nine months ended September 30, 2014, was $7.8 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 September 30, 2014 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 possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in

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preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions.

The following table provides information as of September 30, 2014, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining Three Months ending December 31, 2014	2015	2016	2017	2018	2019	Thereafter	Total
Open purchase orders	$7,417	$29	$—	$—	$—	$—	$—	$7,446
Operating leases	977	2,345	2,074	1,418	1,127	661	3,437	12,039
2033 Senior Notes	—	—	—	—	—	—	114,883	114,883
Deferred payments	—	—	—	—	—	—	—	—
Mortgages and other debts payable [1]	122	461	346	311	258	251	1,371	3,120
Lines of credit	7,761	—	—	—	—	—	—	7,761
Interest commitments	819	2,729	2,713	2,702	2,691	272	57	11,983
Total	$17,096	$5,564	$5,133	$4,431	$4,076	$1,184	$119,748	$157,232

[1] Excludes $4.2 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, new drug application approvals by the U.S. 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 $213.5 million.

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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 $1.1 billion at both September 30, 2014 and December 31, 2013, representing approximately 84% and 79% 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.
- 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 $224.8 million and $226.4 million, respectively, at September 30, 2014 and December 31, 2013. 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

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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 units whose fair value was calculated for purposes of the 2013 impairment testing is derived from the valuation techniques described above, incorporating the related projections and assumptions. An indication of possible impairment occurs when the estimated fair value of the reporting unit is below the carrying value of its equity. The estimated fair value for these reporting units exceeded their related carrying value as of October 1, 2013. As a result, no goodwill impairment was recorded.

The estimated fair value of the reporting unit is highly sensitive to changes in these projections and assumptions; therefore, in some instances changes in these assumptions could impact whether the fair value of a reporting unit is greater than its carrying value. For example, an increase in the discount rate and decline in the projected cumulative cash flow of a reporting unit could cause the fair value of certain reporting units to be below its carrying value. We perform sensitivity analyses around these assumptions in order to assess the reasonableness of the assumptions and the resulting estimated fair values. 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. The excess of fair value over carrying value for our reporting units as of October 1, 2013, was 70%. 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 $858.8 million and $867.9 million, including IPR&D of $793.2 million and $793.3 million, respectively, at September 30, 2014 and December 31, 2013. 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 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.

Equity-based compensation. We recognize equity based compensation as an expense in our financial statements and that cost is measured at the fair value of the awards and expensed over their vesting period. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. 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" and allocate the resulting compensation expense over the corresponding requisite service period associated with each grant. 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

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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 September 30, 2014 and December 31, 2013 was $1.4 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. At September 30, 2014 and December 31, 2013, there were no pre-launch inventories.

RECENT ACCOUNTING PRONOUNCEMENTS

In July 2013, the FASB issued an Accounting Standards Update ("ASU"), ASU 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. ASU 2013-11 is intended to eliminate inconsistent practices regarding the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is available to reduce the taxable income or tax payable that would result from the disallowance of a tax position. ASU 2013-11 is effective for our fiscal year beginning January 1, 2014 and subsequent interim periods. The adoption of ASU 2013-11 does not have a material effect on our Condensed Consolidated Financial Statements.

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.

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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.

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 – 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 at maturity, 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 $2.9 million in foreign exchange forward contracts outstanding at September 30, 2014, primarily to hedge Chilean-based operating cash flows against U.S. dollars. If Chilean Pesos were to strengthen 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 market risk relates to our cash and investments and to our borrowings. We maintain an investment portfolio of money market funds. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment.

At September 30, 2014, we had cash and cash equivalents and marketable securities of $118.3 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2014 was 0%. As of September 30, 2014, the principal value of our credit lines was $7.8 million at a weighted average interest rate of approximately 6.0% for the three months then ended.

Our $87.6 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.

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Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of 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 SEC's rules and forms. 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 not effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q due to a material weakness existing in our internal controls over financial reporting as of December 31, 2013 (described below), which has not been fully remediated as of the end of the period covered by this Quarterly Report on Form 10-Q.

In connection with the preparation of our financial statements for the year ended December 31, 2013, we concluded there was a material weakness in the design and operating effectiveness of our internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness in internal control over financial reporting relates to the Company's financial statement close process at its Chilean subsidiary due to the lack of sufficient controls to assure that inventory and accounts receivable balances are recorded correctly in accordance with U.S. generally accepted accounting principles.

With the oversight of senior management and our audit committee, we have taken steps, and plan to take additional measures, to remediate the underlying causes of the material weakness, primarily through the development and implementation of formal policies, improved processes and documented procedures, as well as the hiring of additional finance personnel.

As part of these ongoing efforts, we have documented and are in the process of testing our internal control over financial reporting in order to report on the effectiveness of our internal controls as of December 31, 2014. We have continued to expend significant internal and external resources in this effort. In particular, we have continued to work with a global accounting firm in preparation for reporting on the effectiveness of our internal controls, and we have engaged an additional accounting firm to assist our local management team to address the underlying cause of the material weakness primarily through the development and implementation of additional policies, improved processes and documented procedures, as well as the hiring of additional finance personnel. However, we can provide no assurance at this time that management will be able to report that our internal control over financial reporting is effective as of December 31, 2014, or that our registered independent public accounting firm will be able to attest that such internal controls are effective.

Notwithstanding the identified material weakness, management believes the Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

Changes to the Company's Internal Control Over Financial Reporting

In addition to the changes above, in connection with the OPKO Renal and OPKO Biologics acquisitions in March 2013 and August 2013, respectively, we began implementing standards and procedures at OPKO Renal and OPKO Biologics, including upgrading and establishing controls over accounting systems, and adding employees and consultants who are trained and experienced in 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 OPKO Renal and OPKO Biologics. These changes to the Company's internal control over financial reporting that occurred during the

Company’s second and third fiscal quarter of 2014 have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On or around October 21, 2014, we received a Civil Investigative Demand (“Demand”) from the United States 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.

Item 1A. Risk Factors

None.

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

In March 2013, OPKO Health, Inc. (the "Company") acquired OPKO Renal (the "OPKO Renal Acquisition"). The OPKO Renal Acquisition requires payments of up to an additional $190.0 million in cash or additional shares of the Company's Common Stock, at the Company's election, upon the achievement of certain milestones. In September 2014, upon achievement of a developmental milestone, the Company satisfied a $20.0 million contingent payment to the former owners of OPKO Renal through the issuance of 2,236,210 shares of the Company's Common Stock, par value $0.01 per share. The Company's Common Stock was issued in reliance upon an exemption from the registration requirements under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit 3.1[1]	Amended and Restated Certificate of Incorporation.
Exhibit 3.2[2]	Amended and Restated By-Laws.
Exhibit 3.3[3]	Certificate of Designation of Series D Preferred Stock.
Exhibit 4.3[4]	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 September 30, 2014.
Exhibit 31.2	Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2014.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2014.
Exhibit 32.2	Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2014.
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2013 for the Company's three month period ended September 30, 2013, and incorporated herein by reference.

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

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

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

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SIGNATURES

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

Date: November 7, 2014

OPKO Health, Inc.

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

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Exhibit Index

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