Opko Health, Inc.
Form 10-Q
August 09, 2010

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2010.

OR

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

For the transition period from _____ to _____.

Commission file number 001-33528

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	75-2402409
(State or Other Jurisdiction of Incorporation or Organization)	(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. þ YES o 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 o NO o

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

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

As of August 5, 2010, the registrant had 255,312,668 shares of common stock outstanding.

Page(s)

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Condensed Consolidated Balance Sheets as of June 30, 2010 and December 31, 2009 (unaudited) 6

Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2010 and June 30, 2009 (unaudited) 7

Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2010 and June 30, 2009 (unaudited) 8

Notes to Financial Statements 9

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations 18

Item 3. Quantitative and Qualitative Disclosures About Market Risk 22

Item 4. Controls and Procedures 23

PART II. OTHER INFORMATION

Item 1. Legal Proceedings 23

Item 1A. Risk Factors 24

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 24

Item 3. Defaults Upon Senior Securities 24

Item 4. (Removed and Reserved) 24

Item 5. Other Information 24

Item 6. Exhibits 24

Signatures 26

Exhibit Index 27

EX-31.1
EX-31.2
EX-32.1
EX-32.2

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, or 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, 2009, and described from time to time in our 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 drug research and development activities may not result in commercially viable products.

The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.

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

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

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

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

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

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.

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

Table of Contents

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

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

We have no experience manufacturing our pharmaceutical product candidates other than at our Mexican facility 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 marketing, sales or distribution organization other than in Chile and Mexico. If we are unable to develop our sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical product candidates.

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

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

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

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

We will 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 profitably.

Failure to obtain 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 and may not proceed as planned; and we may encounter difficulties in integrating acquired businesses.

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

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.

Table of Contents

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do 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 Amex, which could cause our stock price to fall and decrease the liquidity of our common stock.

Future issuances of common stock and hedging activities may depress the trading price of our common stock.

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

We do not intend to pay cash dividends on our common stock in the foreseeable future.

Table of Contents

PART I. FINANCIAL INFORMATION

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

Item 1. Financial Statements

OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands except share data)

	June 30, 2010	December 31, 2009
ASSETS		
Current assets		
Cash and cash equivalents	$ 9,686	$ 42,658
Marketable securities	9,998	
Accounts receivable, net	11,916	8,767
Inventory, net	11,819	10,520
Prepaid expenses and other current assets	2,071	1,873
Total current assets	45,490	63,818
Property and equipment, net	2,509	593
Intangible assets, net	10,631	12,722
Goodwill	4,981	5,408
Investments	3,972	4,447
Other assets	432	442
Total assets	$ 68,015	$ 87,430
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 5,949	$ 4,784
Accrued expenses	4,823	3,918
Current portion of lines of credit	6,110	4,321
Total current liabilities	16,882	13,023
Long-term interest payable to related party		3,409
Deferred tax liabilities	1,080	1,339
Line of credit with related party, net of unamortized discount of $0 and $68, respectively		11,932
Total liabilities	17,962	29,703
Commitments and contingencies		
Shareholders equity		
Series A Preferred stock $0.01 par value, 4,000,000 shares authorized; 987,484 and 1,025,934 shares issued and outstanding (liquidation value of $2,592 and $2,564) at June 30, 2010 and December 31, 2009, respectively	10	10
Series C Preferred Stock $0.01 par value, 500,000 shares authorized; No shares issued or outstanding		

Series D Preferred stock $0.01 par value, 2,000,000 shares authorized; 1,209,677 and 1,209,677 shares issued and outstanding (liquidation value of $31,813 and $30,613) at June 30, 2010 and December 31, 2009, respectively	12	12
Common Stock $0.01 par value, 500,000,000 shares authorized; 255,279,878 and 253,762,552 shares issued and outstanding at June 30, 2010 and December 31, 2009, respectively	2,553	2,538
Treasury stock - 45,154 shares at June 30, 2010 and December 31, 2009, respectively	(61)	(61)
Additional paid-in capital	397,898	393,144
Accumulated other comprehensive income	(108)	1,313
Accumulated deficit	(350,251)	(339,229)
Total shareholders equity	50,053	57,727
Total liabilities and shareholders equity	$ 68,015	$ 87,430

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 data)

	For the three months ended June 30,		For the six months ended June 30,	
	2010	2009	2010	2009
Revenue	$ 7,455	$ 2,347	$ 15,377	$ 4,648
Cost of goods sold	4,850	1,764	10,378	3,325
Gross margin	2,605	583	4,999	1,323
Operating expenses				
Selling, general and administrative	5,644	2,926	9,887	6,183
Research and development	1,575	2,498	2,903	8,157
Other operating expenses, principally amortization of intangible assets	913	406	1,802	812
Total operating expenses	8,132	5,830	14,592	15,152
Operating loss	(5,527)	(5,247)	(9,593)	(13,829)
Other expense, net	(390)	(494)	(730)	(944)
Loss before income taxes and investment loss	(5,917)	(5,741)	(10,323)	(14,773)
Income tax provision (benefit)	54	(103)	101	(138)
Loss before investment loss in investee	(5,971)	(5,638)	(10,424)	(14,635)
Loss from investment in investee	(244)	(38)	(475)	(38)
Net loss	(6,215)	(5,676)	(10,899)	(14,673)
Preferred stock dividend	(661)	(58)	(1,323)	(116)
Net loss attributable to common shareholders	$ (6,876)	$ (5,734)	$ (12,222)	$ (14,789)
Loss per common share, basic and diluted	$ (0.03)	$ (0.03)	$ (0.05)	$ (0.07)
Weighted average number of common shares outstanding, basic and diluted	255,252,433	225,648,244	254,854,652	212,695,483

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

Table of Contents

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

	For the six months ended June 30,	
	2010	2009
Cash flows from operating activities		
Net loss	$ (10,899)	$ (14,673)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,964	935
Accretion of debt discount related to notes payable	136	32
Share based compensation	2,742	1,767
Provision for (recovery of) bad debts	119	(133)
(Reveral of) provision for inventory obsolescence	(3)	52
Loss from investment in investee	475	38
Changes in:		
Accounts receivable	(2,610)	(1,027)
Inventory	(1,170)	(1,140)
Prepaid expenses and other current assets	(516)	45
Other assets	105	(129)
Accounts payable	1,331	(20)
Accrued expenses	(2,947)	(762)
Net cash used in operating activities	(11,273)	(15,015)
Cash flows from investing activities		
Acquisition of business, net of cash	(1,447)	
Investment in investee		(2,300)
Purchase of short-term marketable securities	(14,997)	(4,997)
Maturities of short-term marketable securities	5,000	
Capital expenditures	(510)	(24)
Net cash used in investing activities	(11,954)	(7,321)
Cash flows from financing activities:		
Issuance of common stock for cash, to related parties		25,000
Issuance of common stock for cash		25,990
Repayment of line of credit with related party	(12,000)	
Borrowings under lines of credit	3,500	
Repayments under lines of credit	(1,271)	
Proceeds from bridge loan with related party		3,000
Repayment of bridge loan with related party		(3,000)
Insurance financing		217
Proceeds from the exercise of stock options and warrants	26	621
Repayments of notes payable and capital lease obligations		(231)
Net cash (used in) provided by financing activities	(9,745)	51,597

Net (decrease) increase in cash and cash equivalents	(32,972)	29,261
Cash and cash equivalents at beginning of period	42,658	6,678
Cash and cash equivalents at end of period	$ 9,686	$ 35,939
SUPPLEMENTAL INFORMATION		
Interest paid	$ 4,241	$ 50
Income taxes refunded, net	$ 68	$
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Issuance of capital stock to acquire Pharmacos Exakta	$ 2,000	$

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 specialty healthcare company involved in the discovery, development, and commercialization of pharmaceutical products, medical devices, vaccines, diagnostic technologies, and imaging systems. Initially focused on the treatment and management of ophthalmic diseases, we have since expanded into other areas of major unmet medical need. We are a Delaware corporation, headquartered in Miami, Florida.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation. The accompanying unaudited interim 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 footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary to present fairly the Company s results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three and six months ended June 30, 2010, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2010 or for future periods. The interim 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, 2009.

Principles of consolidation. The accompanying unaudited condensed consolidated financial statements include the accounts of OPKO Health, Inc. and our wholly-owned subsidiaries. All significant intercompany accounts and transactions are eliminated in consolidation.

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

Comprehensive loss. Our comprehensive loss for the three and six months ended June 30, 2010 includes net loss for the three and six months and the cumulative translation adjustment, net, for the translation results of our subsidiaries in Chile and Mexico. Comprehensive loss for the three and six months ended June 30, 2009 is comprised entirely of our net loss.

Revenue recognition. Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Certain of our instrumentation products are sold directly to end-users and require that we deliver, install and train the staff at the end-users facility. As a result, we do not recognize revenue until the product is delivered, installed and training has occurred.

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 income when they occur, the only exception being derivatives that qualify as hedges. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At June 30, 2010 and December 31, 2009, 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 income. Refer to Note 7.

Table of Contents

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

Allowance for doubtful accounts. We analyze accounts receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by our estimate of the collectability of accounts receivable. Estimated allowances for sales returns are based upon our history of product returns. The amount of allowance for doubtful accounts at June 30, 2010 and December 31, 2009, was $0.6 million and $0.4 million, respectively.

Segment reporting. Our chief operating decision-maker (CODM) is comprised of our executive management with the oversight of our board of directors. Our CODM review our operating results and operating plans and make resource allocation decisions on a company-wide or aggregate basis. We currently manage our operations in two reportable segments, pharmaceutical and instrumentation segments. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, diagnostic tests and vaccines, and (ii) the pharmaceutical operations we acquired in Chile and Mexico through the acquisition of Pharma Genexx S.A. (Pharma Genexx) and Pharmacos Exakta S.A. de C.V. (Pharmacos Exakta). The instrumentation segment consists of ophthalmic instrumentation products and the activities related to the research, development, manufacture and commercialization of those products. 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.

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 June 30, 2010 and 2009, we recorded $1.5 million and $1.1 million, respectively, of equity-based compensation expense. For the six month period ending June 30, 2010 and 2009, we recorded $2.7 million, and $1.8 million, respectively, of equity-based compensation expense.

Recent accounting pronouncements. In March 2010, the Financial Accounting Standards Board, or FASB, issued updated guidance to amend and clarify how entities should evaluate credit derivatives embedded in beneficial interests in securitized financial assets. The updated guidance eliminates the scope exception for bifurcation of embedded credit derivatives in interests in securitized financial assets, unless they are created solely by subordination of one financial instrument to another. The update allows entities to elect the fair value option for any beneficial interest in securitized financial assets upon adoption. This guidance is effective by the first day of the first fiscal quarter beginning after June 15, 2010. Early adoption is permitted. We have not adopted this guidance early and are currently evaluating the potential effect of the adoption of this amendment on our results of operation and financial condition.

In March 2010, the FASB reached a consensus to issue an amendment to the accounting for revenue arrangements under which a vendor satisfies its performance obligations to a customer over a period of time, when the deliverable or unit of accounting is not within the scope of other authoritative literature and when the arrangement consideration is contingent upon the achievement of a milestone. The amendment defines a milestone and clarifies whether an entity may recognize consideration earned from the achievement of a milestone in the period in which the milestone is achieved. This amendment is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. The amendment may be applied retrospectively to all arrangements or prospectively for milestones achieved after the effective date. We have not adopted this guidance early and adoption of this amendment is not expected to have a material impact on our results of operation or financial condition.

In January 2010, the FASB issued an amendment to the accounting for fair value measurements and disclosures. This amendment details additional disclosures on fair value measurements, requires a gross presentation of activities

within a Level 3 rollforward and adds a new requirement to the disclosure of transfers in and out of Level 1 and Level 2 measurements. The new disclosures are required of all entities that are required to provide disclosures about recurring and nonrecurring fair value measurements. This amendment was effective as of January 1, 2010, with an

Table of Contents

exception for the gross presentation of Level 3 rollforward information, which is required for annual reporting periods beginning after December 15, 2010, and for interim reporting periods within those years. The adoption of the remaining provisions of this amendment is not expected to have a material impact on our financial statement disclosures.

In October 2009, the FASB issued an amendment to the accounting for multiple-deliverable revenue arrangements. This amendment provides guidance on determining whether multiple deliverables exist, how the arrangements should be separated and how the consideration paid should be allocated. As a result of this amendment, entities may be able to separate multiple-deliverable arrangements in more circumstances than under existing accounting guidance. This guidance amends the requirement to establish the fair value of undelivered products and services based on objective evidence and instead provides for separate revenue recognition based upon management s best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The existing guidance previously required that the fair value of the undelivered item reflect the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This amendment will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption and retrospective application is also permitted. We have not adopted this guidance early and are currently evaluating the potential effect of the adoption of this amendment on our results of operations and financial condition.

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 earnings 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 are determined by applying the treasury stock method.

A total of 20,164,446 and 15,692,101 potential common shares have been excluded from the calculation of net loss per share for the three months ended June 30, 2010 and 2009, respectively, because their inclusion would be anti-dilutive. A total of 19,617,796 and 15,238,119 potential common shares have been excluded from the calculation of net loss per share for the six months ended June 30, 2010 and 2009, respectively, because their inclusion would be anti-dilutive. As of June 30, 2010, the holders of our Series A Preferred Stock and Series D Preferred Stock could convert their Preferred Shares into approximately 1,036,858 and 12,827,952 shares of our Common Stock, respectively.

Table of Contents

NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(in thousands)	June 30, 2010	December 31, 2009
Accounts receivable, net:		
Accounts receivable	$ 12,557	$ 9,118
Less allowance for doubtful accounts	(641)	(351)
	$ 11,916	$ 8,767
Inventories, net:		
Raw materials (components)	$ 3,897	$ 3,764
Work-in process	1,003	1,365
Finished products	7,129	5,632
Less provision for inventory reserve	(210)	(241)
	$ 11,819	$ 10,520
Intangible assets, net:		
Customer relationships	$ 6,993	$ 7,259
Technology	4,597	4,597
Product registrations	3,612	3,829
Tradename	617	578
Covenants not to compete	363	317
Other	7	7
Less amortization	(5,558)	(3,865)
	$ 10,631	$ 12,722

The change in value of the intangible assets reflects the foreign currency fluctuation between the Chilean peso and the US dollar at June 30, 2010 and December 31, 2009.

NOTE 5 ACQUISITION AND INVESTMENTS

On February 17, 2010, we acquired Pharmacos Exakta, a privately-owned Mexican company, engaged in the manufacture, marketing and distribution of ophthalmic and other pharmaceutical products for government and private markets since 1957. Pursuant to a purchase agreement we acquired all of the outstanding stock of Pharmacos Exakta and real property owned by an affiliate of Pharmacos Exakta for a total aggregate purchase price of $3.6 million, of which an aggregate of $1.6 million was paid in cash and $2.0 million was paid in shares of our Common Stock, par value $.01. The number of shares to be issued was determined by the average closing price of the Company s Common Stock as reported on the NYSE Amex for the ten trading days ending on February 12, 2010. A total of 1,372,428 shares of OPKO Common Stock were issued in the transaction which were valued at $2.0 million due to trading restrictions. A portion of the proceeds will remain in escrow for a period of time for working capital adjustments and to satisfy indemnification claims.

On October 1, 2009, we entered into a definitive agreement to acquire Pharma Genexx, a privately-owned Chilean company engaged in the representation, importation, commercialization and distribution of pharmaceutical products, over-the-counter products and medical devices for government, private and institutional markets in Chile. Pursuant to a stock purchase agreement with Pharma Genexx and its shareholders, Farmacias Ahumada S.A., FASA Chile S.A., and Laboratorios Volta S.A., we acquired all of the outstanding stock of Pharma Genexx in exchange for $16 million in cash. The transaction closed on October 7, 2009.

Effective September 21, 2009, we entered into an agreement pursuant to which we invested $2.5 million in cash in Cocrystal Discovery, Inc., a privately held biopharmaceutical company (Cocrystal) in exchange for 1,701,723 shares of Cocrystal s Convertible Series A Preferred Stock. As of June 30, 2010, we own approximately 16% of Cocrystal s outstanding stock.

We have determined that Cocrystal has insufficient resources to carry out its principal activities without additional subordinated financial support. As such, Cocrystal meets the definition of a variable interest entity (VIE). In order to determine the primary beneficiary of the variable interest entity (VIE), we evaluated the related party group to identify who had the most significant power to control Cocrystal. Members of The Frost Group, LLC (the Frost Group) own approximately 4,422,967 shares, representing 42% of Cocrystal s voting stock on an as converted basis, including 4,152,386 held by the Frost Gamma Investments Trust (the Gamma Trust).

Table of Contents

The Frost Group members include a trust controlled by Dr. Frost, who is our Chief Executive Officer and Chairman of the Board of Directors, Dr. Jane H. Hsiao, who is the Vice Chairman of the Board of Directors and Chief Technical Officer, Steven D. Rubin who is Executive Vice President Administration and a director of the Company and Rao Uppaluri who is our Chief Financial Officer. Dr. Frost, Mr. Rubin, and Dr. Hsiao currently serve on the Board of Directors of Cocrystal and represent 50% of its board. In addition, the Gamma Trust influenced the redesign of Cocrystal and can significantly influence the success of Cocrystal through its board representation and voting power. As such, we have determined that the Gamma Trust is the primary beneficiary within the related party group. As a result of our determination that we are not the primary beneficiary, we have accounted for our investment in Cocrystal under the equity method.

On June 10, 2009, we entered into a stock purchase agreement with Sorrento Therapeutics, Inc. (Sorrento), a privately held company with a technology for generating fully human monoclonal antibodies, pursuant to which we invested $2.3 million in Sorrento. We own approximately 53,113,732 shares of Sorrento common stock, or approximately 24% of Sorrento s total outstanding common stock at June 30, 2010. The closing stock price for Sorrento s common stock, a thinly traded stock, as quoted on the over-the-counter markets was $1.75 per share on June 30, 2010.

NOTE 6 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.

As of June 30, 2010, we held money market funds that qualify as cash equivalents and forward contracts for inventory purchases that are required to be measured at fair value on a recurring basis. Refer to Note 7. As of June 30, 2010, we held money market funds that qualify as cash equivalents as well as marketable securities which were comprised of treasury securities, maturing August 12, 2010, that are required to be measured at fair value on a recurring basis. The $10 million of treasury securities are recorded at amortized cost, which reflects their approximate fair value. Our other assets and liabilities carrying value approximate their fair value due to their short-term nature.

Upon the termination of an employee of Ophthalmics Technologies, Inc., or OTI, we became obligated at the former employee s sole option to acquire up to 10% of the shares issued to the employee in connection with the acquisition of OTI at a price of $3.55 per share. In February 2009, this employee exercised his put option and we repurchased 27,154 shares of our Common Stock at $3.55 per share for a total of $0.1 million. In addition, an existing employee of OTI has the same provision within his employment arrangement with a potential obligation of approximately $0.3 million. We have recorded approximately $0.1 million and $0.2 million in accrued expenses as of June 30, 2010 and December 31, 2009, respectively, based on the estimated fair value of the unexercised put option.

The OTI put options were valued at fair value utilizing the Black-Scholes-Merton valuation method. During the three months ended June 30, 2010 and 2009, we recorded a reversal of expense of $24 thousand and $0.1 million, respectively, reflecting our stock price fluctuations. During the six months ended June 30, 2010 and 2009, we recorded a reversal of expense of $40 thousand and $0.1 million, respectively, reflecting our stock price fluctuations.

Any future fluctuation in fair value related to these instruments that is judged to be temporary, including any recoveries of previous write-downs, would be recorded in accumulated other comprehensive income or loss. If we determine that any future valuation adjustment was other-than-temporary, we would record a charge to the consolidated statement of operations as appropriate.

Table of Contents

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

	Fair value measurements as of June 30, 2010			
(in thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$ 8,360	$	$	$ 8,360
Treasury securities	9,998			9,998
Total assets	$ 18,358	$	$	$ 18,358
Liabilities:				
OTI put option	$	$ 137	$	$ 137
Forward contracts		450		450
Total liabilities	$	$ 587	$	$ 587

NOTE 7 DERIVATIVE CONTRACTS

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

We record derivative financial instruments on our balance sheet at their fair value as an accrued expense and the changes in the fair value are recognized in income in other expense net when they occur, the only exception being derivatives that qualify as hedges. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At June 30, 2010, the forward contracts did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in fair values in income.

The outstanding contracts at June 30, 2010, have been recorded at fair value, and their maturity details are as follows:

(in thousands)			Unrealized
Days until maturity	Contract value	Fair value at June 30, 2010	gain (loss)
0 to 30	$ 342	$ 315	$ (27)
31 to 60	1,268	1,205	(63)
61 to 90	451	418	(33)
91 to 120	1,793	1,695	(98)
121 to 180	1,829	1,713	(116)

More than 180	2,197	2,084	(113)
Total	$ 7,880	$ 7,430	$ (450)

NOTE 8 RELATED PARTY TRANSACTIONS

On July 20, 2010, we entered into a use agreement for approximately 1,100 square feet of space in Jupiter, Florida to house our molecular diagnostics operations from The Scripps Research Institute (Scripps). Dr. Frost is a member of the Board of Trustees of Scripps and Dr. Richard Lerner, a member of our board of directors, is also the President of Scripps. Pursuant to the terms of the use agreement, which is effective as of November 1, 2009, gross rent is approximately $40 thousand per year for a two-year term which may be extended, upon mutual agreement, for one additional year.

On June 1, 2010, the Company entered into a cooperative research and development agreement with Academia Sinica in Taipei, Taiwan, 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

Table of Contents

Research Center, Academia Sinica. In connection with the agreement, we are required to pay Academia Sinica approximately $0.2 million over the term of the agreement.

Effective March 5, 2010, the Frost Group assigned two license agreements with Academia Sinica to the Company s subsidiary, OPKO Taiwan, Inc. The license agreements pertain to alpha-galactosyl ceramide analogs and their use as immunotherapies and peptide ligands in the diagnosis and treatment of cancer. In connection with the assignment of the two licenses, the Company agreed to reimburse the Frost Group for the licensing fees previously paid by the Frost Group to Academia Sinica in the amounts of $50 thousand and $75 thousand, respectively, as well as reimbursement of certain expenses.

Effective September 21, 2009, we entered into an agreement pursuant to which the 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 million in Cocrystal, and agreed to invest an additional $5 million payable in two equal installments in September 2009 and March 2010. As a result of an amendment to the Cocrystal Investors agreements dated June 9, 2009, OPKO, rather than the Cocrystal Investors, made the first installment investment ($2.5 million) on September 21, 2009. Refer to Note 5.

On July 20, 2009, the Company entered into a worldwide exclusive license agreement with Academia Sinica in Taipei, Taiwan, for a new technology to develop protein vaccines against influenza and other viral infections. 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.

On June 16, 2009, we entered into an agreement to lease approximately 10,000 square feet of space in Hialeah, Florida to house manufacturing and service operations for our ophthalmic instrumentation business (the Hialeah Facility) from an entity controlled by Dr. Frost and Dr. Jane Hsiao. Pursuant to the terms of a lease agreement, which is effective as of February 1, 2009, gross rent is $0.1 million per year for a one-year lease which may be extended, at our option, for one additional year. From April 2008 through January 2009, we leased 20,000 square feet at the Hialeah Facility from a third party landlord pursuant to a lease agreement which contained an option to purchase the facility. We initially elected to exercise the option to purchase the Hialeah Facility in September 2008. Prior to closing, however, we assigned the right to purchase the Hialeah Facility to an entity controlled by Drs. Frost and Hsiao and leased a smaller portion of the facility as a result of several factors, including our inability to obtain outside financing for the purchase, current business needs, the reduced operating costs for the smaller space and the minimization of risk and expense of unutilized space.

In March 2009, we paid the $45 thousand filing fee to the Federal Trade Commission in connection with filings made by us and Dr. Frost, under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR). The filings permitted Dr. Frost and his affiliates to acquire additional shares of our Common Stock upon expiration of the HSR waiting period on March 23, 2009.

In November 2007, we entered into an office lease with Frost Real Estate Holdings, LLC, an entity affiliated with Dr. Frost. The lease is for approximately 8,300 square feet of space in an office building in Miami, Florida, where the Company s principal executive offices are located. We had previously been leasing this space from Frost Real Estate Holdings on a month-to-month basis while the parties were negotiating the lease. 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. From January 1, 2008 through October 1, 2008, we leased an additional 1,100 square feet of general office and laboratory space on a ground floor annex of our corporate office building pursuant to an addendum to the Lease, which required us to pay annual rent of $19 thousand per year for the annex space.

On September 19, 2007, we entered into an exclusive technology license agreement with Winston Laboratories, Inc. (Winston) pursuant to which we acquired an exclusive license to the proprietary rights of certain products in exchange for the payment of an initial licensing fee, royalties, and payments on the occurrence of certain milestones.

On February 23, 2010, we provided Winston notice of termination of the license agreement, and the agreement terminated on May 24, 2010. Previously, members of the Frost Group, LLC, or the Frost Group, beneficially owned approximately 30% of Winston Pharmaceuticals, Inc., and Dr. Uppaluri, our Chief Financial Officer, served as a

member of Winston s board. Effective May 19, 2010, the members of the Frost Group sold 100% of Winston s capital stock beneficially owned by them (consisting of an aggregate of 18,399,271 outstanding shares of common stock and warrants to purchase an aggregate of 8,958,975 shares of common stock) to an entity whose members include Dr. Joel E. Bernstein, the President and Chief Executive Officer of Winston. As consideration for the sale, the Frost Group members received an aggregate of $789,500 in cash and non-recourse promissory notes in the aggregate principal amount of $10,263,500 (the Promissory Notes). Dr. Uppaluri resigned from the Winston board effective May 19, 2010.

We have a $12.0 million line of credit with the Frost Group, a related party. On June 2, 2010 we repaid all amounts outstanding on the line of credit including $12 million in principal and $4.1 million in interest. We have the ability to redraw funds under the line of credit until its expiration in January 2011. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit at an 11% annual rate, which is due January 11, 2011. The line of credit is collateralized by all of our personal property except our intellectual property.

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

Table of Contents

Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive; nor do we pay for any other fixed or variable operating costs of the airplane. For the three and six months ended June 30, 2010, we reimbursed Dr. Frost approximately $7 thousand and $25 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and six months ended June 30, 2009, we reimbursed Dr. Frost approximately $13 thousand and $46 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

NOTE 9 COMMITMENTS AND CONTINGENCIES

On January 7, 2010, we received a letter from counsel to Nidek Co., Ltd. (Nidek) alleging that Ophthalmic Technologies, Inc. (OTI) or OPKO breached its service obligations to Nidek under the Service Agreement between OTI, Nidek and Newport Corporation, dated December 29, 2006, and the Service Agreement by and between Nidek and OTI, dated the same date. We have had discussions with Nidek regarding the matter, but it is too early to assess the likelihood of litigation in this matter or the probability of a favorable or unfavorable outcome. We do not believe this matter will have a material impact on our results of operations or financial condition. We are also assessing possible claims of indemnification against a supplier in connection with the matter.

On May 6, 2008, we completed the acquisition of Vidus Ocular, Inc., or Vidus. Pursuant to a Securities Purchase Agreement with Vidus, each of its stockholders, and the holders of convertible promissory notes issued by Vidus, we acquired all of the outstanding stock and convertible debt of Vidus in exchange for (i) the issuance and delivery at closing of 658,080 shares of our common stock (the Closing Shares); (ii) the issuance of 488,420 shares of our common stock to be held in escrow pending the occurrence of certain development milestones (the Milestone Shares); and (iii) the issuance of options to acquire 200,000 shares of our common stock. Additionally, in the event that the stock price for our common stock at the time of receipt of approval or clearance by the U.S. Food & Drug Administration of a pre-market notification 510(k) relating to the Aquashunt is not at or above a specified price, we will be obligated to issue an additional 413,850 shares of our common stock.

We have a potential obligation of approximately $0.3 million related to a put option held by an employee. Refer to Note 6.

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

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

NOTE 10 SEGMENTS

We currently manage our operations in two reportable segments, pharmaceutical and instrumentation segments. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, diagnostic tests and vaccines, and (ii) the pharmaceutical operations we acquired in Chile and Mexico through the acquisition of Pharma Genexx and Pharmacos Exakta. The instrumentation segment consists of ophthalmic instrumentation products and the activities related to the research, development, manufacture and commercialization of those products. 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

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

	For the three months ended June 30,		For the six months ended June 30,	
(in thousands)	2010	2009	2010	2009
Revenue				
Pharmaceutical	$ 5,273	$	$ 10,585	$
Instrumentation	2,182	2,347	4,792	4,648
	$ 7,455	$ 2,347	$ 15,377	$ 4,648
Operating loss				
Pharmaceutical	$ (1,415)	$ (1,578)	$ (2,059)	$ (6,648)
Instrumentation	(998)	(1,310)	(1,934)	(1,989)
Corporate	(3,114)	(2,359)	(5,600)	(5,192)
	$ (5,527)	$ (5,247)	$ (9,593)	$ (13,829)
Depreciation and amortization				
Pharmaceutical	$ 529	$ 8	$ 1,043	$ 13
Instrumentation	444	445	888	891
Corporate	20	16	33	31
	$ 993	$ 469	$ 1,964	$ 935
Revenue				
United States	$ 172	$ 22	$ 369	$ 241
Chile	4,257		9,194	
Mexico	1,138		1,391	
All others	1,888	2,325	4,423	4,407
	$ 7,455	$ 2,347	$ 15,377	$ 4,648

	As of	
	June 30, 2010	December 31, 2009
Assets		
Pharmaceutical	$ 33,581	$ 28,813
Instrumentation	11,113	12,262
Corporate	23,321	46,355
	$ 68,015	$ 87,430

During the three months ended June 30, 2010, our two largest customers represented approximately 15% and 13% of our total revenue, respectively. During the three months ended June 30, 2009, our four largest customers represented approximately 19%, 16%, 15%, and 13%, respectively, of our revenue. During the six months ended June 30, 2010, our two largest customers represented approximately 15% and 13% of our total revenue, respectively.

During the six months ended June 30, 2009, our three largest customers represented approximately 19%, 16%, and 15%, respectively, of our revenue. As of June 30, 2010, two customers represented approximately 28% and 16% of our accounts receivable balance, respectively. As of December 31, 2009, two customers represented 32% and 19%, respectively, of our accounts receivable balance.

NOTE 11 SUBSEQUENT EVENTS

We have reviewed all subsequent events and transactions that occurred after the date of our June 30, 2010 consolidated balance sheet date, through the time of filing this Quarterly Report on Form 10-Q on August 9, 2010.

Table of Contents

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

OVERVIEW

You should read this discussion together with the condensed consolidated financial statements, related Notes, and other financial information included elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2009 (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, 2009. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

We are a specialty healthcare company involved in the discovery, development and commercialization of pharmaceutical products, medical devices, vaccines, diagnostic technologies and imaging systems. Initially focused on the treatment and management of ophthalmic diseases, we have since expanded into other areas of major unmet medical need. To date, we have devoted a significant portion of our efforts towards research and development. As of June 30, 2010, we had an accumulated deficit of $350.3 million. Since we do not generate revenue from any of our pharmaceutical product candidates and have only generated limited revenue from our pharmaceutical operations in Chile and Mexico and our instrumentation business, we expect to continue to generate significant losses in connection with the research and development activities relating to our product candidates and other technologies. Such research and development activities are budgeted to expand over 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 will 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.

RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED JUNE 30, 2010 AND 2009

Revenue. Revenue for the three months ended June 30, 2010, was $7.5 million, compared to $2.3 million for the comparable 2009 period. The increase in revenue during the three months ended June 30, 2010 is primarily due to revenue from our Pharma Genexx and Pharmacos Exakta pharmaceutical businesses in Chile and Mexico, respectively. We acquired Pharma Genexx in October 2009 and Pharmacos Exakta in February 2010, and as a result, the 2009 period reflects revenue only from our instrumentation business. Revenue from our instrumentation business decreased slightly from the 2009 period, primarily as a result of decreased pricing for our OCT/SLO product in international markets.

Gross margin. Gross margin for the three months ended June 30, 2010, was $2.6 million compared to $0.6 million for the comparable period of 2009. Gross margin for the three months ended June 30, 2010, increased from the 2009 period primarily as a result of the gross margin generated by our pharmaceutical business in Chile.

Selling, general and administrative expense. Selling, general and administrative expense for the three months ended June 30, 2010, was $5.6 million compared to $2.9 million of expense for the comparable period of 2009. The increase in selling, general and administrative expenses primarily reflects the increase in selling expenses related to our pharmaceutical business as a result of our acquisitions of Pharma Genexx and Pharmacos Exakta, partially offset by decreased professional fees. Selling, general and administrative expenses during the three months ended June 30, 2010 and 2009, primarily include personnel expenses, including equity-based compensation expense of $1.2 million and $0.8 million, respectively, and professional fees.

Research and development expense. Research and development expense during the three months ended June 30, 2010 and 2009, was $1.6 million and $2.5 million, respectively. The decrease for the three months ended June 30, 2010, primarily reflects the inclusion during the 2009 period of the estimated shutdown costs of the Phase III clinical trial, including the cost of analyzing the data collected and performing statistical analysis. Partially offsetting the decrease in research and development expense was increased activity related to our rolapitant and diagnostic testing development programs. Research and development expenses during the three months ended June 30, 2010, includes equity-based compensation expense of $0.3 million, compared to $0.4 million for the 2009 period.

Other operating expenses. Other operating expenses for the three months ended June 30, 2010, as compared to the three months ended June 30, 2009, increased by $0.5 million primarily as a result of the amortization of the intangible assets recorded as part of the acquisition of Pharma Genexx and also include amortization of intangible

18

Table of Contents

assets recorded as part of the acquisitions of OTI and Pharmacos Exakta. The 2009 period only include the amortization expense of the intangible assets acquired from OTI.

Other income and expenses. Other expense was $0.4 million for the three months ended June 30, 2010 compared to $0.5 million for the comparable 2009 period. Other income and expenses primarily consists of income earned from interest on our cash and cash equivalents and interest expense reflects the interest incurred on our lines of credit. On June 2, 2010 we repaid all amounts outstanding on The Frost Group, LLC, (the Frost Group) line of credit including $12 million in principal and $4.1 million in interest. We have the ability to redraw funds under the line of credit until its expiration in January 2011. The Frost Group members include a trust controlled by Dr. Frost, who is the Company s Chief Executive Officer and Chairman of the board of directors, Dr. Jane H. Hsiao, who is the Vice Chairman of the board of directors and Chief Technical Officer, Steven D. Rubin who is Executive Vice President Administration and a director of the Company and Rao Uppaluri who is the Chief Financial Officer of the Company.

Income taxes. For the three months ended June 30, 2010, our income tax provision reflects the income tax payable in Chile, partially offset by our refundable Canadian provincial tax credit. This credit relates to research and development expenses incurred at our OTI locations. The income tax benefit for the three months ended June 30, 2009 reflect only the refundable Canadian provincial tax credit.

FOR THE SIX MONTHS ENDED JUNE 30, 2010 AND 2009

Revenue. Revenue for the six months ended June 30, 2010, was $15.4 million, compared to $4.6 million for the comparable 2009 period. The increase in revenue during the first six months of 2010 is primarily due to revenue from our Pharma Genexx and Pharmacos Exakta pharmaceutical businesses in Chile and Mexico. We acquired Pharma Genexx in October 2009 and Pharmacos Exakta in February 2010, and as a result, the 2009 period reflects revenue only from our instrumentation business.

Gross margin. Gross margin for the six months ended June 30, 2010, was $5.0 million compared to $1.3 million for the comparable period of 2009. Gross margin for the six months ended June 30, 2010, increased from the 2009 period primarily as a result of the gross margin generated by our Pharma Genexx pharmaceutical business in Chile.

Selling, general and administrative expense. Selling, general and administrative expense for the six months ended June 30, 2010, was $9.9 million compared to $6.2 million of expense for the comparable period of 2009. The increase in selling, general and administrative expenses primarily reflects the increase in selling expenses related to our pharmaceutical business as a result of our acquisitions of Pharma Genexx and Pharmacos Exakta, partially offset by decreased professional fees. Selling, general and administrative expenses during the first six months of 2010 and 2009, primarily include personnel expenses, including equity-based compensation expense of $2.2 million and $1.5 million, respectively, and professional fees.

Research and development expense. Research and development expense during the six months ended June 30, 2010 and 2009, was $2.9 million and $8.2 million, respectively. The decrease for the six months ended June 30, 2010, primarily reflects the inclusion during the 2009 period of the cost of the Phase III clinical trial for bevasiranib until March 6, 2009, when the trial was shut down. The 2009 period includes the estimated shutdown costs of the trial, including transitioning patients from the trial onto the standard of care therapy. The shutdown costs include the cost of analyzing the data collected and performing statistical analysis. Partially offsetting this decrease was increased activity related to our rolapitant and diagnostic testing development programs. The six months ended June 30, 2010, includes equity-based compensation expense of $0.5 million, compared to $0.2 million for the 2009 period.

Other operating expenses. Other operating expenses for the six months ended June 30, 2010, as compared to the six months ended June 30, 2009, increased by $1.0 million primarily as a result of the amortization of the intangible assets recorded as part of the acquisition of Pharma Genexx and also include amortization of intangible assets recorded as part of the acquisitions of OTI and Pharmacos Exakta. The 2009 period only includes amortization of the intangible assets acquired from OTI.

Other income and expenses. Other expense was $0.7 million for the first six months of 2010 compared to $0.9 million for the comparable 2009 period. Other income primarily consists of interest earned on our cash and cash equivalents and interest expense primarily reflects the interest incurred on our line of credit with the Frost Group. On June 2, 2010, we repaid all amounts outstanding on the Frost Group line of credit including $12 million in principal and $4.1 million in interest. We have the ability to redraw funds under the line of credit until its expiration in

January 2011.

Table of Contents

Income taxes. For the six months ended June 30, 2010, our income tax provision reflects the income tax payable in Chile, partially offset by our refundable Canadian provincial tax credit. This credit relates to research and development expenses incurred at our OTI locations. The income tax benefit for the six months ended June 30, 2009, reflect only the refundable Canadian provincial tax credit.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2010, we had cash, cash equivalents and marketable securities of approximately $19.7 million. Cash used in operations during 2010 primarily reflects expenses related to selling, general and administrative activities related to our corporate and instrumentation operations, as well as our Chilean operations. Since our inception, we have not generated sufficient income and our primary source of cash has been from the private placement of stock and through credit facilities available to us.

In connection with our acquisition of Pharma Genexx, we entered into line of credit agreements in the aggregate amount of $16.6 million with seven financial institutions in Chile, of which, $10.4 million is unused. These lines of credit are used primarily as a source of working capital for inventory purchases.

We currently have an unutilized $12.0 million line of credit with the Frost Group, a related party. On June 2, 2010, we repaid all amounts outstanding on the line of credit including $12 million in principal and $4.1 million in interest. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit at an 11% annual rate, which is due January 11, 2011. The line of credit is collateralized by all of our personal property except our intellectual property.

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

We believe the cash, cash equivalents and marketable securities on hand and available to us at June 30, 2010 will be sufficient to meet our anticipated cash requirements for operations and debt service for 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 products 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 our research and development of 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.

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

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 award 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

Table of Contents

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

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

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

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. Certain of our products are sold directly to end-users and require that we deliver, install and train the staff at the end-users facility. As a result, we do not recognize revenue until the product is delivered, installed and training has occurred. Return policies in certain international markets for our medical device products provide for stringent guidelines in accordance with the terms of contractual agreements with customers. Our estimates for sales returns are based upon the historical patterns of products returned matched against the sales from which they originated, and management s evaluation of specific factors that may increase the risk of product returns. We analyze accounts receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by management s estimate of the collectability of accounts receivable. The allowance for doubtful accounts recognized in our consolidated balance sheets at June 30, 2010 and December 31, 2009 was $0.6 million and $0.4 million, respectively.

Recent accounting pronouncements: In March 2010, the Financial Accounting Standards Board, or FASB, issued updated guidance to amend and clarify how entities should evaluate credit derivatives embedded in beneficial interests in securitized financial assets. The updated guidance eliminates the scope exception for bifurcation of embedded credit derivatives in interests in securitized financial assets, unless they are created solely by subordination of one financial instrument to another. The update allows entities to elect the fair value option for any beneficial interest in securitized financial assets upon adoption. This guidance is effective by the first day of the first fiscal quarter beginning after June 15, 2010. Early adoption is permitted. We have not adopted this guidance early and are currently evaluating the potential effect of the adoption of this amendment on our results of operation and financial condition.

In March 2010, the FASB reached a consensus to issue an amendment to the accounting for revenue arrangements under which a vendor satisfies its performance obligations to a customer over a period of time, when the deliverable or unit of accounting is not within the scope of other authoritative literature, and when the arrangement consideration is contingent upon the achievement of a milestone. The amendment defines a milestone and clarifies whether an entity may recognize consideration earned from the achievement of a milestone in the period in which the milestone is achieved. This amendment is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. The amendment may be applied retrospectively to all arrangements or prospectively for milestones achieved after the effective date. We have not adopted this guidance early and adoption of this amendment is not expected to have a material impact on our results of operation or financial condition.

In January 2010, the FASB issued an amendment to the accounting for fair value measurements and disclosures. This amendment details additional disclosures on fair value measurements, requires a gross presentation of activities within a Level 3 rollforward, and adds a new requirement to the disclosure of transfers in and out of Level 1 and Level

2 measurements. The new disclosures are required of all entities that are required to provide disclosures about recurring and nonrecurring fair value measurements. This amendment was effective as of January 1, 2010, with an

Table of Contents

exception for the gross presentation of Level 3 rollforward information, which is required for annual reporting periods beginning after December 15, 2010, and for interim reporting periods within those years. The adoption of the remaining provisions of this amendment is not expected to have a material impact on our financial statement disclosures.

In October 2009, the FASB issued an amendment to the accounting for multiple-deliverable revenue arrangements. This amendment provides guidance on determining whether multiple deliverables exist, how the arrangements should be separated and how the consideration paid should be allocated. As a result of this amendment, entities may be able to separate multiple-deliverable arrangements in more circumstances than under existing accounting guidance. This guidance amends the requirement to establish the fair value of undelivered products and services based on objective evidence and instead provides for separate revenue recognition based upon management s best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The existing guidance previously required that the fair value of the undelivered item reflect the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. If the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This amendment will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption and retrospective application is also permitted. We have not adopted this guidance early and are currently evaluating the potential effect of the adoption of this amendment on our results of operations and financial condition.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

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

Our derivative activities, which consist of foreign exchange forward contracts, are initiated to hedge forecasted cash flows that are exposed to foreign currency risk. The foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts maturity dates. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the consolidated statement of operations at maturity, and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. If the counterparties to the exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. We enter into these contracts with counterparties that we believe to be creditworthy and do not enter into any leveraged derivative transactions. We had $7.9 million in foreign exchange forward contracts outstanding at June 30, 2010, primarily to hedge Chilean-based operating cash flows against US dollars. If Chilean Pesos were to strengthen in relation to the US dollar, our hedged foreign currency cash-flows expense would be offset by a loss on the derivative contracts, with a net effect of zero.

We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or other than trading instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk.

Interest Rate Risk Our exposure to market risk relates to our cash and investments and to our borrowings. We maintain an investment portfolio of money market funds and treasury securities. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment

portfolio except for reduced income in a low interest rate environment. At June 30, 2010, we had cash, cash equivalents and marketable securities of $19.7 million. The weighted average interest rate related to our cash and cash equivalents for the three months ended June 30, 2010 was 0%. As of June 30, 2010, the principal value of our credit lines was $6.1 million, and have a weighted average interest rate of 8% for the 6 months then ended.

Table of Contents

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 one month.

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 June 30, 2010. Based on that evaluation, management has 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 our acquisitions of Pharmacos Exakta and Pharma Genexx, we began implementing a new accounting system, as well as standards and procedures, upgrading and establishing controls over accounting systems and adding employees 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 Pharma Genexx and Pharmacos Exakta. Other than as set forth above with respect to Pharma Genexx and Pharmacos Exakta, there have been no changes to the Company s internal control over financial reporting that occurred during the Company s second fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Table of Contents

Item 1A. Risk Factors

There have been no material changes from the risk factors as previously disclosed in the Item 1A of the Company Annual Report on Form 10-K.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and Reserved)

Item 5. Other Information

None.

Item 6. Exhibits.

Exhibit 2.1[(1)]	Merger Agreement and Plan of Reorganization, dated as of March 27, 2007, by and among Acuity Pharmaceuticals, Inc., Froptix Corporation, eXegenics, Inc., e-Acquisition Company I-A, LLC, and e-Acquisition Company II-B, LLC.
Exhibit 2.2[(4)+]	Securities Purchase Agreement dated May 2, 2008, among Vidus Ocular, Inc., OPKO Instrumentation, LLC, OPKO Health, Inc., and the individual sellers and noteholders named therein.
Exhibit 2.3[(5)]	Purchase Agreement, dated February 17, 2010, among Ignacio Levy García and José de Jesús Levy García, Inmobiliaria Chapalita, S.A. de C.V., Pharmacos Exakta, S.A. de C.V., OPKO Health, Inc., OPKO Health Mexicana S. de R.L. de C.V., and OPKO Manufacturing Facilities S. de R.L. de C.V.
Exhibit 3.1[(2)]	Amended and Restated Certificate of Incorporation.
Exhibit 3.2[(3)]	Amended and Restated By-Laws.
Exhibit 4.1[(1)]	Form of Common Stock Warrant.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2010.
Exhibit 31.2	Certification by Rao Uppaluri, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2010.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2010.
Exhibit 32.2	Certification by Rao Uppaluri, Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2010.

Table of Contents

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

(1) Filed with the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 2, 2007, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2008 for the Company s three-month period ended June 30, 2008, and incorporated herein by reference.

(5) Filed with the Company s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2010 for the Company s three-month period ended March 31, 2010, and incorporated herein by reference.

Table of Contents

SIGNATURES

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

Date: August 9, 2010

OPKO Health, Inc.

/s/ Adam Logal
Adam Logal
Executive Director of Finance, Chief Accounting Officer and Treasurer

Table of Contents

Exhibit Index

Exhibit Number	Description
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2010.
Exhibit 31.2	Certification by Rao Uppaluri, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2010.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2010.
Exhibit 32.2	Certification by Rao Uppaluri, Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2010.