

Opko Health, Inc.
Form 10-Q
May 10, 2013
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 March 31, 2013.

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

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

Large accelerated filer Accelerated filer

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

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 April 30, 2013, the registrant had 336,737,265 shares of common stock outstanding.

Table of Contents

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2013 and December 31, 2012 (unaudited)</u>	6
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2013 and March 31, 2012 (unaudited)</u>	7
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2013 and March 31, 2012 (unaudited)</u>	8
<u>Condensed Consolidated Statements of Shareholders' Equity (unaudited)</u>	9
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2013 and March 31, 2012 (unaudited)</u>	10
<u>Notes to Financial Statements (unaudited)</u>	11
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	31
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	37
<u>Item 4. Controls and Procedures</u>	38
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	39
<u>Item 1A. Risk Factors</u>	39
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	39
<u>Item 3. Defaults Upon Senior Securities</u>	39
<u>Item 4. Mine Safety Disclosures</u>	39
<u>Item 5. Other Information</u>	39
<u>Item 6. Exhibits</u>	39
<u>Signatures</u>	41
<u>Exhibit Index</u>	42
EX-2.10	Share Purchase Agreement dated January 8, 2013
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, 2012, 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 may require substantial additional funding, which may not be available to us on acceptable terms, or at all.

We may finance future cash needs primarily through public or private offerings, debt financings or strategic collaborations, which may dilute your stockholdings in the Company.

If our competitors develop and market products that are more effective, safer or less expensive than our future product candidates, our commercial opportunities will be negatively impacted.

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

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

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

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

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

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 Israeli, Mexican, and Spanish 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, Mexico, Spain, and Brazil for sales in those countries and our active pharmaceutical ingredients (APIs) business in Israel, and the sales force for our laboratory business based in Nashville, Tennessee. If we are unable to develop our sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical product candidates.

The success of our business will be heavily dependent on the success of Phase 3 clinical trials for CTAP101 Capsules and Fermagate Tablets.

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

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

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

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

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.

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

We rely heavily on licenses from third parties.

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

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

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

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

Table of Contents

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.

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

We may encounter difficulties in integrating acquired businesses.

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

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

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

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.

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

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**O PKO Health, Inc. and Subsidiaries****CONDENSED CONSOLIDATED BALANCE SHEETS**

(unaudited)

(In thousands except share and per share data)

	March 31, 2013 ⁽¹⁾	December 31, 2012 ⁽¹⁾
ASSETS		
Current assets		
Cash and cash equivalents	\$ 181,596	\$ 27,361
Accounts receivable, net	21,170	21,162
Inventory, net	23,022	22,261
Prepaid expenses and other current assets	11,895	7,873
Total current assets	237,683	78,657
Property, equipment, and investment properties, net	16,750	16,526
Intangible assets, net	82,354	84,238
In-process research and development	203,030	11,546
Goodwill	82,709	80,450
Investments, net	28,546	15,636
Other assets	2,863	2,777
Total assets	\$ 653,935	\$ 289,830
LIABILITIES, SERIES D PREFERRED STOCK, AND EQUITY		
Current liabilities		
Accounts payable	\$ 11,287	\$ 10,200
Accrued expenses	26,673	24,656
Current portion of lines of credit and notes payable	20,264	17,526
Total current liabilities	58,224	52,382
3.00% convertible senior notes, net of discount and estimated fair value of embedded derivatives	196,421	
Other long-term liabilities, principally contingent consideration and deferred tax liabilities	79,512	34,168
Total long-term liabilities	275,933	34,168
Total liabilities	334,157	86,550
Commitments and contingencies		
Series D preferred stock - \$0.01 par value, 2,000,000 shares authorized; no shares issued or outstanding at March 31, 2013 and 1,129,032 shares issued and outstanding (liquidation value of \$30,595) at December 31, 2012		24,386

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

Equity		
Series A Preferred stock - \$0.01 par value, 4,000,000 shares authorized; no shares issued or outstanding at March 31, 2013 and December 31, 2012, respectively		
Series C Preferred Stock - \$0.01 par value, 500,000 shares authorized; no shares issued or outstanding at March 31, 2013 or December 31, 2012		
Common Stock - \$0.01 par value, 500,000,000 shares authorized; 338,828,976 and 305,560,763 shares issued at March 31, 2013 and December 31, 2012, respectively	3,388	3,056
Treasury stock - 2,293,056 shares at both March 31, 2013 and December 31, 2012	(7,457)	(7,457)
Additional paid-in capital	739,778	565,201
Accumulated other comprehensive income	8,093	7,356
Accumulated deficit	(422,985)	(388,770)
Total shareholders' equity	320,817	179,386
Noncontrolling interests	(1,039)	(492)
Total equity	319,778	178,894
Total liabilities, Series D Preferred Stock, and equity	\$ 653,935	\$ 289,830

- (1) As of March 31, 2013 and December 31, 2012, total assets include \$5.7 million and \$5.6 million, respectively, and total liabilities include \$6.2 million and \$5.5 million, respectively related to SciGen (I.L.) Ltd, (SciGen), a consolidated variable interest entity. SciGen's consolidated assets are owned by SciGen and SciGen's consolidated liabilities are those as to which there is no recourse against us. Refer to Note 5.

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 March 31,	
	2013	2012
Revenues:		
Products	\$ 15,527	\$ 8,639
Revenue from services	3,092	87
Revenue from transfer of intellectual property	12,757	51
Total revenues	31,376	8,777
Cost of revenues, excluding amortization of intangible assets	11,757	4,987
Gross margin, excluding amortization of intangible assets	19,619	3,790
Operating expenses:		
Selling, general and administrative	12,424	4,671
Research and development	9,910	4,831
Contingent consideration	1,344	1,144
Amortization of intangible assets	2,714	1,991
Total operating expenses	26,392	12,637
Loss from operations	(6,773)	(8,847)
Other income and (expense), net:		
Interest income	59	27
Interest expense	(2,897)	(351)
Fair value changes of derivative instruments, net	(23,549)	1,117
Other income, net	2,331	181
Other income and (expense), net	(24,056)	974
Loss before income taxes and investment losses	(30,829)	(7,873)
Income tax provision	43	215
Loss before investment losses	(30,872)	(8,088)
Loss from investments in investees	(3,890)	(523)
Net loss	(34,762)	(8,611)
Less: Net loss attributable to noncontrolling interests	(547)	
Net loss attributable to common shareholders before preferred stock dividend	(34,215)	(8,611)
Preferred stock dividend	(420)	(560)
Net loss attributable to common shareholders	\$ (34,635)	\$ (9,171)
Basic and diluted loss per share	\$ (0.11)	\$ (0.03)
Weighted average number of common shares outstanding, basic and diluted	312,932,561	297,543,066

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

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 March 31,	
	2013	2012
Net loss attributable to common shareholders	\$ (34,635)	\$ (9,171)
Other comprehensive income (loss), net:		
Change in foreign currency translation	323	1,390
Available for sale investments:		
Change in other net unrealized gains, net	414	109
Comprehensive loss	\$ (33,898)	\$ (7,672)

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 STATEMENT OF SHAREHOLDERS EQUITY

(unaudited)

(In thousands, except share and per share data)

For the three months ended March 31, 2013

	Common Stock		Treasury		Additional Paid-In Capital	Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total
	Shares	Dollars	Shares	Dollars					
Balance at December 31, 2012	305,560,763	\$ 3,056	(2,293,056)	\$ (7,457)	\$ 565,201	\$ 7,356	\$ (388,770)	\$ (492)	\$ 178,894
Equity-based compensation expense					5,205				5,205
Exercise of Common Stock options	433,250	4			901				905
Exercise of Common Stock warrants	962,929	9			81				90
Series D Preferred Stock dividend					(3,015)				(3,015)
Conversion of Series D Preferred Stock	11,290,320	113			24,273				24,386
Issuance of Common Stock in connection with Silcon acquisition at \$6.73 per share	64,684	1			435				436
Issuance of Common Stock in connection with Cytochroma acquisition at \$7.16 per share	20,517,030	205			146,697				146,902
Net loss attributable common shareholders before preferred stock dividend for the three months ended March 31, 2013							(34,215)		(34,215)
Net loss attributable to noncontrolling interests for the three months ended March 31, 2013								(547)	(547)
Other comprehensive income						737			737
Balance at March 31, 2013	338,828,976	\$ 3,388	(2,293,056)	\$ (7,457)	\$ 739,778	\$ 8,093	\$ (422,985)	\$ (1,039)	\$ 319,778

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

(unaudited)

(In thousands)

	For the three months ended March 31,	
	2013	2012
Cash flows from operating activities		
Net loss	\$ (34,762)	\$ (8,611)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,429	2,328
Non-cash interest on convertible senior notes	1,303	
Amortization of deferred financing costs	145	
Losses from investments in investees	3,890	523
Equity-based compensation employees and non-employees	5,205	1,180
Provision for (recovery of) bad debts	381	(151)
Provision for inventory obsolescence	939	255
Revenue from receipt of equity	(12,540)	(51)
Realized gain on investments available for sale	(2,347)	
Change in fair value of derivatives instruments	23,549	(1,117)
Change in fair value of contingent consideration	1,344	1,144
Deferred income tax benefit	98	
Changes in assets and liabilities of continuing operations, net of the		
effects of acquisitions:		
Accounts receivable	(558)	(2,691)
Inventory	(1,439)	(4,433)
Prepaid expenses and other current assets	(2,570)	(481)
Other assets	71	7
Accounts payable	(103)	(271)
Foreign currency measurement	(340)	(458)
Accrued expenses	(440)	1,253
Cash used in operating activities of continuing operations	(14,745)	(11,574)
Cash provided in operating activities of discontinued operations		75
Net cash used in operating activities	(14,745)	(11,499)
Cash flows from investing activities:		
Investments in investees	(2,500)	(2,700)
Proceeds from sale of investments available for sale	2,528	
Acquisition of businesses, net of cash	78	
Purchase of marketable securities		(14,997)
Capital expenditures	(755)	(175)
Net cash used in investing activities	(649)	(17,872)
Cash flows from financing activities:		
Issuance of 3.00% convertible senior notes, net (including related parties)	170,184	
Payment of Series D dividends, including related parties	(3,015)	
Proceeds from the exercise of Common Stock options and warrants	995	31
Borrowings on lines of credit	8,428	10,337

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

Repayments of lines of credit and capital lease obligations	(6,951)	(5,490)
Net cash provided by financing activities	169,641	4,878
Effect of exchange rate on cash and cash equivalents	(12)	95
Net increase (decrease) in cash and cash equivalents	154,235	(24,398)
Cash and cash equivalents at beginning of period	27,361	71,516
Cash and cash equivalents at end of period	\$ 181,596	\$ 47,118

SUPPLEMENTAL INFORMATION

Interest paid	\$ 242	\$ 177
Income taxes refunded	\$ (118)	\$ (6)
RXi common stock received	\$ 12,500	\$
Non-cash financing:		
Shares issued upon the conversion of:		
Series D Preferred Stock	\$ 24,386	\$
Common Stock warrants, net exercised	\$ 815	\$
Issuance of Common Stock to acquire:		
Cytochroma	\$ 146,902	\$
Silcon	\$ 436	\$

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 biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. We are developing a range of solutions to diagnose, treat and prevent various conditions, including 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. In addition, we recently established pharmaceutical operations in Brazil. We also operate a specialty active pharmaceutical ingredients (APIs) manufacturer in Israel, which we expect to play a valuable role in the development of our pipeline of molecules and compounds for our proprietary molecular diagnostic and therapeutic products. We operate a laboratory business with laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), that has a strong presence in the U.S. urologic pathology market, and will provide us with a platform to commercialize certain of our novel diagnostics tests currently in development. We operate a development stage pharmaceutical company, with operations in the United States and Canada, which is engaged in the development of a vitamin D prohormone to treat secondary hyperparathyroidism (known as CTAP 101 Capsules), and of a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients. We also own an interest in a biopharmaceutical company that develops, manufactures and markets recombinant human health care biotechnology derived products in Israel and whose principal marketed product is a novel third generation Hepatitis B vaccine currently being commercialized in Israel, India and Hong Kong.

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 and warehouse space in Woburn, Massachusetts for our point-of-care diagnostics business, and in Neshar, Israel for our API business. We lease laboratory and office space in Nashville, Tennessee and Burlingame, California for our CLIA-certified laboratory business, and we lease office space in Bannockburn, Illinois, and Markham, Ontario and laboratory space in Toronto, Ontario for the Cytochroma business. Our Chilean operations are located in leased offices and warehouse facilities in Santiago. Our Mexican operations are based in owned offices, an owned manufacturing facility and a leased warehouse facility in Guadalajara. Our Spanish operations are based in owned offices in Barcelona, in an owned manufacturing facility in Banyoles and a leased warehouse facility in Palol de Revardit. Our Brazilian operations are located in leased offices in Sao Paulo.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and notes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three months ended March 31, 2013, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2013 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, 2012.

Reclassifications. Certain prior year amounts in the condensed consolidated financial statements have been reclassified to conform with the 2013 presentation. Due to the acquisition of Prost-Data, Inc., a CLIA-certified laboratory business, (OURLab) in December 2012, we changed our segment presentation to include diagnostics as a reportable segment. As a result of this change in reportable segments, we restated certain prior year amounts in the condensed consolidated financial statements to conform with the 2013 presentation. These reclassifications had no impact on our results of operations. Refer to Note 12.

Principles of consolidation. The accompanying unaudited condensed consolidated financial statements include the accounts of OPKO Health, Inc., our wholly-owned subsidiaries and variable interest entities (VIEs) in which we are deemed to be the primary beneficiary. All significant intercompany accounts and transactions are eliminated in consolidation.

Table of Contents

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

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

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

Goodwill and Intangible Assets. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired when accounted for by the purchase method of accounting and arose from our acquisitions. Goodwill and other intangible assets acquired in business combinations, licensing and other transactions at March 31, 2013 and December 31, 2012 were \$368.1 million and \$176.2 million, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. We determined the fair value of intangible assets, including in-process research and development (IPR&D), using the income method.

Goodwill is tested at least annually for impairment, or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, on an enterprise level by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value.

Fair value measurements. The carrying amounts of our cash and cash equivalents, accounts receivable and accounts payable approximate their fair value due to the short-term maturities of these instruments. Investments that are considered available for sale as of March 31, 2013 are carried at fair value.

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

In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts. Accordingly, the estimates of fair value presented herein may not be indicative of the amounts that could be realized in a current market exchange. Refer to Note 8.

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

Derivative financial instruments. We record derivative financial instruments on our balance sheet at their fair value and the changes in the fair value are recognized in Fair value changes of derivatives instruments, net, when they occur, the only exception being derivatives that qualify as hedges. For the derivative instrument to qualify as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At March 31, 2013 and December 31, 2012, 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 in Fair value changes of derivatives instruments, net. Refer to Note 8. Changes in fair value of our common stock option and common stock warrants holdings of our available for sale investments are recognized in either Other income, net, or Other comprehensive loss. Refer to Note 8. In addition, based on specific terms of the Notes (defined in Note 6) that

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

we issued in January 2013, we have determined that those terms are considered to be embedded derivatives and recorded them at fair value. Refer to Note 6. The changes in fair value of the embedded derivatives are recognized in Fair value changes of derivatives instruments, net. Refer to Note 8.

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

increase or decrease the risk of product returns.

Revenue for services is recognized on the accrual basis at the time test results are reported, which approximates when services are provided. Services are provided to certain patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in sales net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue. For the three months ended March 31, 2013 and 2012, revenue for services also includes \$0.2 million and \$0.1 million, respectively, of revenue related to our consulting agreement with Neovasc, Inc. (Neovasc) and to revenue related to molecular diagnostics collaboration agreements. We recognize this revenue on a straight-line basis over the contractual term of the agreements.

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

Table of Contents

Non-refundable license fees for the out-license of our technology are recognized depending on the provisions of each agreement. We recognize non-refundable upfront license payments as revenue upon receipt if the license has standalone value and 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. For the three months ended March 31, 2013, we recorded \$12.8 million of Revenue from the transfer of intellectual property, of which \$12.5 million related to the sale of substantially all of our assets in the field of RNA interference to RXi Pharmaceuticals Corporation (RXi). Refer to Note 5.

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 included in Accrued expenses and Other long-term liabilities was \$3.1 million and \$1.9 million at March 31, 2013 and December 31, 2012, respectively.

Allowance for doubtful accounts. We analyze accounts receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by our estimate of the collectability of accounts receivable. The amount of allowance for doubtful accounts was \$0.7 million and \$0.5 million at March 31, 2013 and December 31, 2012, respectively.

Equity-based compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the 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 March 31, 2013 and 2012, we recorded \$5.2 million and \$1.2 million, respectively, of equity-based compensation expense.

Segment reporting. Our chief operating decision-maker (CODM) is comprised of our executive management with the oversight of our Board of Directors. Our CODM reviews our operating results and operating plans and makes resource allocation decisions on a Company-wide or aggregate basis. We currently manage our operations in two reportable segments, pharmaceuticals and diagnostics. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, and vaccines, and (ii) the pharmaceutical operations we acquired in Chile, Mexico, Israel, Spain and Brazil. The diagnostics segment consists of two operating segments, our (i) pathology operations we acquired through the acquisition of OURLab and (ii) point-of-care and molecular diagnostics operations. There are no inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

Table of Contents

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

Investments. We have made strategic investments in development stage and emerging companies. We record these investments as equity method investments or investments available for sale based on our percentage of ownership and whether we have significant influence over the operations of the investees. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Losses from investments in investees in our Condensed Consolidated Statement of Operations. Refer to Note 5. For investments classified as available for sale, we record changes in their fair value as unrealized gain or loss in Other comprehensive loss based on their closing price per share at the end of each reporting period. Refer to Note 5.

Recent accounting pronouncements. In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income, (ASU 2013-02). ASU 2013-02 requires the presentation of reclassifications out of accumulated other comprehensive income in either (1) the notes or (2) the face of the financial statements. We adopted ASU 2013-02 for our first quarter ended March 31, 2013. The adoption of ASU 2013-02 did not have a material impact in our condensed consolidated financial statements, but did require certain additional disclosures. Refer to Note 7.

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. Potentially dilutive shares issuable pursuant to the Notes (defined in Note 6) were not included in the computation of net loss per share for the three months ended March 31, 2013, because their inclusion would be anti-dilutive.

Also, a total of 30,119,145 and 27,416,029 potential common shares have been excluded from the calculation of net loss per share for the three months ended March 31, 2013 and 2012, respectively, because their inclusion would be anti-dilutive.

During the three months ended March 31, 2013, 1,511,693 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 1,396,179 shares of Common Stock. Of the 1,511,693 Common Stock options and Common Stock warrants exercised, 115,514 shares were surrendered in lieu of a cash payment via the net exercise feature of the warrant agreements.

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

(In thousands)	March 31, 2013	December 31, 2012
Accounts receivable, net		
Accounts receivable	\$ 21,839	\$ 21,636
Less: allowance for doubtful accounts	(669)	(474)
	\$ 21,170	\$ 21,162
Inventories, net		
Finished products	\$ 19,177	\$ 17,963
Work in-process	970	688
Raw materials	5,152	4,923
Less: inventory reserve	(2,277)	(1,313)
	\$ 23,022	\$ 22,261
Intangible assets, net		
Technology	\$ 52,740	\$ 52,810
Customer relationships	23,151	23,088
Product registrations	9,660	9,637
Tradename	3,757	3,746
Covenants not to compete	8,660	8,662
Other	1,242	367
Less: accumulated amortization	(16,856)	(14,072)
	\$ 82,354	\$ 84,238
Accrued expenses		
Income taxes payable	\$ 1,789	\$ 1,614
Deferred revenue	1,593	1,518
Clinical trials	184	50
Professional fees	601	675
Employee benefits	3,533	3,319
Deferred acquisition payments, net of discount	5,298	6,172
Contingent consideration	5,151	5,126
Other	8,524	6,182
	\$ 26,673	\$ 24,656
Other long-term liabilities:		
Contingent consideration - Cytochroma	\$ 48,110	\$
Contingent consideration - Farmadiet	513	532
Contingent consideration - OPKO Diagnostics	12,006	11,310
Contingent consideration - FineTech		2,578
Contingent consideration - CURNA	528	510
Deferred acquisition payments, net of discount	3,868	3,931
Mortgages and other debts payable	3,706	5,150
Deferred tax liabilities	9,206	9,777
Other, including deferred revenue	1,575	380
	\$ 79,512	\$ 34,168

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

The change in value of the intangible assets and goodwill are primarily due to the acquisitions of Silcon Comércio, Importacao E Exportacao de Produtos Farmaceuticos e Cosmeticos Ltda, (Silcon), and Cytochroma Inc., (Cytochroma), as well as the foreign currency fluctuations between the Chilean and Mexican pesos and the Euro against the U.S. dollar at March 31, 2013 and December 31, 2012.

NOTE 5 ACQUISITIONS, INVESTMENTS, AND LICENSES

Cytochroma acquisition

On March 4, 2013, we acquired Cytochroma, a corporation located in Markham, Canada, whose lead products, both in Phase 3 development, are CTAP101 Capsules, a vitamin D prohormone to treat secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency, and Fermagate Tablets, a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients (the Cytochroma Acquisition).

Table of Contents

In connection with the Cytochroma Acquisition, we delivered 20,517,030 of shares of our Common Stock valued at \$146.9 million based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or \$7.16 per share. The number of shares issued was based on the volume-weighted average price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the date of the purchase agreement for the Cytochroma Acquisition, or \$4.87 per share. The Cytochroma Agreement contains customary representations, warranties, conditions to closing, indemnification rights and obligations of the parties.

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

The following table summarizes the estimated fair value of the net assets acquired and liabilities assumed in the acquisition of Cytochroma 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 \$378 thousand)	\$ 1,224
Intangible assets:	
In-process research and development	191,530
Patents	210
Total intangible assets	191,740
Goodwill	2,411
Plant and equipment	306
Accounts payable and accrued expenses	(1,069)
Total purchase price	\$ 194,612

Goodwill is principally related to the acquired workforce. Goodwill is not tax deductible for income tax purposes.

Silcon asset acquisition

On February 15, 2013, we acquired the assets of Silcon Comércio, Importacao E Exportacao de Produtos Farmaceuticos e Cosmeticos Ltda. (Silcon), a Brazilian pharmaceutical company, pursuant to a purchase agreement entered into on December 26, 2012. Pursuant to the purchase agreement, we paid \$0.3 million in cash and delivered 64,684 shares of our Common Stock at closing valued at \$0.4 million based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or \$6.73 per share. The number of shares issued was based on the average closing price per share of Common Stock as reported on the NYSE for the 10 trading days immediately preceding the execution of the purchase agreement, or \$4.64 per share.

We accounted for this acquisition as an asset acquisition rather than a business combination. As a result we recorded the assets at fair value, with most of the value being allocated to the most significant asset, its pharmaceutical business licenses.

OURLab acquisition

In October 2012, we entered into a definitive merger agreement to acquire OURLab, a Nashville-based CLIA laboratory with 17 phlebotomy sites throughout the U.S. In December 2012, we paid \$9.4 million in cash and delivered 7,072,748 shares of our Common Stock at closing valued at \$32.9 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 \$4.65 per share. The number of shares issued was based on the average closing price per share of our Common Stock as reported on the NYSE for the 15 trading days immediately preceding the execution of the purchase agreement, or \$4.33 per share. Pursuant to the merger agreement, 1,732,102 shares of the stock consideration issued in the transaction are being held in a separate escrow account to secure the indemnification obligations of OURLab.

Table of Contents*Farmadiet acquisition*

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

In connection with the Farmadiet 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 price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the applicable payment date. We have the right to hold back up to 2.8 million (approximately \$3.6 million as of March 31, 2013) from the Deferred Payment to satisfy indemnity claims.

In connection with the Farmadiet Transaction, we also entered into two ancillary transactions (the Ancillary Transactions). In exchange for a 40% 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 (\$1.3 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% (\$1.0 million) will be paid in cash or shares of our Common Stock upon achieving certain milestones. As a result, we recorded \$1.2 million as contingent consideration for the future consideration. We evaluate the contingent consideration on an ongoing basis and the changes in fair value are recognized in earnings until the milestones are achieved. Refer to Note 8. 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 Distribuidora Limitada (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. During the three months ended March 31, 2013, we paid the remaining \$0.8 million that we had agreed to pay upon the legal registration in the name of ALS of certain trademarks and product registrations previously held by Arama Laboratorios y Compañía Limitada.

Pro forma disclosure for acquisitions

The following table includes the pro forma results for the three months ended March 31, 2013 and 2012 of the combined companies as though the acquisition of Cytochroma had been completed as of the beginning of each period, respectively.

(In thousands)	For the three months ended March	
	2013	2012
Revenues	\$ 31,376	\$ 10,958
Net loss	\$ (35,276)	\$ (9,210)
Net loss attributable to common shareholders	\$ (35,149)	\$ (9,766)
Basic and diluted loss per share	\$ (0.11)	\$ (0.03)

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

We incurred a pre-tax loss related to the activities of Cytochroma of \$2.3 million from the date of our acquisition through March 31, 2013.

Table of Contents*Investments*

The total assets, liabilities, and net losses of our equity method investees as of and for the three months ended March 31, 2013 were \$47.5 million, \$15.1 million, and \$21.0 million, respectively. The following table reflects our maximum exposure, accounting method, ownership interest and underlying equity in net assets of each of our unconsolidated investments as of March 31, 2013:

(Dollars in thousands)	Year invested	Accounting method	Ownership at March 31, 2013	Investment	Underlying equity in net assets	Closing share price at March 31, 2013 for investments available for sale
Sorrento	2009	Equity method	20%	\$ 2,300	\$ 1,219	
Cocrystal	2009	Equity method	16%	2,500	675	
Neovasc	2011	Equity method, warrants available for sale	4%	2,013	287	
Fabrus	2010	VIE, equity method	13%	650	(28)	
BZNE common stock	2012	VIE, equity method	12%	1,276	(302)	
RXi	2013	Equity method	21%	15,000	3,766	
TESARO	2010	Investment available for sale	1%	550		\$21.96
Neovasc options	2011	Investment available for sale	N/A	925		CA\$ 2.60
BZNE Note and conversion feature	2012	VIE, investment available for sale	N/A	1,700		
ChromaDex	2012	Investment available for sale	1%	1,320		\$ 0.71
Plus unrealized gains on investments, options and warrants, net				8,920		
Less accumulated losses in investees				(8,608)		
Total carrying value of equity method investees and investments, available for sale				\$ 28,546		

RXi transaction

An element of our growth strategy is to leverage our proprietary technology through a combination of internal development, acquisition, and external partnerships to maximize the commercial opportunities for our portfolio of proprietary pharmaceutical and diagnostic products. Consistent with this strategy, in March 2013, we completed the sale to RXi of substantially all of our assets in the field of RNA interference (the RNAi Assets) (collectively, the Asset Purchase Agreement). As consideration for the RNAi Assets, at the closing of the Asset Purchase Agreement, RXi issued to us 50 million shares of its common stock (the APA Shares). In accounting for the sale of the RNAi Assets, we determined that we did not have any continuing involvement in the development of the RNAi Assets or any other future performance obligations and, as a result, during the three months ended March 31, 2013, we recognized the APA Shares as \$12.5 million of Revenue from transfer of intellectual property in our Condensed Consolidated Statement of Operations.

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

In addition to the Asset Purchase Agreement, we purchased 17,241,380 shares of RXi, for \$2.5 million, as part of a \$16.4 million financing for RXi, which included other related parties. We have determined that our ownership, along with that of our related parties, provides us the ability to exercise significant influence over RXi operations and as such we have accounted for our investment in RXi under the equity method.

Investments in variable interest entities

We have determined that we hold variable interests in Fabrus, Inc. (Fabrus), Biozone Pharmaceutical, Inc. (BZNE) and SciGen (I.L.) Ltd. (SciGen). 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.

Table of Contents

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 voting power. As such, we account for investment in BZNE under the equity method.

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. We determined that power to direct the activities that most significantly impact Fabrus's economic performance is conveyed through the board of directors of Fabrus as no entity is able to appoint the Fabrus governing body that oversees its executive management team. Based on the capital structure, governing documents and overall business operations of Fabrus, we determined that, while a VIE, no single entity has the power to direct the activities that most significantly impact Fabrus's economic performance. We did determine, however, 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.

Consolidated variable interest entities

In June 2012, we entered into a share and debt purchase agreement whereby in exchange for \$0.7 million we acquired shares representing a 45% stock ownership in SciGen from FDS Pharma LLP (FDS). SciGen is a privately-held Israeli company that produces a third-generation hepatitis B-vaccine. In November 2012 and March 2013, we loaned to SciGen a combined \$0.8 million for working capital purposes. We have determined that we hold variable interests in SciGen based on our assessment that SciGen does not have sufficient resources to carry out its principal activities without financial support. In order to determine the fair market value of our investment in SciGen, we have utilized a business enterprise valuation approach.

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

Table of Contents

The following table represents the consolidated assets and non-recourse liabilities related to SciGen as of March 31, 2013 and December 31, 2012. These assets are owned by, and these liabilities are obligations of, SciGen, not us.

(In thousands)	March 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 301	\$ 174
Accounts receivable, net	76	387
Inventories, net	1,399	1,092
Prepaid expenses and other current assets	174	199
Total current assets	1,950	1,852
Property, plant and equipment, net	1,493	1,539
Intangible assets, net	1,150	1,154
Goodwill	815	796
Other assets	324	231
Total assets	\$ 5,732	5,572
Liabilities		
Current liabilities:		
Accounts payable	\$ 1,220	\$ 1,108
Accrued expenses	3,352	2,859
Notes payable	1,329	
Total current liabilities	5,901	3,967
Other long-term liabilities	288	1,529
Total liabilities	\$ 6,189	\$ 5,496

NOTE 6 DEBT

On January 25, 2013, we entered into note purchase agreements (the "Notes") with qualified institutional buyers and accredited investors (collectively the "Purchaser") in a private placement in reliance on exemptions from registration under the Securities Act of 1933, (the "Securities Act"). The Purchasers of the Notes include Frost Gamma Investments Trust, a trust affiliated with Dr. Phillip Frost, our Chairman and Chief Executive Officer, and Hsu Gamma Investment, L.P., an entity affiliated with Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer. The Notes were issued on January 30, 2013. The Notes, which total \$175.0 million, bear interest at the rate of 3.00% per year, payable semiannually on February 1 and August 1 of each year, beginning August 1, 2013. The Notes will mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change as defined in the instruments governing the Notes, subject to certain exceptions, the holders may require us to repurchase all or any portion of their Notes for cash at a repurchase price equal to 100% of the principal amount of the Notes being repurchased, plus any accrued and unpaid interest to but not including the fundamental change repurchase date.

The Notes will be convertible at any time on or after November 1, 2032, through the second scheduled trading day immediately preceding the maturity date, at the option of the holders. Additionally, holders may convert their Notes prior to the close of business on the scheduled trading day immediately preceding November 1, 2032, under the following circumstances: (1) conversion based upon satisfaction of the trading price condition relating to the Notes; (2) conversion based on the Common Stock price; (3) conversion based upon the occurrence of specified corporate events; or (4) if we call the Notes for redemption. The Notes will be convertible into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our election unless we have made an irrevocable election of net share settlement. The initial conversion rate for the Notes will be 141.4827 shares of Common Stock per \$1,000 principal amount of Notes (equivalent to an initial conversion price of approximately \$7.07 per share of Common Stock), and will be subject to adjustment upon the occurrence of certain events. In addition, we will, in certain circumstances, increase the conversion rate for holders who convert their Notes in connection with a make-whole

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

fundamental change (as defined in the Indenture) and holders who convert upon the occurrence of certain specific events prior to February 1, 2017 (other than in connection with a make-whole fundamental change).

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

Table of Contents

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

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

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

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

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

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

	March 31, 2013	Issuance Date
Stock price	\$ 7.63	\$ 6.20
Conversion Rate	141.4827	141.4827
Conversion Price	\$ 7.07	\$ 7.07
Maturity date	February 1, 2033	February 1, 2033
Risk-free interest rate	1.01%	1.12%
Estimated stock volatility	35%	40%
Estimated credit spread	966 basis points	944 basis points

The following table sets forth the fair value of the Notes with and without the embedded derivatives, and the fair value of the embedded derivatives as of the issuance date and March 31, 2013 (in thousands):

	March 31, 2013	Issuance Date
Fair value of Notes:		
With the embedded derivatives	\$ 203,069	\$ 175,000
Without the embedded derivatives	\$ 119,077	\$ 115,796
Estimated fair value of the embedded derivatives	\$ 83,992	\$ 59,204

Changes in certain inputs into the lattice model can have a significant impact on changes in the estimated fair value of the embedded derivatives. For example, a decrease in our estimated credit spread results in an increase in the estimated value of the embedded derivatives. Conversely, a decrease in the price of our Common Stock results in a decrease in the estimated fair value of the embedded derivatives. From the date the Notes were issued through March 31, 2013, we observed an increase in the market price of our Common Stock which resulted in a \$24.8 million

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

increase in the estimated fair value of our embedded derivatives recorded in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations.

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

The principal amounts, unamortized discount and net carrying amounts of the Notes as of March 31, 2013 were as follows:

(In thousands)	Principal Balance	Unamortized Discount	Net Carrying Amount
Notes	\$ 175,000	\$ 62,571	\$ 112,429
	\$ 175,000	\$ 62,571	\$ 112,429

We have entered into line of credit agreements with sixteen financial institutions in Chile and Spain. These lines of credit are used primarily as a source of working capital for inventory purchases.

The following table summarizes the amount outstanding under the lines of credit:

(In thousands)	Interest rate on borrowings	Credit line capacity	March 31, 2013	December 31, 2012
Lender				
Itau Bank	7.10%	\$ 3,000	\$ 3,072	\$ 2,738
Bank of Chile	6.05%	3,000	2,391	2,292
BICE Bank	5.39%	2,000	1,650	2,451
Corp Banca	6.00%	1,000	663	1,248
BBVA Bank	6.36%	3,000	2,785	2,823
Penta Bank	9.48%	1,000	854	833
Security Bank	7.65%	1,500	1,066	
BCI	6.00%	1,500	1,626	
Estado Bank	6.26%	2,000	1,969	1,963
Sabadell Bank	7.60%	192		3
Bilbao Vizcaya Bank	4.90%	384	307	377
Banco Popular	8.25%	384	3	260
Santander Bank	6.00%	192	71	
Banesto	5.80%	192	135	163
Banca March	6.25%	256	233	44
 Total		 \$ 19,600	 \$ 16,825	 \$ 15,195

At both March 31, 2013 and December 31, 2012, the weighted average interest rate on our lines of credit was approximately 6.5%.

Table of Contents

At March 31, 2013 and December 31, 2012, we had mortgage notes and other debt payables related to Farmadiet as follows:

(In thousands)	March 31, 2013	December 31, 2012
Current portion of lines of credit and notes payable	\$ 2,110	\$ 2,331
Other long-term liabilities	3,706	3,916
Total mortgage notes and other debt payables	\$ 5,816	\$ 6,247

The mortgages and other debts payable mature at various dates ranging from 2015 through 2024 bearing variable interest rates from 2.7% up to 8.5%. The weighted average interest rate on the mortgage notes and other debt payable at March 31, 2013 and December 31, 2012 was 4.8% and 4.5%, respectively.

NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME

For the three months ended March 31, 2013 changes in Accumulated other comprehensive income, net of tax, were as follows:

(In thousands)	Foreign currency	Unrealized gains in Accumulated OCI
Balance at December 31, 2012	\$ 3,196	\$ 4,160
Other comprehensive income before reclassifications, net of tax ⁽¹⁾	323	1,405
Amounts reclassified from accumulated other comprehensive income, net of tax ⁽¹⁾		(991)
Net other comprehensive income	323	414
Balance at March 31, 2013	\$ 3,519	\$ 4,574

⁽¹⁾ Effective tax rate of 38.47%.

Amounts reclassified out of accumulated other comprehensive for the three months ended March 31, 2013 related to \$2.3 million realized gain on the sales of certain of our investments available for sale. Of the \$2.3 million gain on the sales of our investments available for sale, \$1.6 million gain was reclassified from unrealized gains in Accumulated other comprehensive income to Other income, net.

Table of Contents**NOTE 8 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 March 31, 2013, classified as available for sale, and carried at fair value is as follows:

	Amortized Cost	As of March 31, 2013			Fair value
		Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Gain/(Loss) in Accumulated Deficit	
(In thousands)					
Common stock investments, available for sale	\$ 1,870	\$ 6,522	\$	\$	\$ 8,392
BZNE Note and conversion feature	1,700	53		287	2,040
Neovasc common stock options	925	629		589	2,143
Neovasc common stock warrants	659	194		473	1,326
Total assets	\$ 5,154	\$ 7,398	\$	\$ 1,349	\$ 13,901

A summary of our investments as of December 31, 2012, classified as available for sale, and carried at fair value is as follows:

	Amortized Cost	As of December 31, 2012			Fair value
		Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Gain/(Loss) in Accumulated Deficit	
(In thousands)					
Common stock investments, available for sale	\$ 2,051	\$ 6,185	\$	\$	\$ 8,236
BZNE Note and conversion feature	1,700	53		287	2,040
Neovasc common stock options	925	293		176	1,394
Neovasc common stock warrants	659	194		(375)	478
Total assets	\$ 5,335	\$ 6,725	\$	\$ 88	\$ 12,148

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

As of March 31, 2013, we have money market funds that qualify as cash equivalents, forward contracts for inventory purchases (Refer to Note 9) and contingent consideration related to the acquisitions of CURNA, Inc. (CURNA), Claros Diagnostics, Inc. (OPKO Diagnostics), FineTech Pharmaceuticals, Ltd. (FineTech), Farmadiet, and Cytochroma that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with Neovasc, we record the related Neovasc options and warrants at fair value.

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 March 31, 2013			Total
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Money market funds	\$ 167,276	\$	\$	\$ 167,276
Certificates of deposit		827		827
Common stock investments, available for sale	8,392			8,392
BZNE Note and conversation feature			2,040	2,040
Neovasc common stock options		2,143		2,143
Neovasc common stock warrants		1,326		1,326
Total assets	\$ 175,668	\$ 4,296	\$ 2,040	\$ 182,004
Liabilities:				
Forward contracts	\$	\$ 21	\$	\$ 21
Embedded conversion option			83,992	83,992
Deferred acquisition payments, net of discount			9,166	9,166
Contingent consideration:				
CURNA			528	528
OPKO Diagnostics			13,721	13,721
FineTech			2,667	2,667
Cytochroma			48,110	48,110
Farmadiet			1,282	1,282
Total liabilities	\$	\$ 21	\$ 159,466	\$ 159,487

(in thousands)	Fair value measurements as of December 31, 2012			Total
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Money market funds	\$ 18,716	\$	\$	\$ 18,716
Certificates of deposit		820		820
Common stock investments, available for sale	8,236			8,236
BZNE Note and conversation feature			2,040	2,040
Neovasc common stock options		1,394		1,394
Neovasc common stock warrants		478		478
Total assets	\$ 26,952	\$ 2,692	\$ 2,040	\$ 31,684
Liabilities:				
Forward contracts	\$	\$ 10	\$	\$ 10

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

Deferred acquisition payments, net of discount				10,103	10,103
Contingent consideration:					
CURNA				510	510
OPKO Diagnostics				12,974	12,974
FineTech				5,262	5,262
Farmadiet				1,310	1,310
Total liabilities	\$	\$	10	\$ 30,159	\$ 30,169

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

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

(In thousands)	Carrying Value	March 31, 2013			
		Total Fair Value	Level 1	Level 2	Level 3
Notes	\$ 112,429	\$ 203,069	\$	\$	\$ 203,069
	\$ 112,429	\$ 203,069	\$	\$	\$ 203,069

As of March 31, 2013 and December 31, 2012, the carrying value of our other assets and liabilities approximates their fair value due to their short-term nature.

Table of Contents

The following tables reconcile the beginning and ending balances of our Level 3 assets and liabilities as of March 31, 2013 and December 31, 2012:

(In thousands)	March 31, 2013			
	BZNE Note and conversion feature	Contingent consideration	Deferred acquisition payments, net of discount	Embedded conversion option
Balance at December 31, 2012	\$ 2,040	\$ 20,056	\$ 10,103	\$
Additions		47,710		59,204
Total losses (gains) for the period:				
Included in results of operations		1,303	(137)	24,788
Payments		(2,761)	(800)	
Balance at March 31, 2013	\$ 2,040	\$ 66,308	\$ 9,166	\$ 83,992

(In thousands)	December 31, 2012		
	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
Total losses (gains) for the period:			
Included in results of operations	1,563	820	430
Included in Other comprehensive loss	53		
Transfer out to equity method investment	(1,276)		
Balance at December 31, 2012	\$ 2,040	\$ 20,056	\$ 10,103

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

BZNE Notes and conversion feature - The stock market 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. The most significant assumptions are the projected revenue growth and operating income (loss). The impact of a change in any of our significant underlying assumptions +/- 1% would not result in a materially different fair value.

Contingent consideration We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to FineTech, OPKO Diagnostics, CURNA, Farmadiet and Cytochroma transactions. The discount rates used range from 6% to 27% and were based on the weighted average cost of capital for those businesses. If the discount rates were to increase by 1%, on each transaction, the contingent consideration would decrease by \$1.6 million. If estimated future sales were to decrease by 10%, the contingent consideration related to CURNA, FineTech and Cytochroma would decrease by \$0.6 million. As of March 31, 2013, of the \$66.3 million of contingent consideration, \$5.2 million is recorded in Accrued expenses and \$61.2 million is recorded in Other-long-term liabilities. As of December 31, 2012, of the \$20.0 million of contingent consideration, \$14.9 million is recorded in Accrued expenses and \$5.1 million is recorded in Other-long-term liabilities.

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

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

NOTE 9 DERIVATIVE CONTRACTS

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.

During the three months ended March 31, 2013, we entered into a foreign exchange, fixed interest rate swap contract that provides for us to pay a fixed interest rate on the underlying loan balance denominated in Chilean Pesos. We entered into this agreement in Chile for purchases of inventory denominated in U.S. dollars. A hypothetical 1% interest rate change or 10% foreign exchange rate change will not have a material impact on our results from operations or financial position.

Table of Contents

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

	Balance Sheet Location	March 31, 2013	December 31, 2012
(In thousands)			
Derivative financial instruments:			
Neovasc common stock options/warrants	Investment, net	\$ 3,469	\$ 1,872
Embedded conversion option	3.00% convertible senior notes, net of discount	83,992	
Forward contracts (1)	Current portion of lines of credit and notes payable	1,107	1,294

(1) The effect on loss in the forward contracts is recorded in Accrued expenses. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At March 31, 2013 and December 31, 2012, our derivative financial instruments do not meet the documentation requirements to be designated as hedges. Accordingly, we recognize the changes in fair value in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations. The following table summarizes the (loss) gain recorded during the three months ended March 31, 2013 and 2012:

	Three Months Ended March 31,	
	2013	2012
(In thousands)		
Derivative gain (loss):		
Neovasc common stock options/warrants	\$ 1,260	\$ 1,030
Notes	(24,788)	
Forward contracts	(21)	87
Total	\$ (23,549)	\$ 1,117

The outstanding contracts at March 31, 2013, have been recorded at fair value, and their maturity details are as follows:

Days until maturity	Contract value	Fair value at	
		March 31, 2013	Decrease of loss
0 to 30	\$ 314	\$ 310	\$ (4)
31 to 60	112	109	(3)
61 to 90	21	21	
91 to 120	269	264	(5)
121 to 180	412	403	(9)
More than 180			
Total	\$ 1,128	\$ 1,107	\$ (21)

The outstanding contracts at December 31, 2012 have been recorded at fair value, and their maturity details are as follows:

(In thousands)	Contract value	Decrease of loss
----------------	----------------	------------------

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

Days until maturity	Fair value at December 31, 2012		
	\$	\$	\$
0 to 30			
31 to 60	581	577	(4)
61 to 90	341	339	(2)
91 to 120	212	210	(2)
121 to 180	170	168	(2)
More than 180			
Total	\$ 1,304	\$ 1,294	\$ (10)

NOTE 10 RELATED PARTY TRANSACTIONS

On January 25, 2013, we entered into the Notes, with the Purchasers for the sale of \$175.0 million aggregate principal amount of Notes in a private placement in reliance on exemptions from registration under the Securities Act. The Purchasers of the Notes include Frost Gamma Investments Trust, a trust affiliated with Dr. Phillip Frost, our Chairman and Chief Executive Officer, and Hsu Gamma Investment, L.P., an entity affiliated with Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer. The Notes were issued on January 30, 2013.

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

During the year ended December 31, 2012, our FineTech subsidiary recorded revenue of \$0.1 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

Table of Contents

molecular diagnostics technology (the Research Agreement). Pursuant to the Research Agreement, we agreed to provide funding of approximately \$0.9 million annually over a five year period. In conjunction with entering into the Research Agreement, we also entered into a license agreement with TSRI for technology relating to libraries of peptide tertiary amides. In addition, we entered into a second license with TSRI for technology relating to highly selective inhibitors of c-Jun-N-Terminal Kinases that may be useful for the treatment of various diseases, including Parkinson's disease. We also entered into a research funding and option agreement to provide funding of approximately \$0.2 million annually over three years to support further development of the technology. Dr. Frost served as a Trustee for TSRI until November 2012 and Dr. Lerner 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 Richard Lerner, a director. Following our investment, we own 1.5% of ChromaDex, the Gamma Trust owns approximately 16% of ChromaDex; Hsu Gamma owns approximately 1%; and certain of our directors own less than 1% of ChromaDex.

In February 2012, we purchased from BZNE \$1.7 million of 10% secured convertible promissory notes (the Notes), convertible into BZNE common stock at a price equal to \$0.20 per common share, which 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.

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 capital stock; Mr. Prego Novo owned approximately 23% of Aero's issued and outstanding capital stock through Olyrcya Trust; and Dr. Hsiao beneficially owned approximately 12% of Aero's issued and outstanding 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 owns less than 1% of BZNE as a result of his 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 \$0.3 million and \$0.1 million, respectively, which were initially secured by a first priority lien on a particular BZNE receivable. The notes to Gamma Trust were subsequently amended and Gamma Trust no longer holds a security interest in the BZNE receivables.

In August 2011, we made an investment in Neovasc. Dr. Frost and other members of our management are shareholders of Neovasc. Prior to the investment, Dr. Frost beneficially owned approximately 36% of Neovasc, Dr. Hsiao owned approximately 6%, and Mr. Rubin owned less than 1%. Dr. Hsiao and Mr. Rubin also serve on the board of directors for Neovasc.

In November 2010, we made an investment in Fabrus. In exchange for the investment, we acquired approximately 13% of Fabrus on a fully diluted basis. Our investment was part of a \$2.1 million financing for Fabrus. 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 served as a Trustee for TSRI until November 2012, and Dr. Lerner served as President of TSRI until December 2011.

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

Effective in September 2009, we entered into an agreement pursuant to which we invested \$2.5 million in Cocrystal in exchange for 1,701,723 shares of Cocrystal's Convertible Series A Preferred Stock. A group of investors, led by the Frost Group (the Cocrystal Investors), previously invested \$5.0 million in Cocrystal, and agreed to invest an additional \$5.0 million payable in two equal installments in September 2009 and March 2010. As a result of an amendment to the Cocrystal Investors' agreements dated June 9, 2009, we, rather than the Cocrystal Investors, made the first installment investment (\$2.5 million) on September 21, 2009.

Table of Contents

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

In 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 our 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 in 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 and in February 2013, we agreed to extend the lease on a month-to-month basis for up to an additional six months.

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. We reimbursed Dr. Frost approximately \$13 thousand and \$65 thousand for Company-related travel by Dr. Frost and other OPKO executives during the three months ended March 31, 2013 and 2012, respectively.

NOTE 11 COMMITMENTS AND CONTINGENCIES

In connection with our acquisitions of CURNA, OPKO Diagnostics, FineTech, Farmadiet, and Cytochroma we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, for the three months ended March 31, 2013, we recorded \$66.3 million as contingent consideration, with \$5.2 million recorded within Accrued expenses and \$61.2 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

On April 29, 2013, we were named in a putative class action filed in the Eighth Judicial District Court in and for Clark County, Nevada against PROLOR Biotech, Inc. (PROLOR), the members of the PROLOR Board of Directors, individually (including Drs. Frost and Hsiao and Steven Rubin), and the Company. From May 1, 2013 through May 6, 2013, we were named in an additional five putative class actions suits filed in the Eighth Judicial District Court in and for Clark County, Nevada against the same defendants. Each of these suits alleges a claim against the members of the PROLOR Board for breach of fiduciary duty and a claim against the Company for aiding and abetting the individual defendants alleged breach of fiduciary duty. Each suit seeks to enjoin the pending transaction between the Company and PROLOR, as well as attorneys fees. Certain of the suits also seek rescission and money damages, and one suit seeks imposition of a constructive trust for any benefits improperly received by the defendants. The Company denies the allegations and intends to vigorously defend the actions. It is still too early to assess the probability of a favorable or unfavorable outcome or the range of loss, if any.

In November 2012, Adrian Goldstein, M.D., a former employee of OURLab, filed a complaint for declaratory judgment and alleged breach of contract against OURLab in the Chancery Court for Davidson County, Tennessee. Dr. Goldstein asserts in his complaint that OURLab breached his employment agreement and owes him additional compensation and further compensation for the value of OURLab under a compensation for sale provision set forth in his employment agreement. Dr. Goldstein seeks recovery of compensatory damages not to exceed \$20 million, plus his attorney s fees and litigation expenses. OURLab believes this action is without merit and is vigorously defending against plaintiff s claims. It is too early to assess the probability of a favorable or unfavorable outcome or the loss or range of loss, if any.

In October 2012, we received a letter from counsel to Optos making certain indemnity claims against us in connection with the sale of our ophthalmic instrumentation business. 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.

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

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

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

Table of Contents

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 on acceptable terms, or at all.

NOTE 12 SEGMENTS

We currently manage our operations in two reportable segments, pharmaceuticals and diagnostics. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, and vaccines, and (ii) the pharmaceuticals operations we acquired in Chile, Mexico, Israel, Spain and Brazil. The diagnostics segment consists of two operating segments, our (i) pathology operations we acquired through the acquisition of OURLab and (ii) point-of-care and molecular diagnostics operations. There are no inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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

Goodwill:		
Pharmaceuticals	\$ 35,103	\$ 32,844
Diagnostics	47,606	47,606
Corporate		
	\$ 82,709	\$ 80,450

During the three months ended March 31, 2013 and 2012, no customer represented more than 10% of our total revenue. As of both March 31, 2013 and December 31, 2012, no customer represented more than 10% of our accounts receivable balance.

Table of Contents

NOTE 13 SERIES D PREFERRED STOCK REDEMPTION

On March 1, 2013, our Board of Directors declared a cash dividend to all Series D Preferred Stockholders as of March 8, 2013. The total cash dividend paid was approximately \$3.0 million. In addition, we also exercised our option to convert all 1,129,032 shares of our outstanding Series D Preferred Stock into 11,290,320 shares of our Common Stock effective of March 8, 2013. Following the conversion there are no outstanding shares of Series D Preferred Stock.

NOTE 14 SUBSEQUENT EVENTS

In April 2013, we entered into an Agreement and Plan of Merger (the "PROLOR Merger Agreement") pursuant to which we will acquire PROLOR Biotech, Inc. ("PROLOR"), a biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins, in an all-stock transaction. Under the terms of the agreement, holders of PROLOR common stock will receive 0.9951 shares of our Common Stock for each share of PROLOR common stock. Based on a price of \$7.03 per share of our Common Stock, the transaction is valued at approximately \$480 million, or \$7.00 per share of PROLOR common stock. The companies expect the transaction to be completed during the second half of 2013. Closing of the transaction is subject to certain conditions including, the approval of PROLOR's and our stockholders and other customary closing conditions. Dr. Frost is PROLOR's Chairman of the Board and a greater than 5% stockholder of PROLOR. Dr. Hsiao and Mr. Rubin are both directors of PROLOR and less than 5% stockholders of PROLOR. The Board of Directors of each of OPKO and PROLOR (with the directors noted above abstaining) have approved the Merger and the Merger Agreement. In addition, the transaction was also approved by PROLOR's Strategic Alternatives Committee.

We have reviewed all subsequent events and transactions that occurred after the date of our March 31, 2013 condensed consolidated balance sheet date, through the time of filing this Quarterly Report on Form 10-Q.

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, 2012 (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, 2012. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Table of Contents

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. We are developing a range of solutions to diagnose, treat and prevent various conditions, including molecular diagnostics tests, laboratory developed tests (LDTs), 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 from which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. We also recently established pharmaceutical operations in Brazil. We operate a specialty active pharmaceutical ingredients (APIs) manufacturer in Israel, which we expect will facilitate the development of our pipeline of molecules and compounds for our proprietary molecular diagnostic and therapeutic products. We operate a full-service medical laboratory specializing in urologic pathology with CLIA-certified laboratory facilities, that will provide us with a platform to commercialize certain of our novel diagnostics tests currently in development. We operate a development stage pharmaceutical company, with operations in the United States and Canada, which is engaged in the development of a vitamin D prohormone to treat secondary hyperparathyroidism (known as CTAP 101 Capsules), and of a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients.

RECENT DEVELOPMENTS

In April 2013 we entered into an Agreement and Plan of Merger (the PROLOR Merger Agreement) pursuant to which we will acquire PROLOR Biotech, Inc. (PROLOR), a biopharmaceutical company focused on developing and commercializing longer-acting proprietary versions of already approved therapeutic proteins, in an all-stock transaction. Under the terms of the agreement, holders of PROLOR common stock will receive 0.9951 shares of our Common Stock for each share of PROLOR common stock. Based on a price of \$7.03 per share of our Common Stock, the transaction is valued at approximately \$480 million, or \$7.00 per share of PROLOR common stock. The companies expect the transaction to be completed during the second half of 2013. Closing of the transaction is subject to certain conditions including, the approval of PROLOR s and our stockholders and other customary closing conditions.

PROLOR s long-acting version of human growth hormone, hGH-CTP, has successfully completed four clinical trials, including a Phase II trial in adults with growth hormone deficiency (GHD). PROLOR has reported that the trials showed that hGH-CTP has the potential to reduce the required dosing frequency of human growth hormone from the current standard of one injection per day to a single weekly injection. PROLOR also stated that hGH-CTP demonstrated a good safety and tolerability profile in these clinical trials. A Phase II trial in children with GHD is currently ongoing, and a Phase III trial in adults with GHD is planned to begin in the second quarter of 2013. Recombinant human growth hormone (hGH) is used for the long-term treatment of children and adults with GHD due to inadequate secretion of endogenous growth hormone. hGH-CTP has been awarded orphan drug designation in the U.S. and Europe for both adults and children with GHD.

In April 2013 we also acquired an approximate ten percent stake in OAO Pharmsynthez (Pharmsynthez), a Russian pharmaceutical company. Our investment was part of an approximate \$60.0 million two-stage financing in Pharmsynthez alongside the Russian Corporation of Nanotechnologies, a Russian state owned company (RUSNANO). RUSNANO invested approximately \$26.1 million in the first step of the transaction. RUSNANO was established in 2007 to foster development of nanotechnology and to encourage the growth of this field in Russia. In addition, we entered into an agreement with Pharmsynthez to develop and market several of our products for sale in Russia and certain other Eastern European countries.

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

Table of Contents

be required to pay us up to \$50.0 million in milestone payments upon the successful development and commercialization of each drug developed by RXi, certain of its affiliates or any of its or their licensees or sublicensees utilizing patents included within the RNAi Assets (each, a Qualified Drug). In addition, RXi will be required to pay us royalties equal to: (a) a mid single-digit percentage of Net Sales (as defined in the Asset Purchase Agreement) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable Royalty Period (as defined in the Asset Purchase Agreement); and (b) a low single-digit percentage of net sales with respect to each Qualified Drug sold for a non-ophthalmologic use during the applicable royalty period. In addition to the Asset Purchase Agreement, we also purchased 17,241,380 shares of RXi, or \$2.5 million, as part of a \$16.4 million financing for RXi, which included other related parties to us. As a result of these transactions, we own approximately 21% of RXi.

In March 2013, we completed the acquisition of Cytochroma Inc., a corporation located in Markham, Canada (Cytochroma), whose lead products, both in Phase 3 development, are CTAP101 Capsules, a vitamin D prohormone to treat secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency, and Fermagate Tablets, a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients (the Cytochroma Acquisition).

In connection with the Cytochroma Acquisition, we delivered 20,517,030 of shares of our Common Stock valued at \$146.9 million based on the closing price per share of our Common Stock as reported by the NYSE on the actual closing date of the acquisition, or \$7.16 per share. The number of shares issued was based on the volume-weighted average price per share of our Common Stock as reported on the NYSE for the ten trading days immediately preceding the date of the purchase agreement for the Cytochroma Acquisition, or \$4.87 per share (the Stock Consideration). The Cytochroma agreement contains customary representations, warranties, conditions to closing, indemnification rights and obligations of the parties. In addition, the Cytochroma Acquisition requires payments of up to an additional \$190.0 million in cash or additional shares of our Common Stock, at our election, upon the achievement of certain milestones relating to development and annual revenue.

In March 2013, our Board of Directors declared a cash dividend to all Series D Preferred stockholders as of March 8, 2013. The total cash dividend paid was approximately \$3.0 million. In addition, the Company also exercised its option to convert all 1,129,032 shares of our outstanding Series D Preferred Stock into 11,290,320 shares of our Common Stock effective of March 8, 2013. Following the conversion there are no outstanding shares of Series D Preferred Stock.

In January 2013, we entered into note purchase agreements, with qualified institutional buyers and accredited investors (collectively, the Purchasers) for the sale of \$175.0 million aggregate principal amount of 3.00% convertible senior notes due 2033 (the Notes) in a private placement in reliance on exemptions from registration under the Securities Act of 1933 (the Securities Act). The Purchasers of the Notes include Frost Gamma Investments Trust, a trust affiliated with Dr. Phillip Frost, our Chairman and Chief Executive Officer, and Hsu Gamma Investment, L.P., an entity affiliated with Dr. Jane H. Hsiao, our Vice Chairman and Chief Technology Officer. The Notes were issued on January 30, 2013.

RESULTS OF OPERATIONS**FOR THE THREE MONTHS ENDED MARCH 31, 2013 AND 2012**

Revenues. Revenues for the first three months of 2013, were \$31.4 million, compared to \$8.8 million for the comparable 2012 period. The increase in revenue principally reflected one-time, non cash revenue related to the RXi Asset Purchase Agreement of \$12.5 million, and revenues related to the post March 31, 2012 acquisitions of ALS Distribuidora Limitada (ALS), Farmadiet Group Holding, S.L. (Farmadiet), SciGen (I.L.) Ltd, (SciGen) and Prost-Data, Inc. (OURLab), which contributed \$1.5 million, \$4.3 million, \$0.7 million and \$2.9 million, respectively, during the 2013 period. Revenue from our Chilean operations, excluding revenue generated by ALS, increased \$0.5 million during the 2013 period, which was partially offset by a decrease of \$0.3 million in revenue from our Mexican operations. Revenue from our Israeli API business increased \$0.4 million during the 2013 period. Revenue related to our molecular diagnostics collaboration agreements and license agreements, excluding the RXi revenue, increased \$0.3 million during the first three months of 2013 compared to the 2012 period.

Gross margin. Gross margin for the first three months of 2013 increased to \$19.6 million from \$3.8 million for the comparable 2012 period. Gross margin for the 2013 period increased compared to the 2012 period primarily as a result of \$12.5 million in one-time, non cash, up-front license revenue consideration received from RXi, as described above, which had no accompanying cost as the cost to develop the technology sold to RXi was previously expensed as a research and development cost when incurred in prior periods. Gross margin for the 2013 period also increased due to gross margins recorded by ALS, Farmadiet and OURLab of \$0.5 million, \$2.6 million, and \$0.2 million, respectively. Gross margin from our Israeli API business increased \$0.4 million during the 2013 period, offset by decreased gross margin generated from our Mexico operations of \$0.6 million.

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

Selling, general and administrative expenses. Selling, general and administrative expenses for the first three months of 2013 were \$12.4 million, compared to \$4.7 million for the comparable 2012 period. The increase in selling, general and administrative expenses during the 2013 period principally resulted from \$4.7 million of such expenses recorded during the 2013 period by ALS, Farmadiet, SciGen, OURLab, and Cytochroma, which businesses were acquired post March 31, 2012. Excluding the selling, general and administrative expenses of the acquired businesses, selling, general and administrative expenses increased by \$3.0 million during the 2013 period principally as a result of increased personnel expenses and professional fees associated with our increased operations. Selling, general and administrative expenses during the first three months of 2013 and 2012, also include equity-based compensation expense of \$1.3 million and \$0.6 million, respectively.

Table of Contents

Research and development expenses. Research and development expenses for the first three months of 2013 and 2012 were \$9.9 million and \$4.8 million, respectively. The increase in research and development expenses during the 2013 period principally resulted from an increase of \$1.7 million related to the Cytochroma development programs, including the cost of the ongoing Phase 3 clinical trials for CTAP 101 Capsules, which are currently enrolling patients. Research and development expenses during the first three months of 2013 and 2012, also include equity-based compensation expense of \$3.9 million and \$0.6 million, respectively. The increase in equity-based compensation expense principally reflects the mark to market impact of Common Stock options granted to non-employees and the associated increase in the trading price of our Common Stock during the 2013 period.

Contingent consideration. Contingent consideration expenses for the first three months of 2013 and 2012 were \$1.3 million and \$1.1 million, respectively. The increase in contingent consideration expense resulted from the change in the fair value of the contingent consideration liabilities due to the time value of money and the impact of the change in the underlying assumptions, if any, during the period. The contingent consideration liabilities relate to potential amounts payable to CURNA, Inc., Claros Diagnostics Inc. (OPKO Diagnostics), FineTech Pharmaceuticals, Ltd., Farmadiet and Cytochroma's former stockholders pursuant to our acquisition agreements in January 2011, October 2011, December 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was \$2.7 million and \$2.0 million for the first three months of 2013 and 2012, respectively. Amortization expense increased due to the acquisitions of ALS, Farmadiet, OURLab and Cytochroma, in April 2012, August 2012, December 2012 and March 2013, respectively.

Other income and (expense), net. During the first three months of 2013, we recorded a \$24.8 million non-cash charge related to the increase in the fair value of the embedded derivatives in the Notes principally due to an increase in the market value of our Common Stock during the 2013 period, partially offset by a gain of \$2.3 million on the sale of certain of our investments available for sale and other income of \$1.3 million related to changes in the fair value of the warrants and options received in connection with our investment in Neovasc, Inc. Other income and (expense), net, for the first three months of 2013, also included \$2.9 million of interest expense primarily related to the interest incurred by the Notes and the amortization of the deferred financing costs and the embedded derivatives of the Notes. For the first three months of 2012, other income, net included \$1.1 million of other income recognized from the change in fair value of the warrants received in connection with our investment in Biozone Pharmaceuticals, Inc., partially offset by the interest incurred in our Chilean lines of credit.

Loss from investment in investees. Loss from investment in investees was \$3.9 million and \$0.5 million for the first three months of 2013 and 2012, respectively. The increase in loss from investment in investees is primarily due to the result of increased research and development activities at our investees as well as the impact of including the activities of RXi for the first three months of 2013.

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

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2013, we had cash, cash equivalents and marketable securities of approximately \$181.6 million. Cash used in operations during 2013 primarily reflects expenses related to selling, general and administrative activities related to our corporate operations, research and development activities and our operations in Chile, Spain, SciGen and Mexico, partially offset by cash provided from our operations at FineTech. Cash used in investing activities primarily reflects the \$2.5 million investment in RXi, capital expenditures of \$0.9 million and net cash

Table of Contents

used in business combinations of \$0.1 million offset partially from the sale of available for sale securities. Cash provided by financing activities primarily reflects the issuance of our 3.00% convertible senior notes and \$1.0 million received from Common Stock option and Common Stock warrant exercises. 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 January 2013, we issued \$175.0 million of Notes. The Notes were sold in a private placement in reliance on exemptions from registration under the Securities Act. A \$4.5 million discount was granted to the placement agent and an additional \$0.4 million in deferred charges were recorded for professional fees related to the issuance. Net cash proceeds from the offering totaled \$170.2 million. Interest on the Notes is payable semiannually on February 1 and August 1, beginning August 1, 2013. Holders of the Notes may require us to repurchase the Notes for 100% of their principal amount, plus accrued and unpaid interest, on February 1, 2019, February 1, 2023 and February 1, 2028, or following the occurrence of a fundamental change as defined in the indenture governing the Notes.

In connection with our acquisitions of CURNA, OPKO Diagnostics, FineTech and Cytochroma we agreed to pay future consideration to the sellers upon the achievement of certain events, including minimum cash payments of \$5.0 million to the former stockholder of FineTech upon the achievement of certain sales milestones, of which \$2.7 million was paid in March 2013; up to an additional \$19.1 million in shares of our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones; and up to an additional \$190.0 million in either shares of our Common Stock or cash, at our option subject to the achievement of certain milestones to the former shareholders of Cytochroma. In connection with the acquisition of Farmadiet, we agreed to pay an additional 3.4 million (US\$4.3 million) in August 2013 and 3.4 million (US\$4.3 million) in February 2014. Further, upon the achievement of certain development milestones, we are obligated to issue 125,000 shares of our Common Stock and 0.8 million (US\$1.0 million) in shares of our Common Stock or cash, at our option.

As of March 31, 2013, we have outstanding lines of credit in the aggregate amount of \$16.8 million with 15 financial institutions in Chile and Spain, of which \$2.8 million is unused. The weighted average interest rate on these lines of credit is approximately 6.5%. These lines of credit are short-term and are generally due within three months. These lines of credit are used primarily as a source of working capital for inventory purchases. The highest balance at any time during the three months ended March 31, 2013 was \$17.7 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

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

We believe that the cash, cash equivalents, and marketable securities on hand at March 31, 2013, which include the net proceeds from the Notes, 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.

Table of Contents

The following table provides information as of March 31, 2013 with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Nine Months ending December 31,							Total
	2013	2014	2015	2016	2017	2018	Thereafter	
Open purchase orders	\$ 8,409	\$ 2	\$	\$	\$	\$	\$	\$ 8,411
Operating leases	1,902	1,807	1,325	1,184	748	254	286	7,506
3.00% convertible senior notes							196,421	196,421
Mortgages and other debts payable (1)	1,972	582	497	389	353	299	1,724	5,816
Lines of credit	16,825							16,825
Interest commitments	4,853	5,270	5,267	5,264	5,264	5,262	506	31,686
Total	\$ 33,961	\$ 7,661	\$ 7,089	\$ 6,837	\$ 6,365	\$ 5,815	\$ 198,937	\$ 266,665

⁽¹⁾ Excludes \$1.3 million of consolidated liabilities related to SciGen, as to which there is no recourse against us.

The preceding table does not include information where the amounts of the obligations are not currently determinable, including contractual obligations in connection with product license agreements and contingent consideration that includes payments upon achievement of certain milestones.

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 Condensed Consolidated Financial Statements.

Table of Contents

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.

Goodwill and Intangible Assets. Goodwill and other intangible assets acquired in business combinations, licensing and other transactions were \$368.1 million and \$176.2 million, respectively, at March 31, 2013 and December 31, 2012, representing approximately 56% and 61% of total assets, respectively.

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

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

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

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

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

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

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

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

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

Goodwill was \$82.7 million and \$80.5 million, respectively, at March 31, 2013 and December 31, 2012. Goodwill is tested at least annually for impairment or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, on an enterprise level by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value. Examples of qualitative factors include our share price, our financial performance compared to budgets, long-term financial plans, macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test performed in the prior year.

Intangible assets were \$285.4 million and \$95.8 million, including IPR&D of \$203.3 million and \$11.5 million, respectively, at March 31, 2013 and December 31, 2012. Intangible assets are tested for impairment whenever events or changes in circumstances warrant a review, although IPRD is required to be tested at least annually. Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products or IPR&D. These assets are initially measured at fair value and therefore any reduction in expectations used in the valuations could potentially lead to impairment. Some of the more common potential risks leading to impairment include competition, earlier than expected loss of exclusivity, pricing pressures, adverse regulatory changes or clinical trial results, delay or failure to obtain regulatory approval and additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation.

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

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

Allowance for doubtful accounts and revenue recognition. Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Our estimates for sales returns are based upon the historical patterns of products returned matched against the sales from which they originated, and management's evaluation of specific factors that may increase or decrease the risk of product returns. Revenue for services is recognized on the accrual basis at the time test results are reported, which approximates when services are provided. Services are provided to certain patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in sales net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue.

We analyze accounts receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by management's estimate of the collectability of accounts receivable. The allowance for doubtful accounts recognized in our Condensed Consolidated Balance Sheets at March 31, 2013 and December 31, 2012 was \$0.7 million and \$0.5 million, respectively.

Recent accounting pronouncements. In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. (ASU 2013-02). ASU 2013-02 requires the presentation of reclassifications out of accumulated other comprehensive income in either (1) the notes or (2) the face of the financial statements. We adopted ASU 2013-02 for our first quarter ended March 31, 2013. The adoption of ASU 2013-02 did not have a material impact in our condensed consolidated financial statements, but did require certain additional disclosures.

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.

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

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

Our derivative activities, which consist of foreign exchange forward contracts, are initiated to hedge forecasted cash flows that are exposed to foreign currency risk. The foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity dates. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the Consolidated Statement of Operations at maturity, and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. If the counterparties to the exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. We had \$1.1 million in foreign exchange forward contracts outstanding at March 31, 2013, primarily to hedge Chilean-based operating cash flows against U.S. dollars. If Chilean Pesos were to strengthen in relation to the U.S. dollar, our loss or gain on hedged foreign currency cash-flows would be offset by the derivative contracts, with a net effect of zero.

Table of Contents

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 March 31, 2013, we had cash and cash equivalents of \$181.6 million. The weighted average interest rate related to our cash and cash equivalents for the three months ended March 31, 2013 was 0%. As of March 31, 2013, the principal value of our credit lines was \$16.8 million at a weighted average interest rate of approximately 6.5% for the three months then ended. In addition, we have outstanding 3.00% convertible senior notes with a face value of \$175 million.

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.

Item 4. 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 March 31, 2013. Based on that evaluation, the CEO and CFO have concluded that the Company's disclosure controls and procedures are effective to ensure that information the Company is required to disclose in reports that it files or submits under the Securities Exchange Act 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 to the Company's Internal Control Over Financial Reporting

In connection with the Farmadiet Group Holding, S.L., SciGen (I.L.) Ltd, Prost-Data, Inc and Cytochroma Inc. acquisitions in August 2012, October 2012, December 2012 and March 2013, respectively, we began implementing standards and procedures at Farmadiet, SciGen and OURLab 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, SciGen, OURLab and Cytochroma. Other than as set forth above with respect to Farmadiet, SciGen, OURLab and Cytochroma, there have been no changes to the Company's internal control over financial reporting that occurred during the Company's first fiscal quarter of 2013 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents**PART II. OTHER INFORMATION****Item 1. Legal Proceedings**

On April 29, 2013, a putative class action was filed in the Eighth Judicial District Court in and for Clark County, Nevada by Peter Turkell against PROLOR Biotech, Inc. (PROLOR), the members of the PROLOR Board of Directors, individually (including Drs. Frost and Hsiao and Steven Rubin), and the Company (styled Peter Turkell v. PROLOR Biotech, Inc. et al., No: A-13-680860-B). On May 1, 2013, a second putative class action was filed in the Eighth Judicial District Court in and for Clark County, Nevada by Floyd A. Fried against PROLOR, the members of the PROLOR Board, individually (including Drs. Frost and Hsiao and Steven Rubin), the Company and its wholly-owned subsidiary, POM Acquisition, Inc. (styled Floyd A. Fried v. PROLOR Biotech, Inc. et al., No: A-13-681060). A third putative class action was filed in the Eighth Judicial District Court in and for Clark County, Nevada by Marc Henzel against PROLOR, the members of the PROLOR Board, individually (including Drs. Frost and Hsiao and Steven Rubin), and the Company (styled Marc Henzel vs. PROLOR Biotech, Inc. et al., No: A-13-681020-C). On May 3, 2013, a fourth putative class action suit was filed in the Eighth Judicial District Court in and for Clark County, Nevada by Bradford W. Baer, Trustee of the B.W. Baer & P. Shapiro-Baer Revocable Trust and Pamela Shapiro-Baer against PROLOR, the members of the PROLOR Board individually (including Drs. Frost and Hsiao and Steven Rubin), and the Company (styled Bradford W. Baer, Trustee of the B.W. Baer & P. Shapiro-Baer Revocable Trust and Pamela Shapiro-Baer v. PROLOR Biotech, Inc. et al., No: A-13-681218-B). On May 6, 2013, a fifth putative class action suit was filed in the Eighth Judicial District Court in and for Clark County, Nevada by James Hegarty against PROLOR, the members of the PROLOR Board individually (including Drs. Frost and Hsiao and Steven Rubin), and the Company (styled James Hegarty v. PROLOR Biotech, Inc. et al., No: A-13-681250-C). On May 6, 2013, a sixth putative class action suit was filed in the Eighth Judicial District Court in and for Clark County, Nevada by Jorge L. Salas, Michael Cardello, Ariel Heimann, Jorge Salas, Israel Kuperman, Ido Greenberg, Gideon Schurr, and Yoav Poles against PROLOR, the members of the PROLOR Board individually (including Drs. Frost and Hsiao and Steven Rubin), and the Company (styled Jorge Salas, et al. v. PROLOR Biotech, Inc. et al., No: A-13-681279-C).

Each of these suits alleges a claim against the members of the PROLOR Board for breach of fiduciary duty and a claim against the Company for aiding and abetting the individual defendants' alleged breach of fiduciary duty. Each suit seeks to enjoin the pending transaction between the Company and PROLOR, as well as attorneys' fees. The Fried suit, the Henzel suit, the Baer suit, the Hegarty suit, and the Salas suit also seek rescission and money damages. The Turkell suit seeks imposition of a constructive trust for any benefits improperly received by the defendants. The Company denies the allegations and intends to vigorously defend the actions.

Item 1A. Risk Factors

Other than as set forth below, 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 year ended December 31, 2012.

Failure to close the proposed merger with PROLOR Biotech, Inc. could have a negative impact on the Company and our financial condition, results of operations, cash flows and stock price.

The proposed merger could cause disruptions to our business or business relationships, which could have an adverse impact on the Company and our financial condition, results of operations and cash flows, including the following:

the diversion of management time on merger-related activities;

risks that the proposed transaction disrupts current plans and operations;

the outcome of any legal proceedings instituted against PROLOR, the Company and/or others relating to the merger agreement;

the effect of the announcement of the merger on the Company's business relationships, operating results and business generally; and

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

the amount of the costs, fees, expenses and charges related to the merger.

In addition, we have incurred, and will continue to incur, significant costs, expenses and fees for professional services and other transaction costs in connection with the merger, and many of these fees and costs are payable by us regardless of whether or not the merger is consummated. Following the announcement of the merger, six putative class action lawsuits have been filed (which name the Company as a defendant) and several law firms specializing in shareholder lawsuits have announced they are investigating the Board of Directors of PROLOR for breaches of fiduciary duty and other violations of state law in connection with the merger. Failure of or delay in closing of the merger could adversely affect the market price of the stock.

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.

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

Item 6. Exhibits.

Exhibit 2.10 ⁺	Share Purchase Agreement, dated January 8, 2013, by and among Cytochroma Inc., Cytochroma Holdings ULC, Cytochroma Canada Inc., Cytochroma Development Inc. Proventiv Therapeutics, LLC, Cytochroma Cayman Islands, Ltd., OPKO Health, Inc., and OPKO IP Holdings, Inc.
Exhibit 2.11 ⁺⁽¹⁾	Asset Purchase Agreement, dated March 1, 2013, by and among RXi Pharmaceuticals Corporation and OPKO Health, Inc.
Exhibit 3.1 ⁽²⁾	Amended and Restated Certificate of Incorporation.
Exhibit 3.2 ⁽³⁾	Amended and Restated By-Laws.
Exhibit 4.3 ⁽⁴⁾	Indenture, dated as of January 30, 2013, between OPKO Health, Inc. and Wells Fargo Bank, National Association.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended March 31, 2013.

Table of Contents

Exhibit 31.2	Certification by Juan F. 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 March 31, 2013.
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 March 31, 2013.
Exhibit 32.2	Certification by Juan F. 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 March 31, 2013.
Exhibit 101.INS*	XBRL Instance Document
Exhibit 101.SCH*	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* 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 Schedule 13D filed with the Securities and Exchange Commission on March 22, 2013, and incorporated herein by reference.
- (2) 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.
- (3) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008, and incorporated herein by reference.
- (4) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2013, and incorporated herein by reference.

Table of Contents

SIGNATURES

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

Date: May 10, 2013

OPKO Health, Inc.

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

Officer and Treasurer

Table of Contents**Exhibit Index**

Exhibit Number	Description
Exhibit 2.10*	Share Purchase Agreement, dated January 8, 2013, by and among Cytochroma Inc., Cytochroma Holdings ULC, Cytochroma Canada Inc., Cytochroma Development Inc. Proventiv Therapeutics, LLC, Cytochroma Cayman Islands, Ltd., OPKO Health, Inc., and OPKO IP Holdings, Inc.
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 March 31, 2013.
Exhibit 31.2	Certification by Juan F. 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 March 31, 2013.
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 March 31, 2013.
Exhibit 32.2	Certification by Juan F. 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 March 31, 2013.
Exhibit 101.INS*	XBRL Instance Document
Exhibit 101.SCH*	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* 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.