

Opko Health, Inc.  
Form 10-Q  
November 09, 2012  
Table of Contents

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2012.

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)

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

**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.  YES  NO

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

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

Large accelerated filer  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  NO

As of November 2, 2012, the registrant had 298,184,058 shares of common stock outstanding.

**Table of Contents****TABLE OF CONTENTS**

	Page
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets as of September 30, 2012 (unaudited) and December 31, 2011</u>	6
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and September 30, 2011 (unaudited)</u>	7
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2012 and September 30, 2011 (unaudited)</u>	8
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and September 30, 2011 (unaudited)</u>	9
<u>Notes to Financial Statements</u>	10
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	28
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 4. Controls and Procedures</u>	35
<b>PART II. OTHER INFORMATION</b>	
<u>Item 1. Legal Proceedings</u>	36
<u>Item 1A. Risk Factors</u>	36
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
<u>Item 3. Defaults Upon Senior Securities</u>	36
<u>Item 4. Mine Safety Disclosures</u>	36
<u>Item 5. Other Information</u>	36
<u>Item 6. Exhibits</u>	36
<u>Signatures</u>	38
<u>Exhibit Index</u>	39
EX-2.8 Stock Purchase Agreement	
EX-31.1 Section 302 Certification of CEO	
EX-31.2 Section 302 Certification of CFO	
EX-32.1 Section 906 Certification of CEO	
EX-32.2 Section 906 Certification of CFO	
EX-101.INS XBRL Instance Document	
EX-101.SCH XBRL Taxonomy Extension Schema Document	
EX-101.CAL XBRL Taxonomy Extension Calculation Linkbase Document	
EX-101.DEF XBRL Taxonomy Extension Definition Linkbase Document	
EX-101.LAB XBRL Taxonomy Extension Label Linkbase Document	
EX-101.PRE XBRL Taxonomy Extension Presentation Linkbase Document	



---

**Table of Contents**

**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q contains forward-looking statements, as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in Item 1A-Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2011, 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 may not result in commercially viable products.

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 FDA or other non-U.S. regulatory authorities.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.

We expect to 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.

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

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.

**Table of Contents**

The loss of Phillip Frost, 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.

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 our Spanish, Israeli and Mexican facilities, and we therefore rely on third parties to manufacture and supply our pharmaceutical product candidates, and would need to meet various standards necessary to satisfy FDA regulations if and when we commence manufacturing.

We currently have no pharmaceutical or diagnostic marketing, sales or distribution capabilities other than in Chile, Spain and Mexico for sales in those countries and our active pharmaceutical ingredients ( APIs ) business in Israel. 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 product candidates.

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 also 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.

We do not have an exclusive arrangement in place with Dr. Tom Kodadek with respect to technology or intellectual property that may be material to our business.

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.

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

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.

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

Failure to obtain and maintain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.

We may not have the funding available to pursue acquisitions.

**Table of Contents**

Acquisitions may disrupt our business, distract our management and may not proceed as planned; and 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 could adversely impact our operations.

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.

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 NYSE, which could cause our stock price to fall and decrease the liquidity of our Common Stock.

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

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

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

**Table of Contents****PART I. FINANCIAL INFORMATION**

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to the Company, OPKO, we, our, ours, and us 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**

(In thousands except share and per share data)

	September 30, 2012 (unaudited)	December 31, 2011 (audited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 23,428	\$ 71,516
Marketable securities	18,923	
Accounts receivable, net	19,142	12,544
Inventories, net	21,488	13,339
Prepaid expenses and other current assets	5,004	2,179
Current assets of discontinued operations		4
<b>Total current assets</b>	<b>87,985</b>	<b>99,582</b>
Property and equipment, net	12,845	5,358
Intangible assets, net	82,586	76,730
Goodwill	49,738	39,815
Investments, net	14,998	6,717
Other assets	1,870	1,287
<b>Total assets</b>	<b>\$ 250,022</b>	<b>\$ 229,489</b>
<b>LIABILITIES, SERIES D PREFERRED STOCK, AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,238	4,891
Accrued expenses	21,794	4,956
Current portion of lines of credit and notes payable	17,408	8,757
Current liabilities of discontinued operations	1	174
<b>Total current liabilities</b>	<b>46,441</b>	<b>18,778</b>
Other long-term liabilities, principally contingent consideration and deferred tax liabilities	32,930	25,443
<b>Total liabilities</b>	<b>79,371</b>	<b>44,221</b>
Commitments and contingencies:		
Series D Preferred Stock - \$0.01 par value, 2,000,000 shares authorized; 1,129,032 shares and 1,129,032 shares issued and outstanding (liquidation value of \$30,035 and \$28,355) at September 30, 2012 and December 31, 2011, respectively	24,386	24,386
Shareholders' equity:		
Series A Preferred Stock - \$0.01 par value, 4,000,000 shares authorized; no shares issued or outstanding at September 30, 2012 or December 30, 2011		

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

Series C Preferred Stock - \$0.01 par value, 500,000 shares authorized; no shares issued or outstanding at September 30, 2012 or December 30, 2011		
Common Stock - \$0.01 par value, 500,000,000 shares authorized; 298,151,813 shares and 297,503,033 shares issued at September 30, 2012 and December 30, 2011, respectively	2,982	2,975
Treasury Stock - 2,293,326 shares and 2,488,477 shares at September 30, 2012 and December 31, 2011, respectively	(7,457)	(8,092)
Additional paid-in capital	529,958	524,814
Accumulated other comprehensive income	9,004	907
Accumulated deficit	(388,222)	(359,722)
<b>Total shareholders' equity</b>	<b>146,265</b>	<b>160,882</b>
Total liabilities, Series D Preferred Stock, and shareholders' equity	\$ 250,022	\$ 229,489

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

**Table of Contents****OPKO Health, Inc. and Subsidiaries****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(unaudited)

(In thousands, except share and per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2012	2011	2012	2011
<b>Revenues:</b>				
Product sales	\$ 11,495	\$ 6,760	\$ 30,051	\$ 22,113
Other revenue	300	47	732	72
<b>Total revenues</b>	<b>11,795</b>	<b>6,807</b>	<b>30,783</b>	<b>22,185</b>
Cost of goods sold, excluding amortization of intangible assets	7,487	4,017	19,028	13,085
<b>Gross margin, excluding amortization of intangible assets</b>	<b>4,308</b>	<b>2,790</b>	<b>11,755</b>	<b>9,100</b>
<b>Operating expenses:</b>				
Selling, general and administrative	7,322	4,348	17,428	14,102
Research and development	3,621	3,301	12,942	7,097
Contingent consideration	556		2,665	
Other operating expenses, principally amortization of intangible assets	2,178	945	6,277	2,615
<b>Total operating expenses</b>	<b>13,677</b>	<b>8,594</b>	<b>39,312</b>	<b>23,814</b>
<b>Operating loss from continuing operations</b>	<b>(9,369)</b>	<b>(5,804)</b>	<b>(27,557)</b>	<b>(14,714)</b>
<b>Other income and (expense), net:</b>				
Interest income	49	159	123	175
Interest expense	(393)	(456)	(975)	(802)
Other income (expense), net	224	(374)	1,279	(130)
<b>Other income and (expense), net</b>	<b>(120)</b>	<b>(671)</b>	<b>427</b>	<b>(757)</b>
<b>Loss from continuing operations before income taxes and investment losses</b>	<b>(9,489)</b>	<b>(6,475)</b>	<b>(27,130)</b>	<b>(15,471)</b>
Income tax provision (benefit)	(128)	(27)	89	199
<b>Loss from continuing operation before investment losses</b>	<b>(9,361)</b>	<b>(6,448)</b>	<b>(27,219)</b>	<b>(15,670)</b>
Loss from investments in investees	(468)	(301)	(1,464)	(1,175)
<b>Loss from continuing operations</b>	<b>(9,829)</b>	<b>(6,749)</b>	<b>(28,683)</b>	<b>(16,845)</b>
Income (loss) from discontinued operations, net of tax	183	(1,487)	183	(2,841)
<b>Net loss</b>	<b>(9,646)</b>	<b>(8,236)</b>	<b>(28,500)</b>	<b>(19,686)</b>
Preferred stock dividend	(560)	(600)	(1,680)	(1,860)

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

Net loss attributable to common shareholders	\$ (10,206)	\$ (8,836)	\$ (30,180)	\$ (21,546)
Loss per share, basic and diluted:				
Loss from continuing operations	\$ (0.03)	\$ (0.02)	\$ (0.10)	\$ (0.07)
Income (loss) from discontinued operations	0.00	(0.01)	0.00	(0.01)
Net loss per share	\$ (0.03)	\$ (0.03)	\$ (0.10)	\$ (0.08)

Weighted average number of common shares  
outstanding, basic and diluted 298,103,882 285,582,259 297,762,469 277,359,789

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

**Table of Contents****OPKO Health, Inc. and Subsidiaries****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(unaudited)

(In thousands)

	For the three months ended September 30,		For the nine months ended September 30,	
	2012	2011	2012	2011
Net loss attributable to common shareholders	\$ (10,206)	\$ (8,836)	\$ (30,180)	\$ (21,546)
Other comprehensive loss, net:				
Change in foreign currency translation adjustment	1,960	(2,548)	2,570	(2,312)
Available for sale investments:				
Change in unrealized gains (losses), net	322	(175)	5,527	(175)
Comprehensive loss	\$ (7,924)	\$ (11,559)	\$ (22,083)	\$ (24,033)

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

**Table of Contents****OPKO Health, Inc. and Subsidiaries****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(unaudited)

(in thousands)

	For the nine months ended September 30,	
	2012	2011
<b>Cash flows from operating activities:</b>		
Net loss	\$ (28,500)	\$ (19,686)
(Income) loss from discontinued operations, net of tax	(183)	2,841
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,447	2,858
Accretion of debt discount related to notes payable		2
Equity-based compensation - employees and non-employees	3,281	5,350
Loss from investments in investees	1,464	1,175
Provision for bad debt	11	260
Provision for inventory obsolescence	1,520	534
Revenue from receipt of equity in Neovasc	(159)	
Unrealized gains on derivative instruments	(1,309)	
Change in fair value of contingent consideration	2,665	
Changes in assets and liabilities of continuing operations, net of the effects of acquisitions:		
Accounts receivable	(184)	(2,523)
Inventory	(4,443)	4,080
Prepaid expenses and other current assets	(1,312)	224
Other assets	77	53
Accounts payable	(331)	(3,652)
Foreign currency measurement	(204)	
Accrued expenses	459	852
Cash used in operating activities of continuing operations	(19,701)	(7,632)
Cash provided by (used in) operating activities of discontinued operations	14	(4,280)
Net cash used in operating activities	(19,687)	(11,912)
<b>Cash flows from investing activities:</b>		
Acquisition of businesses, net of cash	(10,512)	(10,538)
Purchase of marketable securities	(28,923)	(100,161)
Maturities of short-term marketable securities	10,000	59,982
Investments in investees	(2,700)	(2,013)
Capital expenditures	(1,064)	(1,249)
Net cash used in investing activities	(33,199)	(53,979)
<b>Cash flows from financing activities:</b>		
Issuance of Common Stock, including related parties, net		104,828
Purchase of Common Stock held in treasury		(7,832)
Redemption of Series A Preferred Stock		(1,792)
Borrowings under lines of credit	29,389	10,056
Repayments under lines of credit	(26,108)	(10,761)
Proceeds from the exercise of Common Stock options and warrants	1,702	774

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

Net cash provided by financing activities	4,983	95,273
Effect of exchange rate changes on cash and cash equivalents	(185)	(163)
Net (decrease) increase in cash and cash equivalents	(48,088)	29,219
Cash and cash equivalents at beginning period	71,516	18,016
Cash and cash equivalents at end of period	\$ 23,428	\$ 47,235

SUPPLEMENTAL INFORMATION

Interest paid	\$ 613	\$ 608
Income taxes paid	515	355
Non-cash financing activities:		
Issuance of Common Stock to acquire Farmadiet	805	
Common Stock warrants, net exercised	7	1,155

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

## **Table of Contents**

OPKO Health, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

### **NOTE 1 BUSINESS AND ORGANIZATION**

We are a multi-national pharmaceutical 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 molecular diagnostics tests, laboratory developed tests, point-of-care 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 and Mexico, which are generating revenue and which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. We also operate a specialty active pharmaceutical ingredients ( APIs ) manufacturer in Israel, which is currently generating revenue and positive cash flow, and which we expect to play a valuable role in the development of our pipeline of peptoids and other molecules for our proprietary molecular diagnostic and therapeutic products. We continue to actively explore opportunities to acquire complementary pharmaceuticals, compounds, technologies, and businesses.

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, which is where our molecular diagnostics research and development and oligonucleotide research and development operations are based, respectively. We lease office, manufacturing, research and development and warehouse space in Woburn, Massachusetts for our point-of-care diagnostics business, and in Nesher, Israel for our API business. Our Chilean operations are located in leased offices and a leased warehouse facility in Santiago, Chile. Our Mexican operations are based in owned offices, manufacturing facilities and in a leased warehouse facility in Guadalajara, Mexico. Our Spanish operations are based in owned offices in Barcelona, Spain and in an owned manufacturing facility in Banyoles, Spain.

### **NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Basis of presentation.* The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States 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 for the three and nine months ended September 30, 2012 and cash flows for the nine months ended September 30, 2012, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2012 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, 2011.

*Reclassifications.* As further discussed in Note 6, the results of operations and the assets and the liabilities related to the instrumentation business have been accounted for as discontinued operations. Accordingly, the results of the operations related to the instrumentation business from prior periods have been reclassified to discontinued operations.

*Principles of consolidation.* The accompanying unaudited condensed consolidated financial statements include the accounts of OPKO Health, Inc. and our wholly-owned subsidiaries. All significant 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 of America 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

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

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.

## **Table of Contents**

*Marketable securities.* Investments with original maturities of greater than 90 days and remaining maturities of less than one year are classified as marketable securities. Marketable securities include U.S. treasury securities and certificates of deposit. Unrealized gains and losses on investments are included in Accumulated other comprehensive income ( OCI ) as a separate component of shareholders' equity. Realized gains and losses, dividends, interest income, and declines in value judged to be other-than-temporary credit losses are included in Other income and (expense), net. Amortization of any premium or discount arising at purchase is included in Interest income.

*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.

*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 products returned and allowances taken, matched against the sales from which they originated, and management's evaluation of specific factors that may increase the risk of product returns.

Other revenue includes revenue related to 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. Other revenue for the three and nine months ended September 30, 2012, includes \$0.3 million and \$0.7 million, respectively, of revenue related to our consulting agreement with Neovasc, Inc. and to revenue related to molecular diagnostics collaboration agreements. Refer to Note 5. We recognize this revenue on a straight-line basis over the contractual term of the agreements.

Non-refundable license fees for the out-license of our technology are recognized depending on the provisions of each agreement. We recognize non-refundable upfront license payments as revenue upon receipt if the license has standalone value and 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 as 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.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as Other revenue 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 Other revenue over the term of the arrangement as we complete our performance obligations.

Total deferred revenue recorded as Accrued expenses and Other long-term liabilities at September 30, 2012 and December 31, 2011, was \$1.4 million and \$0.9 million, respectively.

*Derivative financial instruments.* We record derivative financial instruments on our balance sheet at their fair value and the changes in the fair value are recognized in Other income (expense), net, when they occur, the only exception being derivatives that qualify as hedges. For the

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

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

**Table of Contents**

and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2012 and December 31, 2011, our forward contracts for inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in fair values of the forward contracts in Other income (expense), net. Refer to Note 8. Changes in fair value of our common stock option and common stock warrant holdings of our available for sale investments are recognized in either Other income (expense), net, or Other comprehensive loss, net. Refer to Note 7.

*Product warranties.* Product warranty expense is recorded concurrently with the recording of revenue for product sales. The costs of warranties are accounted for as a component of cost of sales. We estimate warranty costs based on our estimated historical experience and adjust for any known product reliability issues.

*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 allowance for doubtful accounts was \$0.3 million and \$0.4 million at September 30, 2012 and December 31, 2011, respectively.

*Segment reporting.* Our chief operating decision-maker ( CODM ) is comprised of our executive management team 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 one reportable segment, pharmaceuticals. 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, diagnostic tests and vaccines, and (ii) the pharmaceutical operations we acquired in Chile, Mexico, Israel and Spain through the acquisition of OPKO Chile S.A. ( OPKO Chile ), Exakta-OPKO S.A. de C.V ( Exakta-OPKO ), FineTech Pharmaceuticals Ltd. ( FineTech ) and Farmadiet Group Holding, S.L. ( Farmadiet ), respectively. We evaluate the performance of each operating segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

*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 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, 2012 and 2011, we recorded \$1.1 million and \$1.8 million, respectively, of equity-based compensation expense. For the nine months ended September 30, 2012 and 2011, we recorded \$3.3 million and \$5.4 million, respectively, of equity-based compensation expense.

*Recent accounting pronouncements.* On January 1, 2012, we adopted an amendment issued by the Financial Accounting Standards Board ( FASB ) to the accounting standards related to fair value measurements and disclosure requirements. This amendment revises the existing guidance on the use and application of fair value measurements and maintains a definition of fair value that is based on the notion of exit price. The adoption of this amendment did not have a material impact on our condensed consolidated financial statements.

On January 1, 2012, we adopted amendments issued by the FASB to the accounting standards related to the presentation of comprehensive income. These amendments revise the manner in which entities present comprehensive income in their financial statements and remove the option to present items of other comprehensive income in the statement of changes in stockholders' equity. These amendments require an entity to report components of comprehensive income in either (1) a continuous statement of comprehensive income, or (2) two separate but consecutive statements of net income and other comprehensive income. We modified our condensed consolidated financial statements presentation using the latter alternative.

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

On January 1, 2012, we adopted revised guidance issued by the FASB related to the testing of goodwill for impairment. Under the revised guidance, an entity has the option to perform a qualitative assessment of whether it is more-likely-than-not that a reporting unit's fair value is less than its carrying value prior to performing the two-step quantitative goodwill impairment test. If, based on the qualitative factors, an entity determines that the fair value of the reporting unit is greater than its carrying amount, then the entity would not be required to perform the two-step quantitative impairment test for that reporting unit. However, if the qualitative assessment indicates that it is not more-likely-than-not that the reporting unit's fair value exceeds its carrying value, then the quantitative assessment

**Table of Contents**

must be performed. An entity is permitted to perform the qualitative assessment on none, some or all of its reporting units and may also elect to bypass the qualitative assessment and begin with the quantitative assessment of goodwill impairment. This amendment did not have a material impact on our condensed consolidated financial statements.

**NOTE 3 LOSS PER SHARE**

Basic loss per share is computed by dividing our net loss by the weighted average number of shares outstanding during the period. Diluted loss per share is computed by dividing our net loss 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.

A total of 26,022,072 and 26,263,152 potential common shares have been excluded from the calculation of net loss per share for the three months ended September 30, 2012 and 2011, respectively, because their inclusion would be anti-dilutive. In addition, a total of 26,836,546 and 27,375,394 potential common shares have been excluded from the calculation of net loss per share for the nine months ended September 30, 2012 and 2011, respectively, because their inclusion would be anti-dilutive. As of September 30, 2012, the holders of our Series D Preferred Stock could convert their preferred shares into approximately 12,110,750 shares of our Common Stock.

During the nine months ended September 30, 2012, we issued 748,783 shares of our Common Stock as a result of Common Stock options and Common Stock warrants exercised.

**Table of Contents****NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS**

(In thousands)	September 30, 2012 (unaudited)	December 31, 2011 (audited)
Accounts receivable, net		
Accounts receivable	\$ 19,490	\$ 12,984
Less: allowance for doubtful accounts	(348)	(440)
	\$ 19,142	\$ 12,544
Inventories, net		
Finished products	\$ 17,750	\$ 11,100
Work-in process	633	277
Raw materials	4,513	2,287
Less: reserve for obsolescence	(1,408)	(325)
	\$ 21,488	\$ 13,339
Intangible assets, net		
Customer relationships	\$ 19,232	\$ 18,386
In-process research and development	11,504	10,000
Technology	50,211	47,100
Product registrations	9,638	3,895
Tradenname	1,921	827
Covenants not to compete	1,758	1,560
Other	297	297
Less: accumulated amortization	(11,975)	(5,335)
	\$ 82,586	\$ 76,730
Accrued expenses		
Income taxes payable	\$ 649	\$ 484
Deferred revenue	955	530
Clinical trials	58	7
Professional fees	817	632
Employee benefits	1,910	907
Deferred acquisition payments, net of discount	5,983	
Contingent consideration	7,992	
Other	3,430	2,396
	\$ 21,794	\$ 4,956
Other long-term liabilities		
Contingent consideration	\$ 13,909	\$ 18,002
Deferred acquisition payments, net of discount	3,769	
Deferred tax liabilities	10,845	6,863
Long-term debt	3,954	
Other including deferred revenue	453	578
	\$ 32,930	\$ 25,443

The change in value of the intangible assets includes the acquisitions of Farmadiet and ALS Distribuidora Limitada ( ALS ) (Refer to Note 5) and the foreign currency fluctuation between the Chilean and Mexican pesos against the US dollar at September 30, 2012 and December 31, 2011.



---

**Table of Contents**

**NOTE 5 ACQUISITIONS, INVESTMENTS, AND LICENSES**

*Farmadiet acquisition*

In August 2012, we entered into a stock purchase agreement pursuant to which we acquired all of the outstanding stock of Farmadiet, a Spanish company engaged in the development, manufacture, marketing, and sale of pharmaceutical, nutraceutical, and veterinary products in Europe (the Transaction ).

In connection with the 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 ) will be 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. On the date of acquisition, we recorded the €6.8 million Deferred Payments at \$7.8 million, net of a discount of \$0.6 million. The discount will be amortized as interest expense through the respective payment dates. The Deferred Payments are required to be paid in Euro and as such, the final U.S. dollar amount to be paid will be based on the exchange rate at the time the Deferred Payments are made. In the event we elect to pay the Deferred Payments in shares of our Common Stock, the number of shares issuable shall be calculated using the average closing sales price per share of our Common Stock as reported on the New York Stock Exchange ( NYSE ) for the ten trading days immediately preceding the applicable payment date. We have the right to hold back up to \$3.4 million from the Deferred Payment to satisfy indemnity claims.

In connection with the Transaction, we also entered into two ancillary transactions (the Ancillary Transactions ). In exchange for a forty percent interest held by one of the sellers in one of Farmadiet s subsidiaries, we agreed to issue up to an aggregate of 250,000 shares of our Common Stock, of which (a) 125,000 shares were issued on the closing date, and (b) 125,000 will be issued upon achieving certain milestones. In addition, we acquired an interest held by an affiliate of Farmadiet in a product in development in exchange for which we agreed to pay up to an aggregate of 1.0 million (\$1.1 million) payable at our option in cash or shares of our Common Stock, of which (a) 25% (\$0.3 million) was paid at closing through delivery of 70,421 shares of our Common Stock, and 75% (\$0.8 million) will be paid in cash or shares of our Common Stock upon achieving certain milestones. The final U.S. dollar amount to be paid will be based on the exchange rate at the time the milestones are achieved. The number of shares of our Common Stock issued is determined based on the average closing sales price for our Common Stock on the NYSE for the ten trading days preceding the required payment date.

*ALS acquisition*

In April 2012, we completed the acquisition of ALS, a privately-held Chilean pharmaceutical company, pursuant to a stock purchase agreement entered into in January 2012. In connection with the transaction, we agreed to pay up to a total of \$4.0 million in cash to the sellers. Pursuant to the purchase agreement, we paid (i) \$2.4 million in cash at the closing, less certain liabilities, and (ii) \$0.8 million in cash at the closing into a separate escrow account to satisfy possible indemnity claims. We agreed to pay an additional \$0.8 million, the remainder of the \$4.0 million purchase price, upon the legal registration in the name of ALS of certain trademarks and product registrations previously held by Arama Laboratorios y Compañía Limitada.

**Table of Contents**

The following table summarizes the preliminary fair value allocation of the net assets acquired and liabilities assumed in the acquisitions of Farmadiet and ALS at the dates of acquisition, which are subject to change while contingencies that existed on the acquisition dates are resolved:

(In thousands)	
Current assets (includes cash of \$230)	\$ 9,134
Intangible assets:	
Customer relationships	436
Technology	5,437
In-process research and development	1,459
Product registrations	5,230
Covenants not to compete	187
Tradename	1,029
Total intangible assets	13,778
Goodwill	8,520
Plant and equipment	7,229
Other assets	611
Accounts payable and accrued expenses	(3,667)
Deferred tax liability	(3,169)
Deferred payment	(7,755)
Debt assumed	(7,829)
Contingent consideration	(1,197)
Total purchase price	\$ 15,655

*FineTech acquisition*

In December 2011, we purchased all of the issued and outstanding shares of FineTech, a privately-held Israeli pharmaceutical company focused on the development and production of APIs. At closing, we delivered to the seller \$27.7 million, of which \$10.0 million was paid in cash and \$17.7 million was paid in shares of our Common Stock. The shares delivered at closing were valued at \$17.7 million based on the closing sales price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or \$4.90 per share. The number of shares issued was based on the average closing sales price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the execution of the purchase agreement, or \$4.84 per share. Upon finalization of the closing financial statements of FineTech, we recorded an additional \$0.5 million purchase price adjustment related to a working capital surplus, as defined in the purchase agreement, which was paid to the seller in February 2012. In addition, the purchase agreement provides for the payment of additional cash consideration subject to the achievement of certain sales milestones.

The following table summarizes the preliminary fair value allocation of the net assets acquired and liabilities assumed in the acquisition of FineTech at the date of acquisition, which are subject to change while contingencies that existed on the acquisition date are resolved:

(In thousands)	
Current assets (including cash of \$2,000)	\$ 3,358
Intangible assets:	
Customer relationships	14,200
Technology	2,700
Covenants not to compete	1,500
Tradename	400
Total intangible assets	18,800
Goodwill	11,623
Plant and equipment	1,358
Other assets	1,154

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

Accounts payable and accrued expenses	(910)
Deferred tax liability	(2,457)
Contingent consideration	(4,747)
Total purchase price	\$ 28,179

**Table of Contents***Claros Diagnostics acquisition*

In October 2011, we acquired Claros Diagnostics, Inc. ( *OPKO Diagnostics* ) pursuant to an agreement and plan of merger. We paid \$10.0 million in cash, subject to certain set-offs and deductions, and \$22.5 million in shares of our Common Stock, based on the closing sales price per share of our Common Stock as reported by the NYSE on the closing date of the merger, or \$5.04 per share. The number of shares issued was based on the average closing sales price per share of our Common Stock as reported by the NYSE for the ten trading days immediately preceding the date of the merger, or \$4.45 per share. Pursuant to the merger agreement, \$5.0 million of the stock consideration was held in a separate escrow account until October 2012 to secure the indemnification obligations of Claros Diagnostics under the Claros Diagnostics, Inc. merger agreement. In December 2011, we made a \$0.2 million claim against the escrow for certain undisclosed liabilities. In addition, the merger agreement provides for the payment of up to an additional \$19.1 million in shares of our Common Stock upon and subject to the achievement of certain milestones.

The following table summarizes the preliminary fair value allocation of the net assets acquired and liabilities assumed in the acquisition of OPKO Diagnostics at the date of acquisition, which are subject to change while contingencies that existed on the acquisition date are resolved:

(In thousands)	
Current assets (including cash of \$351)	\$ 378
Technology	44,400
Goodwill	17,977
Equipment	333
Other assets	18
Accounts payable and accrued expenses	(655)
Deferred tax liability	(17,254)
Contingent consideration	(12,745)
<b>Total purchase price</b>	<b>\$ 32,452</b>

*Investments*

In February 2012, we made a \$1.0 million investment in ChromaDex Corporation ( *ChromaDex* ), a publicly-traded company and leading provider of proprietary ingredients and products for the dietary supplement, nutraceutical, food and beverage, functional food, pharmaceutical and cosmetic markets, in exchange for 1,333,333 shares of ChromaDex common stock, at \$0.75 per share. In connection with our investment, we also entered into a license, supply and distribution agreement with ChromaDex pursuant to which we obtained exclusive distribution rights to certain of its products in Latin America. Our investment was part of a \$3.7 million private placement by ChromaDex. Other investors participating in the private financing included certain related parties. Refer to Note 9.

We have determined that our ownership, along with that of our related parties, do not provide us with significant influence over the operations of ChromaDex and as a result, we account for ChromaDex as an investment, available for sale, and we record changes in the fair value of ChromaDex as an unrealized gain or loss in Other comprehensive loss each reporting period. Refer to Note 7. The closing price of ChromaDex was \$0.78 per share on September 30, 2012.

In February 2012, we purchased from Biozone Pharmaceuticals, Inc., a publicly traded company that specializes in drug development, manufacturing, and marketing ( *BZNE* ), \$1.7 million of 10% secured convertible promissory notes (the *BZNE Notes* ), convertible into BZNE common stock at a price equal to \$0.20 per common share, which BZNE Notes are due and payable on February 24, 2014 and ten year warrants (the *BZNE Warrants* ) to purchase 8.5 million shares of BZNE common stock at an exercise price of \$0.40 per share. In July 2012, we exercised the BZNE Warrants and received 7,650,000 shares of BZNE common stock. The BZNE Notes are secured pursuant to a security agreement by a first priority lien in the assets of BZNE, including the stock of its subsidiaries. As further consideration for the purchase of the BZNE Notes by us, BZNE granted us exclusive, worldwide distribution rights to its enhanced formulation of propofol, which license was terminated in September 2012. The parties also entered into a license agreement pursuant to which we acquired a world-wide license for the development and commercialization of products utilizing BZNE'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. Refer to Note 9.

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

We have accounted for the BZNE Notes as an investment, available for sale. We recorded the BZNE Notes and BZNE Warrants at fair value on the date of acquisition. We record changes in fair value for the BZNE Notes as an unrealized gain or loss in Other comprehensive loss each reporting period and we record changes in fair value for the beneficial conversion feature of the BZNE Notes in Other income (expense), net in our Condensed Consolidated Statements of Operations. Refer to Note 7.

---

**Table of Contents**

The stock market trading activity in BZNE does not represent an active market and as such, we determined the fair market value utilizing a business enterprise valuation approach in order to determine the fair value of our investment.

In August 2011, we made an investment in Neovasc Inc. ( Neovasc ), a Canadian publicly-traded medical technology company based in Vancouver, Canada. Neovasc is developing devices to treat cardiovascular diseases and is also a leading supplier of tissue components for the manufacturers of replacement heart valves. 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. We recorded the warrants on the date of grant at their estimated fair value of \$0.7 million using the Black-Scholes-Merton Model. Prior to the warrants being readily convertible into cash, we recorded an unrealized gain of \$0.2 million in Other comprehensive loss. We record changes in fair value for the Neovasc warrants in Other income (expense), net in our Condensed Consolidated Statement of Operations. Refer to Note 7. We also entered into an agreement with Neovasc to provide strategic advisory services to Neovasc as it continues to develop and commercialize its novel cardiac devices. In connection with the consulting agreement, Neovasc granted us 913,750 common stock options. The options were granted at (Canadian) \$1.00 per share and vest annually over three years. We valued the options using the Black-Scholes-Merton Model at \$0.8 million on the date of grant and will recognize the revenue over four years as Other revenue. In August 2012, Neovasc granted us an additional 86,250 common stock options. The options were granted at (Canadian) \$1.30 per share and vested immediately. We valued the options using the Black-Scholes-Merton Model at \$0.1 million on the date of grant and will recognize the revenue over three years as Other revenue. We record changes in the fair value of Neovasc options as an unrealized gain or loss in Other comprehensive loss each reporting period. Refer to Note 7. The closing price of Neovasc was \$1.39 per share (Canadian) on September 30, 2012.

In December 2010, we entered into a license agreement with TESARO, Inc. ( TESARO ) granting TESARO exclusive rights to the development, manufacture, commercialization and distribution of rolapitant and a related compound (the TESARO License ). In connection with the TESARO License, we also received an equity position in TESARO. We recorded the equity investment at \$0.7 million, the estimated fair value of the TESARO common stock based on a discounted cash flow model. Neither we nor our related parties have the ability to significantly influence TESARO and as such, we accounted for our investment in TESARO under the cost method until June 2012 on which date, TESARO had an initial public offering. As a result of the initial public offering, we determined TESARO had a readily determinable fair value and we changed the accounting for our investment in TESARO from a cost method investment to an investment, available for sale, and we recorded an unrealized gain in Other comprehensive loss of \$5.3 million. We record changes in the fair value as an unrealized gain or loss in Other comprehensive loss each reporting period. Refer to Note 7. The closing price of TESARO was \$14.23 per share on September 30, 2012.

In November 2010, we made a \$0.7 million investment in Fabrus, Inc. ( Fabrus ), a privately-held early stage biotechnology company with next generation therapeutic antibody drug discovery and development capabilities. Fabrus is using its proprietary antibody screening and engineering approach to discover promising lead compounds against several important oncology targets. Our investment was part of a \$2.1 million financing for Fabrus and included other related parties. Refer to Note 9.

In September 2009, we entered into an agreement pursuant to which we invested \$2.5 million in cash in Cocrystal Discovery, Inc., a privately-held biopharmaceutical company ( Cocrystal ), in exchange for 1,701,723 shares of Cocrystal's Convertible Series A preferred stock. Cocrystal is focused on the discovery and development of novel antiviral drugs using a combination of protein structure-based approaches. Refer to Note 9. In October 2011, Cocrystal received an investment of \$7.5 million from Teva Pharmaceutical Industries Ltd. ( Teva ). Dr. Phillip Frost, our Chief Executive Officer and Chairman of our Board of Directors, is Chairman of the Board of Directors of Teva. In connection with that investment, we determined Cocrystal no longer meets the definition of a variable interest entity as it has sufficient capital to carry out its principal activities without additional financial support. As a result of our and our related parties' ownership interest, we and our related parties have the ability to significantly influence Cocrystal, and we account for our investment under the equity method.

## **Table of Contents**

In June 2009, we entered into a stock purchase agreement with Sorrento Therapeutics, Inc. ( Sorrento ), a publicly-held company with a technology for generating fully human monoclonal antibodies, pursuant to which we invested \$2.3 million in Sorrento. The closing stock price for Sorrento's common stock, a thinly-traded stock, as quoted on the over-the-counter markets was \$0.25 per share on September 30, 2012. Refer to Note 9.

### *Variable interest entities*

We have determined that we hold variable interests in two entities ( VIE ), Fabrus and BZNE. 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 order to determine the primary beneficiary of Fabrus, 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 Fabrus. The related party group when considering our investment in Fabrus includes the Company, Frost Gamma Investments Trust, of which Dr. Frost is the sole trustee (the Gamma Trust ), Hsu Gamma Investment, L.P., of which Dr. Jane Hsiao is the general partner ( Hsu Gamma ), and the Richard Lerner Family Trust, of which Dr. Richard Lerner is the general partner. Drs. Frost, Hsiao and Lerner are all members of our Board of Directors. As of September 30, 2012, we own approximately 13% of Fabrus and Drs. Frost, Hsiao and Lerner own a total of 24% of Fabrus' voting stock on an as converted basis, including 16% held by the Gamma Trust. Drs. Frost and Hsiao currently serve on the board of directors of Fabrus and represent 40% of its board. Based on this analysis, we determined that neither we nor our related parties have the power to direct the activities of Fabrus. However, we did determine that our related parties can significantly influence the success of Fabrus through our board representation and voting power. Accordingly, as we and our related parties have the ability to exercise significant influence over Fabrus' operations, we account for our investment in Fabrus under the equity method.

In order to determine the primary beneficiary of BZNE, we evaluated our investment and our related parties' investments, as well as our investment combined with the related party group's investments to identify if we had the power to direct the activities that most significantly impact the economic performance of BZNE. We determined that power to direct the activities that most significantly impact BZNE's economic performance is conveyed through the board of directors of BZNE and no entity is able to appoint the BZNE governing body that oversees its executive management team. Based on the capital structure, governing documents and overall business operations of BZNE, we determined that, while a VIE, no single entity has the power to direct the activities that most significantly impact BZNE's economic performance. However, we determined that we and our related parties can significantly influence the success of BZNE through our rating power. As such, we account for investment in BZNE under the equity method.

**Table of Contents**

The total assets, liabilities, and net losses of our equity method investees as of and for the nine months ended September 30, 2012 were \$29.6 million, \$11.0 million, and \$11.4 million, respectively. The following table reflects our maximum exposure, accounting method, ownership interest and underlying equity in net assets of each of our investments:

(Dollars in thousands)

Investee Name	Year Acquired	Accounting Method	Ownership September 30, 2012	Investment	Underlying equity in net assets
Sorrento	2009	Equity method	19%	\$ 2,300	\$ 1,596
Cocrystal	2009	Equity method	16%	2,500	1,012
Neovasc	2011	Equity method, cost (warrants)	4%	2,013	146
Fabrus	2010	VIE, equity method	13%	650	53
BZNE common stock	2012	VIE, equity method	12%	1,276	(9)
Less: accumulated losses in investees				(4,115)	
<b>Total carrying value of equity method investees</b>				<b>4,624</b>	
BZNE Note and conversion					
feature	2012	VIE, investment available for sale	N/A	1,700	
ChromaDex	2012	Investment, available for sale	1%	1,000	
Neovasc options	2011	Investment, available for sale	N/A	925	
TESARO	2010	Investment, available for sale	2%	731	
Plus: unrealized gains on investments, options and warrants, net				6,018	
<b>Total carrying value of investments, available for sale</b>				<b>10,374</b>	
<b>Total</b>				<b>\$ 14,998</b>	

**NOTE 6 DISCONTINUED OPERATIONS**

In September 2011, we entered into an agreement with Optos, Inc., a subsidiary of Optos plc (collectively Optos) to sell our ophthalmic instrumentation business. Upon closing in October 2011, we received \$17.5 million of cash and will receive royalties up to \$22.5 million on future sales.

The assets and liabilities related to our instrumentation business have identifiable cash flows that are independent of the cash flows of other groups of assets and liabilities and we will not have a significant continuing involvement with the related products beyond one year after the closing of the transaction. Therefore, the accompanying Condensed Consolidated Balance Sheets report the assets and liabilities related to our instrumentation business as discontinued operations in all periods presented, and the results of operations related to our instrumentation business have been classified as discontinued operations in the accompanying Condensed Consolidated Statements of Operations for all periods presented.

The following table presents the major classes of assets and liabilities that have been presented as assets of discontinued operations and liabilities of discontinued operations in the accompanying Condensed Consolidated Balance Sheets:

(In thousands)	September 30, 2012	December 31, 2011
<b>Assets:</b>		
Other current assets	\$	\$ 4
<b>Total assets of discontinued operations</b>	<b>\$</b>	<b>\$ 4</b>
<b>Liabilities:</b>		

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

Trade accounts payable	\$		\$	1
Accrued expenses and other liabilities		1		173
Total liabilities of discontinued operations	\$	1	\$	174

**Table of Contents**

The following table presents summarized financial information for the discontinued operations included in the Condensed Consolidated Statements of Operations:

(In thousands)	For the three months ended September 30,		For the nine months ended September 30,	
	2012	2011	2012	2011
Total revenue	\$	\$ 730	\$	\$ 4,142
Operating income (loss)	183	(1,481)	183	(2,819)
Income (loss) before provision for income taxes	183	(1,487)	183	(2,841)
Net income (loss)	\$ 183	\$ (1,487)	\$ 183	\$ (2,841)

The income from discontinued operations for the three and nine months ended September 30, 2012 primarily represents collection of an accounts receivable balance retained as part of the sale to Optos.

**NOTE 7 FAIR VALUE MEASUREMENTS**

We record fair value 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, 2012, classified as available for sale, and carried at fair value is as follows:

(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	\$ 1,731	\$ 5,407	\$	\$	\$ 7,138
BZNE Note and conversion feature	1,700	53		287	2,040
Neovasc common stock options	925	249		119	1,293
Neovasc common stock warrants	659	194		(375)	478
Total assets	\$ 5,015	\$ 5,903	\$	\$ 31	\$ 10,949

Any future fluctuation in fair value related to these instruments that is judged to be temporary, including any recoveries of previous write-downs, would be recorded in Accumulated other comprehensive income. If we determine that any future valuation adjustment was other-than-temporary, we would record a loss during the period that such determination is made.

**Table of Contents**

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

(In thousands)	Fair value measurements as of September 30, 2012			Total
	Quote prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
<b>Assets:</b>				
Money market funds	\$ 14,505	\$	\$	\$ 14,505
US Treasury securities	14,997			14,997
Certificates of deposit		10,423		10,423
Forward contracts		59		59
Common stock investments	7,138			7,138
BZNE Note and conversion feature			2,040	2,040
Neovasc common stock options		1,293		1,293
Neovasc common stock warrants		478		478
<b>Total assets</b>	<b>\$ 36,640</b>	<b>\$ 12,253</b>	<b>\$ 2,040</b>	<b>\$ 50,933</b>
<b>Liabilities:</b>				
Deferred acquisition payments, net of discount	\$	\$	\$ 9,752	\$ 9,752
CURNA contingent consideration			510	510
OPKO Diagnostics contingent consideration			15,098	15,098
FineTech contingent consideration			5,042	5,042
Farmadiet contingent consideration			1,251	1,251
<b>Total liabilities</b>	<b>\$</b>	<b>\$</b>	<b>\$ 31,653</b>	<b>\$ 31,653</b>

The following table reconciles the beginning and ending balances of our Level 3 assets and liabilities:

(In thousands)	BZNE Note and conversion feature	Contingent consideration	Deferred acquisition payments, net of discount
Balance at December 31, 2011	\$	\$ 18,002	\$
Additions	1,700	1,234	9,673
<b>Change in fair value included in:</b>			
Operating expenses		2,665	
Other income and (expense), net	1,563		79
Other comprehensive loss	53		
Transfer out to equity method investment	(1,276)		
<b>Balance at September 30, 2012</b>	<b>\$ 2,040</b>	<b>\$ 21,901</b>	<b>\$ 9,752</b>

Our U.S. Treasury security matures on December 20, 2012 (\$15.0 million). We intend to hold the U.S. Treasury security until its maturity. Of the \$21.9 million of contingent consideration, \$8.0 million is recorded in Accrued expenses and \$13.9 million is recorded in Other long-term liabilities. We valued the contingent consideration utilizing a discounted cash flow model for the expected payments. The carrying value of our other assets and liabilities approximates their fair value due to their short-term nature.

**NOTE 8 DERIVATIVE CONTRACTS**

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

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.

We record derivative financial instruments as Accrued expenses or Other current assets on our Condensed Consolidated Balance Sheets at their fair value and the corresponding gain or loss as Other income (expense), net. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation

**Table of Contents**

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, 2012, the forward contracts did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in fair values in Other income (expense), net.

The outstanding forward contracts at September 30, 2012, have been recorded at fair value and their maturity details are as follows (dollars in thousands):

Days until maturity	Contract value	Fair value at September 30, 2012	Effect on loss
0 to 30	\$ 1,798	\$ 1,834	\$ (36)
31 to 60	1,273	1,288	(15)
61 to 90	320	328	(8)
91 to 120			
121 to 180			
More than 180			
<b>Total</b>	<b>\$ 3,391</b>	<b>\$ 3,450</b>	<b>\$ (59)</b>

In addition, the Neovasc warrants and vested Neovasc options are accounted for as derivatives as they are readily convertible into cash. As a result, the fluctuations in fair value are recorded in Other income (expense), net as an unrealized gain or loss. We value the Neovasc warrants and options based on the Black-Scholes-Merton valuation model. The conversion feature of the BZNE Notes is also accounted for as a derivative and the changes in the fair value are recorded in Other income (expense), net.

**NOTE 9 RELATED PARTY TRANSACTIONS**

During the nine months ended September 30, 2012, our FineTech subsidiary recorded revenue of \$0.2 million for the sale of APIs to 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 The Scripps Research Institute ( 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. Dr. Frost serves as a Trustee for TSRI and Dr. Lerner 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. Mr. Curt Lockshin, our Vice President, Corporate R&D Initiatives, serves as a member of the Board of Directors of ChromaDex. Following our investment, we own 1.5% of ChromaDex, the Gamma Trust owns approximately 16% of ChromaDex; Hsu Gamma owns approximately 1%; and Dr. Lerner owns less than 1% of ChromaDex. Refer to Note 5.

In February 2012, we purchased from the BZNE Notes, convertible into BZNE common stock at a price equal to \$0.20 per common share, which BZNE Notes are due and payable on February 24, 2014 and ten year warrants to purchase 8.5 million shares of BZNE common stock at an exercise price of \$0.40 per share. Refer to Note 5.

Mr. Roberto Prego Novo is the Chairman of BZNE and presently serves as a consultant to us. Dr. Frost and Mr. Prego Novo previously invested in BZNE in February and March, 2011. On May 16, 2011, BZNE acquired the assets and assumed the liabilities of Aero Pharmaceuticals, Inc. ( Aero ) in exchange for which BZNE issued an aggregate of 8,331,396 shares of its restricted common stock to Aero. On September 21, 2011, BZNE issued an additional 13,914 shares to Aero due to the late filing of a registration statement. Prior to the transaction, Dr. Frost, through the Gamma Trust, beneficially owned approximately 46% of Aero's issued and outstanding common stock; Mr. Prego Novo owned approximately 23% of Aero's issued and outstanding common stock through Olyrca Trust; and Dr. Hsiao beneficially owned approximately 12% of Aero's issued and outstanding common stock. Each of Drs. Frost and Hsiao and Mr. Prego Novo beneficially owned approximately 9.2%, 1.7%, and 8.2% of BZNE, respectively, following the purchase of Aero by BZNE. Mr. Rubin beneficially own less than 1% of BZNE as a result of his

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

prior ownership of Aero shares. In April 2012 and June 2012, Dr. Frost, through the Gamma Trust, also made loans to BZNE in the principal amounts of \$0.3million and \$0.1 million, respectively, which were initially secured by a first priority lien on particular BZNE receivables. The notes to Frost Gamma were subsequently amended and Frost Gamma no longer holds a security interest in the BZNE receivables.

---

**Table of Contents**

In August 2011, we made an investment in Neovasc. Refer to Note 5. 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 for Neovasc.

In March 2011, we issued 27,000,000 shares of our Common Stock. The 27,000,000 shares of our Common Stock issued included an aggregate of 3,733,000 shares purchased by the Gamma Trust and Hsu Gamma at the public offering price. The Gamma Trust purchased an aggregate of 3,200,000 shares for approximately \$12.0 million, and Hsu Gamma purchased an aggregate of 533,000 shares for approximately \$1.9 million. Jefferies & Company, Inc. and J.P. Morgan Securities LLC acted as joint book-running managers for the offering. UBS Investment Bank and Lazard Capital Markets LLC acted as co-lead managers for the offering and Ladenburg Thalmann & Co. Inc., a subsidiary of Ladenburg Thalmann Financial Services Inc., acted as co-manager for the offering. Dr. Frost is the Chairman of the Board of Directors and principal shareholder of Ladenburg Thalmann Financial Services Inc.

In January 2011, we entered into a definitive agreement with CURNA, Inc. ( CURNA ) and each of CURNA's stockholders and option holders, pursuant to which we agreed to acquire all of the outstanding stock of CURNA in exchange for \$10.0 million in cash, plus \$0.6 million in liabilities, of which \$0.5 million was paid at closing. At the time of the transaction, TSRI owned approximately 4% of CURNA.

We had a \$12.0 million line of credit with the Frost Group, LLC (the Frost Group ) which expired on March 31, 2012. The Frost Group members include a trust controlled by Dr. Frost, who is the Company's Chief Executive Officer and Chairman of our Board of Directors, Dr. Hsiao, who is the Vice Chairman of our Board of Directors and Chief Technical Officer and Mr. Rubin who is Executive Vice President Administration and a director of the Company. On June 2, 2010 we repaid all amounts outstanding on the line of credit including \$12.0 million in principal and \$4.1 million in interest. We did not have any borrowings under the line of credit at any time during 2011 and 2012. We were obligated to pay interest upon maturity, capitalized quarterly, on any outstanding borrowings under the line of credit at an 11% annual rate. The line of credit was collateralized by all of our U.S. personal property except our intellectual property.

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. Other investors participating in the financing include the Gamma Trust and Hsu Gamma. In connection with the financing, Drs. Frost and Hsiao joined the Fabrus Board of Managers. Dr. Lerner owns approximately 5% of Fabrus. Mr. Vaughn Smider, Founder and CEO of Fabrus, is an Assistant Professor at TSRI. Dr. Frost serves as a Trustee for TSRI and Dr. Lerner served as President of TSRI until December 2011.

In July 2010, we entered into a use agreement for approximately 1,100 square feet of space in Jupiter, Florida to house our molecular diagnostics operations with TSRI. Pursuant to the terms of the use agreement, which was effective as of November 1, 2009, gross rent was approximately \$40 thousand per year for a two-year term. We ceased use of this space in September 2011.

In June 2010, we entered into a cooperative research and development agreement with Academia Sinica in Taipei, Taiwan ( Academia Sinica ), for pre-clinical work for a compound against various forms of cancer (the Academia Sinica Agreement ). Dr. Alice Yu, a member of our Board of Directors, is 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 such agreement.

In July 2009, we entered into a worldwide exclusive license agreement with Academia Sinica for a new technology to develop protein vaccines against influenza and other viral infections. Effective March 5, 2010, the Frost Group assigned two license agreements with Academia Sinica to us. The license agreements pertain to alpha-galactosyl ceramide analogs and their use as immunotherapies and peptide ligands in the diagnosis and treatment of cancer. In connection with the assignment of the two licenses, we agreed to reimburse \$0.1 million to the Frost Group for the licensing fees previously paid by the Frost Group to Academia Sinica, as well as reimbursement of certain expenses totaling \$50 thousand.

Effective September 2009, we entered into an agreement pursuant to which we invested \$2.5 million in Cocystal in exchange for 1,701,723 shares of Cocystal's Convertible Series A preferred stock. A group of investors, led by

---

**Table of Contents**

the Frost Group (the Cocrystal Investors ), previously invested \$5.0 million in Cocrystal, and agreed to invest an additional \$5 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. Refer to Note 5.

In June 2009, we entered into an agreement to lease approximately 10,000 square feet of space in Hialeah, Florida, to house manufacturing and service operations for our ophthalmic instrumentation business from an entity controlled by Drs. Frost and Hsiao. Effective as of July 1, 2011, the lease was amended to include an additional 5,000 square feet of space at the same rate per square foot then in effect under the lease. Following the amendment, gross rent payable under the lease was \$0.2 million per year. Upon the closing of the sale of our instrumentation business to Optos, we assigned the lease to Optos. Refer to Note 6.

In June 2009, we entered into a stock purchase agreement with Sorrento, pursuant to which we invested \$2.3 million in Sorrento. Refer to Note 5. 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 November 2007, we entered into an office lease with Frost Real Estate Holdings, LLC ( Frost Holdings ), an entity affiliated with Dr. Frost. The lease is for approximately 8,300 square feet of space in an office building in Miami, Florida, where the Company's principal executive offices are located. The lease provides for payments of approximately \$18 thousand per month in the first year increasing annually to \$24 thousand per month by the fifth year, plus applicable sales tax. The rent is 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.

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, 2012, we reimbursed Dr. Frost approximately \$52 thousand and \$181 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2011, we reimbursed Dr. Frost approximately \$14 thousand and \$127 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

**NOTE 10 COMMITMENTS AND CONTINGENCIES**

In connection with our acquisitions of CURNA, OPKO Diagnostics, FineTech and Farmadiet we agreed to pay future consideration upon the achievement of certain events. As a result, we recorded \$21.9 million as contingent consideration, with \$8.0 million recorded within Accrued expenses and \$13.9 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets as of September 30, 2012. Refer to Note 5.

On or around October 30, 2012, we received a letter from counsel to Optos making certain indemnity claims against us in connection with the sale of our instrumentation business. Refer to Note 6. It is too early to assess the likelihood of litigation in this matter or the probability of a favorable or unfavorable outcome. However, we do not currently believe this matter will have a material impact on our results of operations or financial condition.

**Table of Contents**

We are a party to 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 revenue from any of our diagnostic and pharmaceutical product candidates. Our research and development activities are projected to expand over a period of time and will require further resources if we are to be successful in commercializing our product candidates. 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.

**NOTE 11 SEGMENTS**

We currently manage our operations in one reportable segment, pharmaceuticals. 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, diagnostic tests and vaccines, and (ii) the pharmaceutical operations we acquired in Chile, Spain, Mexico, and Israel through the acquisition of OPKO Chile, Farmadiet, Exakta-OPKO, and FineTech, respectively. 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. We previously recorded our ophthalmic instrumentation business as its own reporting segment.

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

(In thousands)	For three months ended		For the nine months ended	
	September 30,		September 30,	
	2012	2011	2012	2011
<b>Operating loss from continuing operations</b>				
Pharmaceutical	\$ (5,593)	\$ (262)	\$ (17,053)	\$ (3,601)
Corporate	(3,776)	(5,542)	(10,504)	(11,113)
	\$ (9,369)	\$ (5,804)	\$ (27,557)	\$ (14,714)
<b>Depreciation and amortization</b>				
Pharmaceutical	\$ 2,618	\$ 997	\$ 7,315	\$ 2,731
Corporate	44	43	132	127
	\$ 2,662	\$ 1,040	\$ 7,447	\$ 2,858
<b>Product sales</b>				
United States	\$	\$	\$	\$
Chile	6,781	5,356	19,669	17,545
Spain	1,997		1,997	
Israel	1,516		4,661	
Mexico	1,201	1,404	3,724	4,568
	\$ 11,495	\$ 6,760	\$ 30,051	\$ 22,113

**Table of Contents**

(In thousands)	September 30, 2012	As of December 31, 2011
<b>Assets:</b>		
Pharmaceutical	\$ 198,483	\$ 154,437
Corporate	51,539	75,048
Discontinued operations		4
	<b>\$ 250,022</b>	<b>\$ 229,489</b>

During the three and nine months ended September 30, 2012, no customer represented more than 10% of our total revenues. During the three and nine months ended September 30, 2011, our largest customer represented 20% and 18% of our total revenues, respectively. As of September 30, 2012, no customer represented more than 10% of our accounts receivable balance. As of December 31, 2011, one customer represented 29% of our accounts receivable balance.

**NOTE 12 SUBSEQUENT EVENTS**

On October 18, 2012, we entered into a definitive merger agreement to acquire Prost-Data, Inc., doing business as OURLab, a Nashville-based CLIA laboratory with 18 phlebotomy sites throughout the U.S. We believe OURLab provides us with a commercial platform to support the U.S. commercial launch of our panel of kallikrein biomarkers and associated algorithm (4Kscore) for the detection of prostate cancer. We agreed to pay an aggregate purchase price of \$40.0 million, of which \$9.4 million shall be payable in cash, and \$30.6 million payable in shares of our Common Stock, subject to our ability to hold back up to \$4.0 million of the cash otherwise payable at closing as escrow for potential indemnity claims.

On or around October 30, 2012, we received a letter from counsel to Optos making certain indemnity claims against us in connection with the sale of our instrumentation business. Refer to Note 6. It is too early to assess the likelihood of litigation in this matter or the probability of a favorable or unfavorable outcome. However, we do not currently believe this matter will have a material impact on our results of operations or financial condition.

On October 17, 2012 we completed the acquisition of a forty-five percent stake in a private Israeli company that produces a third-generation hepatitis B vaccine in its biologics manufacturing facility in Rehovot, Israel.

We have reviewed all subsequent events and transactions that occurred after the date of our September 30, 2012 consolidated balance sheet date, through the time of filing this Quarterly Report on Form 10-Q.

**Table of Contents**

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**OVERVIEW**

*You should read this discussion together with the condensed consolidated financial statements, related notes, and other financial information included elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2011 (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, 2011. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.*

We are a multi-national pharmaceutical 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 molecular diagnostics tests, laboratory developed tests, point-of-care 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 have already established pharmaceutical platforms in Spain, Chile and Mexico, which are generating revenue and which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. We also operate a specialty active pharmaceutical ingredients ( APIs ) manufacturer in Israel, which is currently generating revenue and positive cash flow, and which we expect will play a valuable role in the development of our pipeline of peptoids and other molecules for our proprietary molecular diagnostic and therapeutic products. We continue to actively explore opportunities to acquire complementary pharmaceuticals, compounds, technologies, and businesses.

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 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 when needed on acceptable terms, or at all.

**Table of Contents**

**RECENT DEVELOPMENTS**

On October 18, 2012, we entered into a definitive merger agreement to acquire Prost-Data, Inc., doing business as OURLab, a Nashville-based CLIA laboratory with 18 phlebotomy sites throughout the U.S. We believe OURLab provides us with a commercial platform to support the U.S. commercial launch of our panel of kallikrein biomarkers and associated algorithm (4Kscore) for the detection of prostate cancer. We agreed to pay an aggregate purchase price of \$40.0 million, of which \$9.4 million shall be payable in cash, and \$30.6 million payable in shares of our Common Stock, subject to our ability to hold back up to \$4.0 million of the cash otherwise payable at closing as escrow for potential indemnity claims.

On October 17, 2012 we completed the acquisition of a forty-five percent stake in a private Israeli company that produces a third-generation hepatitis B vaccine in its biologics manufacturing facility in Rehovot, Israel.

In August 2012, we acquired all of the outstanding stock of Farmadiet Group Holding, S.L., a Spanish company ( Farmadiet ) engaged in the development, manufacture, marketing, and sale of pharmaceutical, nutraceutical, and veterinary products in Europe.

**RESULTS OF OPERATIONS**

**FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011**

*Revenues.* Revenues for the three months ended September 30, 2012 were \$11.8 million, compared to \$6.8 million for the comparable 2011 period. The increase in revenues during the three months period ended September 30, 2012 is primarily due to \$2.0 million of revenues generated by our Farmadiet business, which we acquired in August 2012, \$1.5 million of revenues generated by our FineTech Pharmaceuticals Ltd. ( FineTech ) API business, which we acquired in December 2011, and an increase of \$1.5 million of revenues generated in Chile primarily related to our acquisition of ALS in April 2012.

*Gross margin.* Gross margin for the three months ended September 30, 2012 was \$4.3 million, compared to \$2.8 million for the comparable period of 2011. Gross margin for the three months ended September 30, 2012 increased from the comparable period of 2011 primarily as a result of \$1.2 million of gross margin generated by Farmadiet and \$0.9 million of gross margin generated by our FineTech. This increase was partially offset by a decrease in gross margin generated by our Chilean pharmaceutical business primarily as a result of a \$0.7 million provision for inventory obsolescence recorded in the 2012 period.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for the three months ended September 30, 2012 were \$7.3 million, compared to \$4.3 million for the comparable period of 2011. The increase in selling, general and administrative expenses is primarily the result of increased personnel expenses as a result of the acquisitions of Farmadiet, Claros Diagnostics, Inc. ( OPKO Diagnostics ) and FineTech as well as increased professional fees. Selling, general and administrative expenses during the three months ended September 30, 2012 and 2011 primarily consisted of personnel expenses, including equity-based compensation expense of \$1.1 million and \$1.3 million, respectively, and professional fees.

*Research and development expenses.* Research and development expenses during the three months ended September 30, 2012 were \$3.6 million, compared to \$3.3 million for the comparable period of 2011. Research and development expenses for the three months ended September 30, 2012 increased principally due to activities related to our OPKO Diagnostics development programs, which we acquired in October 2011. These increases were partially offset by lower equity based compensation due to decreased mark to market adjustments for certain of our consultant stock option awards. As a result, the three months ended September 30, 2012 included an immaterial amount of equity-based compensation expense, compared to the three months ended September 30, 2011, which included equity-based compensation expense of \$1.3 million.

*Contingent consideration expenses.* Contingent consideration expenses for the three months ended September 30, 2012 were \$0.6 million, which represent the change in the fair value of the contingent consideration liabilities due to the time value of money. Contingent consideration liabilities relates to potential amounts payable to former stockholders of Farmadiet, FineTech and OPKO Diagnostics pursuant to our agreements to acquire them in August 2012, December 2011 and October 2011, respectively. The comparable period of 2011 did not include such expenses.

**Table of Contents**

*Other operating expenses.* Other operating expenses were \$2.2 million for the three months ended September 30, 2012, compared to \$0.9 million for the comparable period of 2011. Other operating expenses primarily include the amortization of intangible assets. Amortization expenses increased due to the acquisitions of Farmadiet, ALS, FineTech and OPKO Diagnostics in August 2012, April 2012, December 2011 and October 2011, respectively.

*Other income and (expense), net.* Other income and (expense), net was (\$0.1) million for the three months ended September 30, 2012, compared to other income and (expense), net of (\$0.7) million for the comparable 2011 period. Other income and (expense), net primarily consists of our interest incurred on our lines of credit in Chile and interest incurred on our lines of credit and deferred payments in Spain, partially offset by interest earned on our cash and cash equivalents and the benefit from our Chilean and Mexico operations functional currencies strengthening during the three months ended September 30, 2012. Other income and (expense), net includes \$0.2 million of other income recognized for the change in fair value of the warrants received in connection with our investment in Neovasc, Inc. ( Neovasc ).

*Discontinued operations.* We had \$0.2 million of income from discontinued operations for the three months ended September 30, 2012, compared to a loss of \$1.5 million for the comparable period of 2011. The income for the three months ended September 30, 2012 reflect the recovery of certain retained accounts receivable from our ophthalmic instrumentation business following the October 2011 sale, of the business to Optos, Inc., a subsidiary of Optos plc (collectively Optos ). The 2011 results reflect the operating loss of our ophthalmic instrumentation business for that period. Following our sale to Optos, we no longer have ongoing operations related to that business.

*Income taxes.* Our income tax benefit reflects the income tax benefit resulting from our businesses in Chile, Spain and Mexico. Our Israeli operations will benefit from a tax holiday during 2012. We have recorded a full valuation allowance against our deferred tax assets in the U.S. for both periods.

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011**

*Revenues.* Revenues for the nine months ended September 30, 2012 were \$30.8 million, compared to \$22.2 million for the comparable 2011 period. The increase in revenues during the nine months ended September 30, 2012 is primarily due to \$4.7 million of revenues generated by Fine Tech, which we acquired in December 2011, \$2.0 million of revenues generated by Farmadiet following our August 2012 acquisition, \$2.1 million of revenues generated in Chile primarily related to the ALS acquisition in April 2012 and \$0.7 million of deferred revenue recognized in connection with our agreements with Neovasc and our molecular diagnostics collaboration agreements, partially offset by decreased revenues from our Mexican operations of \$0.8 million.

*Gross margin.* Gross margin for the nine months ended September 30, 2012 was \$11.8 million, compared to \$9.1 million for the comparable period of 2011. Gross margin for the nine months ended September 30, 2012, increased from the 2011 period primarily as a result of the gross margin of \$3.1 million generated by FineTech, \$1.2 million of gross margin generated by Farmadiet and \$0.7 million of deferred revenue recognized in connection with our agreements with Neovasc and our molecular diagnostics collaboration agreements. These increases were partially offset by a decrease in gross margin generated by our Chilean pharmaceutical business, primarily as a result of a \$1.2 million provision for inventory obsolescence recorded in the 2012 period along with decreased gross margin of \$0.6 million from our Mexican operations compared to the 2011 period.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for the nine months ended September 30, 2012 were \$17.4 million, compared to \$14.1 million for the comparable period of 2011. The increase in selling, general and administrative expenses is primarily the result of increased personnel expenses, professional fees and expenses as a result of the acquisitions of Farmadiet, OPKO Diagnostics and FineTech. Selling, general and administrative expenses during the nine months ended September 30, 2012 and 2011 consist primarily of personnel expenses, including equity-based compensation expense of \$2.3 million and \$2.2 million, respectively, and professional fees.

*Research and development expenses.* Research and development expenses during the nine months ended September 30, 2012 and 2011 were \$12.9 million and \$7.1 million, respectively. The increase in research and development expenses primarily reflects activities related to our OPKO Diagnostics development programs, which we acquired in October 2011. In addition, we have also increased staffing and related activities for our CURNA, Inc. ( CURNA ) and molecular diagnostics development programs during the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011. Partially offsetting these increases, equity based compensation decreased

**Table of Contents**

during the nine months ended September 30, 2012, as compared to the nine months ended September 30, 2011, to \$1.0 million from \$3.0 million, respectively, due to lower mark to market adjustments for our consultant stock option grants. Research and development expenses for the nine months ended September 30, 2011 primarily consisted of activities related to our molecular diagnostics development programs and post-acquisition activities related to CURNA.

*Contingent consideration expenses.* Contingent consideration expenses for the nine months ended September 30, 2012 were \$2.7 million, which represent the change in the fair value of the contingent consideration liabilities due to the time value of money. Contingent consideration liabilities relates to potential amounts payable to former stockholders of Farmadiet, FineTech and OPKO Diagnostics pursuant to our agreements to acquire those entities in August 2012, December 2011 and October 2011, respectively. The comparable period of 2011 did not include any such expenses.

*Other operating expenses.* Other operating expenses were \$6.3 million for the nine months ended September 30, 2012, compared to \$2.6 million for the comparable period of 2011. Other operating expenses primarily include the amortization of intangible assets. Amortization expense increased due to the acquisitions of Farmadiet, ALS, FineTech and OPKO Diagnostics in August 2012, April 2012, December 2011 and October 2011, respectively.

*Other income and (expense), net.* Other income and (expense), net was \$0.4 million for the nine months ended September 30, 2012, compared to (\$0.8) million for the comparable 2011 period. Other income and (expense), net for the nine months ended September 30, 2012 includes \$1.5 million of other income recognized for the change in fair value of the warrants received in connection with our investment in Biozone Pharmaceuticals, Inc., partially offset by other expense recognized for the decrease in fair value of the warrants received in connection with our investments in Neovasc. Other income and (expense), net also includes our interest incurred on our lines of credit in Chile and lines of credit and deferred payments in Spain, partially offset by interest earned on our cash and cash equivalents and the benefit from our Chilean and Mexico operations functional currencies strengthening during the nine months ended September 30, 2012.

*Discontinued operations.* We had \$0.2 million of income from discontinued operations for the nine months ended September 30, 2012, compared to a loss of \$2.8 million for the comparable period of 2011. The income for the nine months ended September 30, 2012 reflects the recovery of certain retained accounts receivable from our ophthalmic instrumentation business following the October 2011 sale of the business to Optos, while the 2011 results reflect the operating loss of our ophthalmic instrumentation business for that period. Following our sale of the instrumentation business to Optos, we no longer have ongoing operations related to that business.

*Income taxes.* Our income tax provision reflects the income tax in Chile, Spain and Mexico. Our Israeli operations will benefit from a tax holiday during 2012. We have recorded a full valuation allowance against our deferred tax assets in the U.S. for both periods.

**LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2012, we had cash, cash equivalents and marketable securities of approximately \$42.4 million. Cash used in operations during 2012 primarily reflects expenses related to selling, general and administrative activities related to our corporate operations, research and development activities, and our operations in Chile, Israel, Spain and Mexico. During the nine months ended September 30, 2012, we utilized approximately \$13.2 million of cash for our acquisitions of Farmadiet and ALS, as well as for our investments in Biozone and ChromaDex. Since our inception, we have not generated sufficient gross margins 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 October 2012, we entered into a definitive merger agreement to acquire Prost-Data, Inc., doing business as OURLab, a Nashville-based CLIA laboratory with 18 phlebotomy sites throughout the U.S. In connection with the transaction, we agreed to pay an aggregate purchase price of \$40.0 million, of which \$9.4 million shall be payable in cash, and \$30.6 million payable in shares of Common Stock, subject to our ability to hold back up to \$4 million of the cash otherwise payable at closing as escrow for potential indemnity claims.

In conjunction with the acquisition of Farmadiet we will pay €6.8 million (\$8.7 million) over the period ending February 2014. The payments are required to be paid in Euro and as such, the final U.S. dollar amount to be paid will be based on the exchange rate at the time the payments are made. The payments may be made at our option in cash or shares of our Common Stock.

In addition, we also entered into two ancillary transactions related to the acquisition of Farmadiet. In exchange for a forty percent interest held by one of the sellers in one of Farmadiet's subsidiaries, we agreed to issue up to an aggregate of 250,000 shares of our Common Stock, of which (a) 125,000 shares were issued on the closing date, and (b) 125,000 will be issued upon achieving certain milestones. We also acquired an interest held by an affiliate of Farmadiet in a product in development in exchange for which we agreed to pay up to an aggregate of \$1.1 million payable at our option in cash or shares of our Common Stock, of which (a) \$0.3 million was paid at closing through delivery of 70,421 shares of

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

our Common Stock, and \$0.8 million will be paid in cash or shares of our Common Stock upon achieving certain milestones. The final U.S. dollar amount to be paid will be based on the exchange rate of the time the milestones are achieved.

---

**Table of Contents**

In connection with the acquisition of ALS, we paid (i) \$2.4 million in cash at the closing, less certain liabilities, and (ii) \$0.8 million in cash at the closing into a separate escrow account to satisfy possible indemnity claims. We agreed to pay an additional \$0.8 million, the remainder of the \$4.0 million purchase price, upon the legal registration in the name of ALS of certain trademarks and product registrations previously held by the seller Arama Laboratorios y Compañía Limitada.

In connection with our acquisitions of CURNA, OPKO Diagnostics and FineTech, 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, and up to an additional \$19.1 million in shares of the our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones.

As of September 30, 2012, we had outstanding lines of credit in the aggregate amount of \$15.9 million with 15 financial institutions in Chile and Spain, with an additional \$6.4 million available for additional borrowings. The weighted average interest rate on these lines of credit is approximately 7% for the nine months ended September 30, 2012. These lines of credit are short-term and are generally due within three months. We use these lines of credit primarily as a source of working capital for inventory purchases. The highest balance at any time during the three months ended September 30, 2012, was \$15.9 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

Our unutilized \$12.0 million line of credit with the Frost Group, LLC expired on March 31, 2012 and no amounts were borrowed after June 2, 2010 when it was repaid in full. The Frost Group members include a trust controlled by Dr. Frost, who is the Company's Chief Executive Officer and Chairman of our Board of Directors, Dr. Hsiao, who is the Vice Chairman of our Board of Directors and Chief Technical Officer and Mr. Rubin who is Executive Vice President - Administration and a director of the Company.

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 the cash, cash equivalents, and marketable securities on hand at September 30, 2012 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 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.

We intend to finance additional research and development projects, clinical trials and our future operations with a combination of available cash on hand, payments from potential strategic research and development, licensing and/or marketing arrangements, public offerings, private placements, debt financing and revenues from future product sales, if any. There can be no assurance, however, that additional capital will be available to us on acceptable terms, or at all.

**Table of Contents****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.

*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 significant analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model. We also perform significant analyses to estimate forfeitures of equity-based awards. We are required to adjust our forfeiture estimates on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates may have a material impact on our Consolidated Financial Statements.

*Goodwill and intangible assets.* The allocation of the purchase price for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination.

Purchase price allocations and appraisals inherently require significant estimates and assumptions, including but not limited to, determining the timing and estimated costs to complete the in-process research and development projects, projecting regulatory approvals, estimating future cash flows, and developing appropriate discount rates. We believe the estimated fair values assigned to the ALS, OPKO Diagnostics, FineTech and Farmadiet assets acquired and liabilities assumed are based on reasonable assumptions. However, the fair value estimates for the purchase price allocation may change during the allowable allocation period, which is up to one year from the acquisition date, if additional information becomes available that would require changes to our estimates.

*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.

*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 the risk of product returns. 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 consolidated balance sheets at September 30, 2012 and December 31, 2011 was \$0.3 million and \$0.4 million, respectively.

*Recent accounting pronouncements.* On January 1, 2012, we adopted an amendment issued by the Financial Accounting Standards Board ( FASB ) to the accounting standards related to fair value measurements and disclosure requirements. This amendment revises the existing guidance on the use and application of fair value measurements and maintains a definition of fair value that is based on the notion of exit price. The adoption of this amendment did not have a material impact on our condensed consolidated financial statements.

On January 1, 2012, we adopted amendments issued by the FASB to the accounting standards related to the presentation of comprehensive income. These amendments revise the manner in which entities present comprehensive income in their financial statements and remove the option to present items of other comprehensive income in the statement of changes in stockholders' equity. These amendments require an entity to report

---

**Table of Contents**

components of comprehensive income in either (1) a continuous statement of comprehensive income, or (2) two separate but consecutive statements of net income and other comprehensive income. We modified our condensed consolidated financial statements presentation using the latter alternative.

On January 1, 2012, we adopted revised guidance issued by the FASB related to the testing of goodwill for impairment. Under the revised guidance, an entity has the option to perform a qualitative assessment of whether it is more-likely-than-not that a reporting unit's fair value is less than its carrying value prior to performing the two-step quantitative goodwill impairment test. If, based on the qualitative factors, an entity determines that the fair value of the reporting unit is greater than its carrying amount, then the entity would not be required to perform the two-step quantitative impairment test for that reporting unit. However, if the qualitative assessment indicates that it is not more-likely-than-not that the reporting unit's fair value exceeds its carrying value, then the quantitative assessment must be performed. An entity is permitted to perform the qualitative assessment on none, some or all of its reporting units and may also elect to bypass the qualitative assessment and begin with the quantitative assessment of goodwill impairment. This amendment did not have a material impact on our condensed consolidated financial statements.

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

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

**Foreign Currency Exchange Rate Risk** 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 and swaps, 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 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 enter into these contracts with counterparties that we believe to be creditworthy and do not enter into any leveraged derivative transactions. We had \$3.4 million in foreign exchange forward contracts outstanding at September 30, 2012, primarily to hedge Chilean-based operating cash flows against US dollars. If Chilean Pesos were to strengthen in relation to the US 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, 2012, we had cash, cash equivalents and marketable securities of \$42.4 million. The weighted average interest rate earned related to our cash and cash equivalents for the three months ended September 30, 2012 was approximately 0%. As of September 30, 2012, the outstanding amount under our credit lines was \$15.9 million at a weighted average interest rate of approximately 7% for the nine months ended September 30, 2012.

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.



**Table of Contents**

**Item 4. Controls and Procedures**

***Disclosure Controls and Procedures***

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer ( CEO ) and Chief Financial Officer ( CFO ), has evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Securities and Exchange Commission ( SEC ) Rule 13a-15(e) as of September 30, 2012. Based on that evaluation, the CEO and CFO have concluded that the Company's disclosure controls and procedures were effective as of such date to ensure that information the Company is required to disclose in reports that it files or submits under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

***Changes in Internal Control Over Financial Reporting***

In connection with the Farmadiet Group Holding, S.L., ( Farmadiet ) and FineTech Pharmaceuticals Ltd., ( FineTech ) acquisitions in August 2012 and December 2011, respectively, we began implementing standards and procedures at Farmadiet and FineTech 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 Farmadiet and FineTech. Other than as set forth above with respect to Farmadiet and FineTech, there have been no changes to the Company's internal control over financial reporting that occurred during the Company's third fiscal quarter of 2012 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

FineTech's assets constituted \$36.7 million and \$28.3 million of total and net assets, respectively, as of September 30, 2012. FineTech's revenue for the three and nine months ended September 30, 2012 constituted \$1.5 million and \$4.7 million of revenue, respectively. In addition, FineTech's net loss constituted \$0.3 million and \$1.0 million of net loss for the three and nine months ended September 30, 2012, respectively.

Farmadiet's assets constituted \$31.3 million and \$9.2 million of total and net assets, respectively, as of September 30, 2012. Farmadiet's revenue for both the three and nine months ended September 30, 2012 constituted \$2.0 million of revenue. In addition, Farmadiet's net loss constituted \$0.3 million of net loss for both the three and nine months ended September 30, 2012.

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are a party to 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.

**Item 1A. Risk Factors**

There have been no material changes from the risk factors as previously disclosed in the Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not Applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits.**

Exhibit 2.8+	Stock Purchase Agreement, dated August 2, 2012, among Farmadiet Group Holding, S.L., the Sellers party thereto, and Shebeli XXI, S.L.U.
Exhibit 3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation.
Exhibit 3.2 <sup>(2)</sup>	Amended and Restated By-Laws.
Exhibit 3.3 <sup>(3)</sup>	Certificate of Designation of Series D Preferred Stock.
Exhibit 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, 2012.
Exhibit 31.2	Certification by Juan Rodriguez, 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, 2012.
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, 2012.
Exhibit 32.2	Certification by Juan Rodriguez, 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, 2012.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.

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

101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

**Table of Contents**

- \* As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of sections 11 and 12 of the Securities Act of 1933, as amended, or section 18 of the Securities Exchange Act of 1934, as amended.
- + Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.
- (1) Filed with the Company's Current Report on Form 8-A filed with the Securities and Exchange Commission on June 11, 2007, 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.

**Table of Contents**

**SIGNATURES**

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

Date: November 9, 2012

**OPKO Health, Inc.**

/s/ Adam Logal  
Adam Logal  
Vice President, Finance, Chief Accounting

Officer and Treasurer

38

**Table of Contents****Exhibit Index**

<b>Exhibit Number</b>	<b>Description</b>
Exhibit 2.8+	Stock Purchase Agreement, dated August 2, 2012, among Farmadiet Group Holding, S.L., the Sellers party thereto, and Shebeli XXI, S.L.U.
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, 2012.
Exhibit 31.2	Certification by Juan Rodriguez, 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, 2012.
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, 2012.
Exhibit 32.2	Certification by Juan Rodriguez, 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, 2012.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

\* As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of sections 11 and 12 of the Securities Act of 1933, as amended, or section 18 of the Securities Exchange Act of 1934, as amended.

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