Opko Health, Inc.
Form 10-Q
November 09, 2009

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 September 30, 2009.

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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this Chapter) 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	Smaller reporting company o
		(Do not check if a 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 o NO þ
As of November 3, 2009, the registrant had 253,744,539 shares of common stock outstanding.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report 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, 2008, and described from time to time in our reports filed with the Securities and Exchange Commission. 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.

Following the recommendation of the Independent Data Monitoring Committee, we terminated the Phase III clinical trial of bevasiranib, our most advanced product candidate. As a result, we may not continue to develop or be able to successfully commercialize bevasiranib.

Our current and planned clinical trials may not satisfy the requirements of the FDA or other non-United States 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.

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 and we therefore intend to 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. 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-United States governments often impose strict price controls, which may adversely affect our future profitability.

Our business may become subject to 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 majority 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 Exchange, which could cause our stock price to fall and decrease the liquidity of our common stock.

Future issuances of common stock 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.

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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands except share data)

	September 30, 2009	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	$ 58,391	$ 6,678
Marketable securities	5,000	
Accounts receivable, net	1,395	1,005
Inventory	5,447	4,063
Prepaid expenses and other current assets	1,536	1,720
Total current assets	71,769	13,466
Property and equipment, net	551	659
Intangible assets, net	5,118	6,336
Goodwill	1,097	1,097
Investments	4,697	
Other assets	371	206
Total assets	$ 83,603	$ 21,764
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 1,253	$ 2,221
Accrued expenses	3,064	5,394
Current portion of notes payable and capital lease obligations	27	97
Total current liabilities	4,344	7,712
Long-term liabilities and capital lease obligations	2,996	1,826
Line of credit with related party, net unamortized discount of $84 and $133, respectively	11,916	11,867
Total liabilities	19,256	21,405
Commitments and contingencies		
Shareholders equity		
Series A Preferred stock $0.01 par value, 4,000,000 shares authorized; 932,667 and 953,756 shares issued and outstanding (liquidation value of $2,507 and $2,384) at September 30, 2009 and December 31, 2008, respectively	9	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 0 shares issued and outstanding (liquidation value of $30,013 and $0) at September 30, 2009 and December 31, 2008	12	
Common Stock $0.01 par value, 500,000,000 shares authorized; 253,683,005 and 199,020,379 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	2,536	1,991
Treasury stock - 45,154 and 18,000 shares at September 30, 2009 and December 31, 2008, respectively	(61)	(24)
Additional paid-in capital	392,181	307,498
Accumulated deficit	(330,330)	(309,116)
Total shareholders equity	64,437	359
Total liabilities and shareholders equity	$ 83,603	$ 21,764

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

OPKO Health, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2009	2008	2009	2008
Revenue	$ 1,501	$ 4,050	$ 6,149	$ 7,753
Cost of goods sold	1,055	2,969	4,380	7,324
Gross margin	446	1,081	1,769	429
Operating expenses				
Selling, general and administrative	3,089	3,722	9,272	12,284
Research and development	2,805	4,913	10,962	14,748
Write-off of acquired in-process research and development				1,398
Other operating expenses, principally amortization of intangible assets	406	427	1,218	1,281
Total operating expenses	6,300	9,062	21,452	29,711
Operating loss	(5,854)	(7,981)	(19,683)	(29,282)
Other expense, net	(458)	(350)	(1,402)	(868)
Loss before income taxes and investment loss	(6,312)	(8,331)	(21,085)	(30,150)
Income tax benefit	(23)	(4)	(161)	(64)
Loss before investment losses in investees	(6,289)	(8,327)	(20,924)	(30,086)
Loss from investments in investee	(65)		(103)	
Net loss	(6,354)	(8,327)	(21,027)	(30,086)
Preferred stock dividend	(72)	(53)	(188)	(163)
Net loss attributable to common shareholders	$ (6,426)	$ (8,380)	$ (21,215)	$ (30,249)
Loss per common share, basic and diluted	$ (0.03)	$ (0.04)	$ (0.09)	$ (0.16)
Weighted average number of common shares outstanding, basic and diluted	252,986,149	187,625,641	226,273,290	184,361,260

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

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

	For the nine months ended September 30,	
	2009	2008
Cash flows from operating activities		
Net loss	$ (21,027)	$ (30,086)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,401	1,366
Write-off of acquired in-process research and development		1,398
Accretion of debt discount related to notes payable	49	156
Share based compensation	3,536	5,770
Provision for bad debts	58	70
Provision for inventory obsolescence	80	130
Losses from investments in investees	103	
Changes in:		
Accounts receivable	(448)	(460)
Inventory	(1,464)	(147)
Prepaid expenses and other current assets	184	(142)
Other assets	(167)	(152)
Accounts payable	(968)	(611)
Accrued expenses	(1,382)	1,260
Net cash used in operating activities	(20,045)	(21,448)
Cash flows from investing activities		
Acquisition of business, net of cash		48
Investments in investees	(4,800)	
Purchase of marketable securities	(9,997)	
Maturities of marketable securities	4,997	
Capital expenditures	(75)	(284)
Net cash used in investing activities	(9,875)	(236)
Cash flows from financing activities:		
Issuance of common stock for cash, to related parties	25,000	15,000
Issuance of common stock for cash	25,990	
Issuance of Series D preferred stock and warrants for cash, including related parties	30,000	
Proceeds from bridge loan with related party	3,000	
Repayment of bridge loan with related party	(3,000)	
Insurance financing	217	327
Proceeds from the exercise of stock options and warrants	716	351
Repayments of notes payable and capital lease obligations	(290)	(2,766)
Net cash provided by financing activities	81,633	12,912
Net increase (decrease) in cash and cash equivalents	51,713	(8,772)
Cash and cash equivalents at beginning of period	6,678	23,373

Cash and cash equivalents at end of period	$ 58,391	$ 14,601
SUPPLEMENTAL INFORMATION		
Interest paid	$ 51	$ 100
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Issuance of capital stock to acquire Vidus in 2008	$	$ 1,319

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

OPKO Health, Inc.

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 such as oncology, infectious diseases and neurological disorders. 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 (GAAP) 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 GAAP 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 nine months ended September 30, 2009, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2009 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, 2008.

In June 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Codification (ASC , or the Codification) as the source of authoritative generally accepted accounting principles (GAAP) recognized by the FASB for
non-governmental entities. The Codification is effective for financial statements issued for reporting periods that end after September 15, 2009. The Codification superseded all then-existing non-Securities and Exchange Commission (SEC) accounting and reporting standards. The Codification did not change rules and interpretations of the SEC which are also sources of authoritative GAAP for SEC registrants. Because the Codification did not change GAAP, the Codification had no impact on our consolidated financial statements or footnotes.

Principles of consolidation. The accompanying unaudited condensed consolidated financial statements as of September 30, 2009 and December 31, 2008 and for the three and nine months ended September 30, 2009 and 2008 include our accounts and our majority-owned subsidiaries. The condensed consolidated financial statements as of September 30, 2009 and December 31, 2008 include our accounts and our majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

As discussed in Note 7, we have made an investment in Cocrystal Discovery, Inc., (Cocrystal) and determined that Cocrystal is a VIE. In general, a VIE is a corporation, partnership, limited-liability corporation, trust, or any other legal structure used to conduct activities or hold assets that either (1) has an insufficient amount of equity to carry out its principal activities without additional subordinated financial support, (2) has a group of equity owners that are unable to make significant decisions about its activities, or (3) has a group of equity owners that do not have the obligation to absorb losses or the right to receive returns generated by its operations. We have determined that we are not the primary beneficiary of Cocrystal. Refer to Note 7.

Use of estimates. The preparation of financial statements in conformity with GAAP 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 has no components other than net loss for all periods presented.

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. During the three months ended September 30, 2009, revenue derived

from sales to two significant international customers represented approximately 17% and 10% of

our revenue, respectively. During the three months ended September 30, 2008, revenue derived from sales to three significant international customers represented 18%, 17% and 15% of our revenue, respectively. During the nine months ended September 30, 2009, revenue derived from sales to three significant international customers represented approximately 18%, 14%, and 12% of our revenue, respectively. During the nine months ended September 30, 2008, revenue derived from sales to three significant international customers represented approximately 15%, 14% and 12% of our revenue, respectively.

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.

The following table reflects the amounts recorded for the three months ended September 30, 2009 and 2008.

(in thousands)	September 30, 2009	September 30, 2008
Beginning balance	$ 295	$ 226
Accrual for products sold	39	153
Settlements in kind or expired	(116)	(114)
Ending balance	$ 218	$ 265

The following table reflects the amounts recorded for the nine months ended September 30, 2009 and 2008.

(in thousands)	September 30, 2009	September 30, 2008
Beginning balance	$ 259	$ 227
Accrual for products sold	167	208
Settlements in kind or expired	(208)	(170)
Ending balance	$ 218	$ 265

Allowance for returns and doubtful accounts. Allowances for estimated sales returns are based upon our history of product returns. The amount of allowance for doubtful accounts at September 30, 2009 and December 31, 2008, was $0.4 million and $0.4 million, respectively. As of September 30, 2009, accounts receivable from two of our international distributors represented approximately 32% and 15%, respectively, of our net accounts receivable balance. As of December 31, 2008, accounts receivable from two of our international distributors represented approximately 47% and 19%, respectively, of our net accounts receivable balance.

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. Accordingly, we have aggregated our instrumentation and pharmaceutical and device research and development activities into a single segment reporting basis. Our products are being used by and developed for retina specialists, ophthalmologists, and optometrists, among others.

Equity-Based Compensation. We account for equity-based compensation as an expense in our financial statements and such cost is measured at the fair value of the award. Equity-based compensation arrangements to non-employees are accounted for 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 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. During the three and nine months ended September 30, 2009 we recorded $1.8 million and $3.5 million, respectively, of equity-based compensation expense. During the three and nine months ended September 30, 2008, we recorded $1.6 million and $5.8 million, respectively, of equity-based compensation expense. During the nine months ended September 30, 2009 and 2008, we issued 2,912,593 and 4,741,184 shares of common stock, respectively, in connection with the exercise of stock options.

Fair value. We adopted the required provisions of ASC 820-10, Fair Value Measurements and Disclosures (Fair Value Measurements and Disclosures Standard), as of January 1, 2008, and adopted certain deferred provisions on January 1, 2009. The Fair Value Measurements and Disclosures Standard is a technical standard which defines fair value, establishes a consistent framework for measuring fair value, and expands disclosures for each major asset and liability category measured at fair value on either a recurring or a nonrecurring basis. The Fair Value Measurements and Disclosures Standard clarifies that fair value is 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 September 30, 2009, we held money market funds and treasury securities, maturing December 17, 2009, that qualify as cash equivalents as well as marketable securities which were comprised of treasury securities, maturing October 22, 2009, that are required to be measured at fair value on a recurring basis. We have $10 million of treasury securities that are recorded at amortized cost, which reflects their approximate fair value. We intend to hold the treasury securities through their maturity.

In addition, the Ophthalmic Technologies Inc., or (OTI), put options were valued at fair value utilizing the Black-Scholes valuation method. Refer to Note 9. During the three and nine months ended September 30, 2009, we recorded a reversal of expense of $35 thousand and $0.1 million, respectively, reflecting our stock price fluctuations. During the three and nine months ended September 30, 2008, we recorded $18 thousand and $0.1 million of expense, respectively, reflecting our stock price fluctuations during that period.

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.

Our financial assets and liabilities measured at fair value on a recurring basis, are as follows (in thousands):

	Fair value measurements as of September 30, 2009			
	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	$ 52,625	$	$	$ 52,625
Treasury securities	9,999			9,999
Total assets	$ 62,624	$		$ 62,624
Liabilities:				
OTI put option	$	$ 153	$	$ 153
Total	$ 62,624	$ 153	$	$ 62,777

Recent accounting pronouncements. On June 30, 2009, we adopted ASC 855-10-55 Subsequent Events Disclosure (Subsequent Events Standard), which established general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued. The Subsequent Events Standard defines two types of subsequent events. The effects of events or transactions that provide additional evidence about conditions that existed at the balance sheet date, including the estimates inherent in the process of preparing financial statements, are recognized in the financial statements. The effects of events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after that date are not recognized in the financial statements. Refer to Note 10.

In June 2009, the FASB issued Statement No. 167 (SFAS 167), Accounting for Variable Interest Entities. SFAS 167 amends FASB Interpretation No. 46(R) (FIN No. 46(R)), Consolidation of Variable Interest Entities, to require a comprehensive qualitative analysis to be performed to determine whether a holder of variable interests in a variable interest entity also has a controlling financial interest in that entity. In addition, it requires the same such analysis be applied to entities previously designated as qualified special-purpose entities under SFAS 140. SFAS 167 is effective as of the start of the first annual reporting period beginning after November 15, 2009, for interim periods within the first annual reporting period, and for all subsequent annual and interim reporting periods. We do not expect the adoption of SFAS 167 to have a material impact on our consolidated financial position, results of operations, or cash flows.

NOTE 3 LOSS PER SHARE

Basic loss per common share is computed by dividing our net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common 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 20,998,353 and 20,139,831 potential common shares have been excluded from the calculation of net loss per common share for the three months ended September 30, 2009 and 2008, respectively, because their inclusion would be anti-dilutive. A total of 17,154,864 and 24,617,550 potential common shares have been excluded from the calculation of net loss per common share for the nine months ended September 30, 2009 and 2008, respectively, because their inclusion would be anti-dilutive. In addition, our Series A preferred stock, if converted, could be converted into 1,002,617 shares of our common stock at September 30, 2009 and our Series D preferred stock, if converted, could be converted into 12,102,146 shares of our common stock at September 30, 2009.

NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(in thousands)	September 30, 2009	December 31, 2008
Accounts receivable, net:		
Accounts receivable	$ 1,786	$ 1,412
Less allowance for doubtful accounts	(391)	(407)
	$ 1,395	$ 1,005
Inventories, net:		
Raw materials (components)	$ 2,829	$ 2,635
Work-in process	1,512	934
Finished products	1,344	749
Less provision for inventory reserve	(238)	(255)
	$ 5,447	$ 4,063
Intangible assets, net:		
Technology	$ 4,597	$ 4,597
Customer relationships	2,978	2,978
Covenants not to compete	317	317
Tradename	195	195
Other	7	7
Less amortization	(2,976)	(1,758)
	$ 5,118	$ 6,336

NOTE 5 PRIVATE PLACEMENTS OF STOCK

Effective as of September 18, 2009, we entered into a securities purchase agreement (the Preferred Purchase Agreement) with the private investors named therein (the Preferred Investors), pursuant to which the Preferred Investors agreed to purchase an aggregate of 1,209,677 shares (the Preferred Shares) of the Company s newly-designated 8.0% Series D Cumulative Convertible Preferred Stock, par value $0.01 per share (Series D Preferred Stock), at a purchase price of $24.80 per share, together with warrants (the Warrants) to purchase up to an aggregate of 3,024,196 shares of the Company s common stock, par value $.01 (the Common Stock) at an exercise price of $2.48 per share (the Preferred Investment). Initially, the Series D Preferred Stock is convertible into ten shares of the Company s Common Stock, and the Preferred Shares purchase price was based on the average closing price of the Company s Common Stock as reported on the NYSE Amex for the five days preceding the execution of the Preferred Purchase Agreement. In connection with the Preferred Investment, the Company issued the Preferred Shares and received an aggregate of $30.0 million on September 28, 2009.

The Company agreed to issue the Preferred Shares and the Warrants in reliance upon the exemption from registration under Section 4(2) of the Securities Act of 1933, as amended (the Act). The Preferred Shares issued in the Preferred Investment, including the shares of the Company s Common Stock into which the Preferred Shares and Warrants may be converted, are restricted securities as that term is defined by Rule 144 under the Act, subject to a three year contractual lockup, and no registration rights have been granted.

On September 22, 2009, the Company filed with the Secretary of State of the State of Delaware a Certificate of Designation of the Powers, Preferences and Relative, Participating, Optional and Other Special Rights of 8.0% Series D Cumulative Convertible Preferred Stock, and Qualifications, Limitations and Restrictions Thereof (the

Certificate of Designation). A summary of the Certificate of Designation is set forth below:

Dividends. Holders of the Series D Preferred Stock are entitled to receive, when, as and if declared by the Company s Board of Directors, dividends on each share of Series D Preferred Stock at a rate per annum equal to 8.0% of the sum of (a) $24.80, plus (b) any and all declared and unpaid and accrued dividends thereon, subject to adjustment for any stock split, combination, recapitalization or other similar corporate action (the Liquidation Amount). All dividends shall be cumulative, whether or not earned or declared, accruing on an annual basis from the issue date of the Series D Preferred Stock.

Voting. The Holders of Series D Preferred Stock have the right to receive notice of any meeting of holders of the Company s Common Stock or Series D Preferred Stock and to vote (on an as-converted into Common Stock basis)

upon any matter submitted to a vote of the holders of Common Stock or Series D Preferred Stock. Except as otherwise expressly set forth in the Company s Amended and Restated Certificate of Incorporation, as amended from time to time, the holders of Series D Preferred Stock will vote on each matter submitted to them with the holders of Common Stock and all other classes and series of the Company s capital stock entitled to vote on such matter, taken together as a single class.

Rank. With respect to dividend distributions (other than required dividends to the holders of the Company s Series A Preferred Stock) and distributions upon liquidation, winding up or dissolution of the Company, the Series D Preferred Stock ranks senior to all classes of Common Stock, the Company s Series A Preferred Stock, the Company s Series C Preferred Stock, and to each other class of the Company s capital stock existing now or hereafter created that are not specifically designated as ranking senior to or pari passu with the Series D Preferred Stock.

Liquidation Preference. Upon the occurrence of a Liquidation Event (as defined in the Certificate of Designation), holders of Series D Preferred Stock are entitled to be paid, subject to applicable law, out of the assets of the Company available for distribution to its stockholders, an amount in cash (the Liquidation Payment) for each share of Series D Preferred Stock equal to the greater of (x) the Liquidation Amount for each such share of Series D Preferred Stock outstanding plus (i) any declared and unpaid dividends and (ii) accrued dividends or (y) the amount for each share of Series D Preferred Stock the holders would be entitled to receive pursuant to the Liquidation Event if all of the shares of Series D Preferred Stock had been converted into Common Stock as of the date immediately prior to the date fixed for determination of stockholders entitled to receive a distribution in such Liquidation Event. Such Liquidation Payment will be paid before any cash distribution will be made or any other assets distributed in respect of any class of securities junior to the Series D Preferred Stock, including, without limitation, Common Stock and the Company s Series A Preferred Stock.

Conversion. The holder of any share of Series D Preferred Stock may at any time and from time to time convert such share into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing (A) the Liquidation Amount of the share by (B) the Conversion Price, which is initially $2.48, subject to adjustment as provided in the Certificate of Designation. Initially, the Series D Preferred Stock is convertible into 10 shares of the Company s Common Stock.

Mandatory Conversion. The Company may, at any time, convert the outstanding Series D Preferred Stock into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing (A) the Liquidation Amount of the shares by (B) the Conversion Price, but only if the closing bid price of the Common Stock exceeds $5.00 per share during any thirty (30) consecutive trading days prior to each conversion. Initially, the Series D Preferred Stock is convertible into 10 shares of the Company s Common Stock.

Redemption. To the extent it is lawfully able to do so, the Company may redeem all of the then outstanding shares of Series D Preferred Stock by paying in cash an amount per share equal to $24.80 plus all declared or accrued unpaid dividends on such shares, subject to adjustment for any stock dividends or distributions, splits, subdivisions, combinations, reclassifications, stock issuances or similar events with respect to the Common Stock.

On May 26, 2009, May 29, 2009, and June 1, 2009, we entered into stock purchase agreements with a total of seven accredited investors (Investors) pursuant to which the Investors agreed to make a $31.0 million investment in the Company in exchange for 31,000,000 shares of our Common Stock at $1.00 per share, representing a range of discounts of approximately 16-21% to the average closing price of our Common Stock on the NYSE Amex for the five trading days immediately preceding the closing date of the agreements.

On February 23, 2009, we entered into a Stock Purchase Agreement with Frost Gamma Investments Trust (the Gamma Trust), of which Phillip Frost, M.D., our Chairman and CEO, is the sole trustee, pursuant to which the Gamma Trust agreed to make a $20.0 million cash investment in the Company in exchange for 20,000,000 shares (the Shares) of our Common Stock, at $1.00 per share, representing an approximately 20% discount to the average closing price of our Common Stock on the NYSE Amex for the five trading days immediately preceding the effective date of Audit Committee and stockholder approval of the transaction. We issued the Shares and received the proceeds on April 27, 2009.

NOTE 6 PROMISSORY NOTE

On March 4, 2009, the Gamma Trust advanced $3.0 million to us pursuant to a Promissory Note we issued to the Gamma Trust (the Note). The entire amount of this advance and all accrued interest thereon was due and payable

on the earlier of May 4, 2009, or such earlier date following the closing of the stock purchase transaction with the Gamma Trust discussed in Note 5. The Note bears interest at a rate equal to 11% per annum and may be prepaid in whole or in part without penalty or premium. We repaid the Note and $48 thousand of interest on April 27, 2009.

NOTE 7 INVESTMENTS IN BIOTECHNOLOGY COMPANIES

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. 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, QuikByte Software, Inc., a Colorado corporation (Quikbyte), acquired Sorrento pursuant to a Merger Agreement dated July 14, 2009 (the Merger Agreement) by and among QuikByte, Sorrento, and certain other parties named therein. At the effective time of the Merger (the Merger), all of the issued and outstanding shares of Sorrento common stock (the Sorrento Shares) were converted into the right to receive shares of QuikByte common stock, par value $0.0001 per share (the QuikByte Common Stock).

On September 18, 2009, QuikByte entered into a Stock Purchase Agreement (the QuikByte Stock Purchase Agreement) with investors (the QuikByte Investors) pursuant to which QuikByte received an aggregate investment of $2.0 million in exchange for shares of QuikByte Common Stock (the QuikByte Financing). The QuikByte Investors included Dr. Phillip Frost, our Chairman and Chief Executive Officer, and other members of OPKO management. Upon completion of the Merger, after giving effect to the QuikByte Financing, OPKO owned approximately 53,113,732 shares of QuikByte Common Stock, or approximately 24% of QuikByte s total outstanding common stock at September 30, 2009. The closing stock price for QuickByte, a thinly traded stock, as quoted on the over-the-counter markets was $0.50 per share.

Effective September 21, 2009, the Company entered into an agreement pursuant to which the Company invested $2.5 million 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. A group of investors led by The Frost Group, LLC (the Frost Group), whose members include the Gamma Trust, Jane Hsiao, the Company s Vice Chairman and Chief Technical Officer, Steven D. Rubin, the Company s Executive Vice President Administration and a director, and Rao Uppaluri, the Company s Chief Financial Officer (the Frost 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 Frost Investor agreements dated June 9, 2009, OPKO, rather than the Frost Investors, made the first installment investment ($2.5 million) on September 21, 2009. Following the first investment, the members of the Frost Group owned a total of 2,948,645 shares of Cocrystal, representing 33.65% of Cocrystal s voting stock on an as converted basis and the Gamma Trust owned a majority of those shares, owning 2,768,257 shares. Following the final installment investment of $2.5 million in Cocrystal by the Frost Investors in or around March 2010, the Company will own approximately 16% of Cocrystal and members of the Frost Group will 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 Gamma Trust. Dr. Frost, Mr. Rubin, and Dr. Hsiao currently serve on the Board of Directors of Cocrystal and represent 50% of its board.

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 VIE. In order to determine the primary beneficiary of the VIE, we evaluated the related party group to identify who had the most significant power to control Cocrystal. The Gamma Trust holds in excess of 32% of the voting stock of Cocrystal on a fully diluted basis as of the date of our investment and after the March 2010 investment by the Frost Investors, will hold in excess of 42% of the voting stock. 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.

NOTE 8 RELATED PARTY TRANSACTIONS

On September 18, 2009, we entered into a securities purchase agreement with various investors. Refer to Note 5. Included among the investors is the Gamma Trust, Hsu Gamma Investment, L.P, a limited partnership controlled by Jane H. Hsiao, the Company s Vice Chairman and Chief Technical Officer, and Oracle Partners LP, a limited partnership in which Dr. Frost is a limited partner.

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, we anticipate paying gross rent of $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 back 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.

On June 10, 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. Refer to Note 7. Dr. Richard Lerner, a member of our Board of Directors, serves as a consultant and scientific advisory board member to Sorrento and owns less than one percent of its shares.

Effective September 21, 2009, the Company entered into an agreement pursuant to which the Company invested $2.5 million in Cocrystal in exchange for 1,701,723 shares of Cocrystal s Series A Preferred Stock. The Frost Investors, led by the Frost Group, 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 Frost Investor agreements dated June 9, 2009, OPKO, rather than the Frost Investors, made the first installment investment ($2.5 million) on September 21, 2009. Refer to Note 7.

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 May 26, 2009, May 29, 2009, and June 1, 2009, we entered into stock purchase agreements with a total of seven accredited investors pursuant to which we agreed to sell an aggregate of 31 million shares of the Company s Common Stock in exchange for $31 million. Under the terms of each investment, OPKO issued shares to the investors at a price of $1.00 per Share. Refer to Note 5. Oracle Partners, LP and Vector Group Ltd. were among the investors in the transaction and purchased 4 million and 5 million shares of our Common Stock, respectively. Dr. Frost is a limited partner in Oracle Partners LP. Dr. Frost may also be deemed to beneficially own 11.5% of Vector Group Ltd. s outstanding stock.

On March 4, 2009, the Gamma Trust advanced $3.0 million to us under a Promissory Note we issued to the Gamma Trust, which was repaid in full on April 27, 2009. Refer to Note 6.

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.

On February 23, 2009, we entered into a Stock Purchase Agreement with the Gamma Trust, of which Dr Frost is the sole trustee. Refer to Note 5.

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. The lease provides for payments of approximately $0.3 million during 2009. The rent is inclusive of operating expenses, property taxes and parking.

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. During the three and nine

months ended September 30, 2009, we recorded general and administrative expenses of approximately $9 thousand and $55 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the comparable periods of 2008, we recorded approximately $5 thousand and $91 thousand of general and administrative expense.

We have a fully utilized $12.0 million line of credit with the Frost Group. The Frost Group members include a trust controlled by Dr. Frost, Dr. Jane H. Hsiao, our Vice Chairman of the board of directors and Chief Technical Officer, Steven D. Rubin, is Executive Vice President Administration and a director of the Company, and Rao Uppaluri, the Chief Financial Officer of the Company. We are obligated to pay interest upon maturity, compounded 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.

On September 19, 2007, we entered into an exclusive technology license agreement with Winston Laboratories, Inc. (Winston). Subsequent to our entering into the license agreement with Winston, on November 13, 2007, a group of investors led by the Frost Group, made an investment in Winston. Currently, the group of investors, led by Dr. Frost, Dr. Hsiao, Mr. Rubin and Dr. Uppaluri, beneficially own approximately 30% of Winston Pharmaceuticals, Inc., and Mr. Uppaluri has served as a member of Winston s board of directors since September 2008.

NOTE 9 COMMITMENTS AND CONTINGENCIES

On May 7, 2007, Ophthalmic Imaging Systems, or OIS, sued Steven Verdooner, its former president and our then Executive Vice President, Instrumentation, in California Superior Court for the County of Sacramento. OIS later amended its complaint to add claims against the Company and The Frost Group, LLC alleging breach of fiduciary duty, intentional interference with contract and intentional interference with prospective economic advantage. Trial in the matter was scheduled to commence on April 28, 2009. In order to avoid the expense and uncertainty of litigation, and without making any admission of wrongdoing or liability, we entered into a settlement agreement to fully and finally resolve the lawsuit on May 4, 2009. The impact of the settlement was not material to the Company.

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.

In the event of a termination of an existing employee of OTI, we would become obligated at such 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 connection with the potential obligation, we have recorded approximately $0.2 million in accrued expenses as of September 30, 2009, based on the estimated fair value of the unexercised put option.

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 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.

NOTE 10 SUBSEQUENT EVENTS

On October 12, 2009, we entered into an asset purchase agreement (the Schering Agreement) with Schering-Plough Corporation (Schering) to acquire assets relating to Schering s neurokinin-1 (NK-1) receptor

antagonist

program. Under the terms of the Schering Agreement, we will pay Schering $2 million in cash upon closing and up to an additional $27 million upon certain development milestones. Rolapitant, the lead product in the NK-1 program, recently completed Phase II clinical testing for prevention of nausea and vomiting related to cancer chemotherapy and surgery, and other indications. Phase I clinical testing has also been initiated for a second compound in the same class.

In connection with its merger with Merck & Co., Inc., which closed on November 3, 2009 (the Merger), Schering determined to divest its oral and intravenous formulations of rolapitant and other assets in its NK-1 program. Closing of the transaction between OPKO and Schering is expected to occur during the fourth quarter of this year.

On October 1, 2009, we entered into a definitive agreement to acquire Pharma Genexx S.A. (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. 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 US$16 million in cash. A portion of the proceeds will remain in escrow for a period of time to satisfy indemnification claims. Closing of the transaction occurred on October 7, 2009.

We have reviewed all subsequent events and transactions that occurred after our September 30, 2009 unaudited condensed consolidated balance sheet date as of November 6, 2009, through the time of filing this Quarterly Report on Form 10-Q on November 6, 2009.

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, 2008 (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, 2008. 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 such as oncology, infectious diseases and neurological disorders. We actively explore opportunities to acquire complementary pharmaceuticals, compounds, and technologies, which could, individually or in the aggregate, materially increase the scale of our business. We also intend to continue exploring strategic opportunities in medical markets that would allow us to benefit from our business and global distribution expertise.

We expect to incur substantial losses as we continue the development of our product candidates and establish a sales and marketing infrastructure in anticipation of the commercialization of our product candidates. We currently have limited commercialization capabilities, and it is possible that we may never successfully commercialize any of our pharmaceutical product candidates. To date, we have devoted a significant portion of our efforts towards research and development. As of September 30, 2009, we had an accumulated deficit of $330.3 million. Since we do not generate revenue from any of our pharmaceutical product candidates and have only generated limited revenue from our instrumentation business, we expect to continue to generate 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 SEPTEMBER 30, 2009 AND 2008

Revenue. Revenue for the three months ended September 30, 2009, was $1.5 million, compared to $4.1 million for the comparable 2008 period. Revenue for the three months ended September 30, 2009 was negatively impacted by decreased sales prices of our OPKO Spectral OCT SLO (OCT/SLO) product and decreased unit volume. In addition, results for the 2008 period reflect unit shipments in the ordinary course, as well as the fulfillment of orders received, but not shipped during the second quarter of 2008. During the second quarter of 2008, we chose to halt shipment of product while we addressed a warning letter we received from the U.S. Food and Drug Administration.

Gross margin. Gross margin for the three months ended September 30, 2009, was $0.4 million compared to a gross margin of $1.1 million for the comparable period of 2008. Gross margin declined for the three months ended September 30, 2009, as compared to the same period in 2008 as a result of the decrease in sales volume during the 2009 period. Gross margin as a percent of sales improved slightly in the 2009 period.

Selling, general and administrative expense. Selling, general and administrative expense for the three months ended September 30, 2009, was $3.1 million compared to $3.7 million of expense for the comparable period of 2008. Selling, general and administrative expenses during the three months ended September 30, 2009 and 2008, primarily include personnel expenses, including equity-based compensation expense of $0.8 million and $0.9 million, respectively, and professional fees. The decrease in selling, general and administrative expenses primarily reflects decreased personnel costs and sales commissions to our international distributors.

Research and development expense. Research and development expense during the three months ended September 30, 2009, was $2.8 million compared to $4.9 million for the comparable period of 2008. The decrease for the three months ended September 30, 2009, primarily reflects the decision in March 2009 to terminate the Phase

III clinical trial for bevasiranib. All site close-out activities were completed during the second quarter of 2009 and all activities for the Phase III trial were completed during the third quarter of 2009. The decrease in research and development expense in the 2009 period as a result of the clinical trial shut down was partially offset by increased costs relating to the Aquashunt™ clinical trial which began in the first quarter of 2009 and ongoing development costs for our ophthalmic instrumentation business, which are primarily personnel-related expenses. The 2008 period primarily reflects the cost of our Phase III clinical trial for bevasiranib, including costs of clinical trial site and monitoring expenses, personnel costs and outside professional fees. The amount for the three months ended September 30, 2009, includes equity-based compensation expense of $1.0 million, compared to the 2008 period which includes $0.7 million of equity-based compensation expense.

Other operating expenses. Other operating expenses primarily include amortization of our intangible assets acquired from OTI.

Other income and expenses. Other expense was $0.5 million for the first three months of 2009 compared to $0.4 million for the 2008 period. Other income primarily consists of interest earned on our cash and cash equivalents and interest expense reflects the interest incurred on our line of credit. As a result of reduced interest rates during the three months ended September 30, 2009, interest earned decreased significantly.

Income taxes. Income tax benefit for the three months ended September 30, 2009 and 2008, reflects a Canadian provincial tax credit that is refundable once we file our tax return. This credit relates to research and development expenses incurred at our OTI locations.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2009 AND 2008

Revenue. Revenue for the nine months ended September 30, 2009, was $6.1 million, compared to $7.8 million for the comparable 2008 period. The decrease in revenue for the nine months ended September 30, 2009, as compared to the first nine months of 2008 is the result of a decrease in the average sales price of our OCT/SLO product and a slight decrease in the number of units shipped. We believe revenue for the nine months ended September 30, 2009, was also impacted by our limited participation at tradeshows during 2008 while we focused on enhancing the product and our manufacturing processes. We began marketing and selling our OCT/SLO product in the U.S. at the beginning of 2009.

Gross margin. Gross margin for the nine months ended September 30, 2009, was $1.8 million compared to gross margin of $0.4 million for the comparable period of 2008. Gross margin for the nine months ended September 30, 2009, improved as a result of the cost reduction initiatives we began implementing in 2008 to reduce our costs associated with the OCT/SLO product. During the first half of 2008, we changed a number of suppliers and processes related to our OCT/SLO product which resulted in lower manufacturing costs, resulting in higher gross margins on that product during the second half of 2008 and the first nine months of 2009. During the nine months ended September 30, 2008, we incurred approximately $0.9 million in expense related to production development including bringing a portion of the manufacturing process for our OCT/SLO product in-house.

Selling, general and administrative expense. Selling, general and administrative expense for the nine months ended September 30, 2009, was $9.3 million compared to $12.3 million of expense for the comparable period of 2008. Selling, general and administrative expenses during the first nine months of 2009 and 2008, primarily include personnel expenses, including equity-based compensation expense of $2.3 million and $3.8 million, respectively, and professional fees. The decrease in selling, general and administrative expenses primarily reflects decreased personnel costs, including severance and approximately $1.4 million related to the acceleration of vesting for stock options in connection with the termination of certain employees in 2008. In addition, there were decreased sales commissions to our international distributors in the nine months of 2009. Partially offsetting these decreases was an increase in professional fees during the nine months ended September 30, 2009, as compared to the 2008 period. We anticipate selling, general and administrative expenses will increase during the remainder of 2009 while we increase our sales and marketing activities to promote and support our OCT/SLO product, including the launch costs in the U.S. and participation in additional tradeshows in the U.S. and internationally.

Research and development expense. Research and development expense during the nine months ended September 30, 2009, was $11.0 million compared to $14.7 million for the comparable period of 2008. The decrease for the nine months ended September 30, 2009, primarily reflects the decrease in activity of the Phase III clinical trial for bevasiranib which was terminated in March 2009. The 2008 period primarily reflects the cost of our Phase III

clinical trial for bevasiranib, including costs of clinical trial site and monitoring expenses, personnel costs and outside professional fees. The decrease in research and development expense also reflects the decrease in personnel

costs, including equity-based compensation partially offset by increased costs relating to the Aquashunt™ clinical trial which began in the first quarter of 2009 and ongoing development costs for our ophthalmic instrumentation business, which are primarily personnel-related expenses. The amount for the nine months ended September 30, 2009, includes equity-based compensation expense of $1.2 million, compared to the 2008 period which includes $1.9 million of equity-based compensation expense. The amount for the 2009 period includes the shutdown costs of the trial, including transitioning patients from the trial onto the standard of care therapy and the costs of analyzing the data collected and performing statistical analysis.

Write-off of Acquired In-Process Research and Development. On May 6, 2008, we acquired Vidus, a privately held company that is developing Aquashunt , for the treatment of glaucoma, in a stock for stock transaction. We recorded the assets and liabilities at fair value, and as a result, we recorded acquired in-process research and development expense and recorded a charge of $1.4 million. We did not have any such activity during the nine months ended September 30, 2009.

Other operating expenses. Other operating expenses primarily include amortization of our intangible assets acquired from OTI.

Other income and expenses. Other expense was $1.4 million for the first nine months of 2009 compared to $0.9 million, net of $0.3 million of interest income for the comparable 2008 period. Other income primarily consists of interest earned on our cash and cash equivalents and interest expense reflects the interest incurred on our line of credit. As a result of reduced interest rates, interest earned during the nine months ended September 30, 2009, decreased significantly.

Income taxes. Income tax benefit for the nine months ended September 30, 2009 and 2008, reflects a Canadian provincial tax credit that is refundable once we file our tax return. This credit relates to research and development expenses incurred at our OTI locations.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2009, we had cash, cash equivalents and marketable securities of approximately $63.4 million compared to $6.7 million on December 31, 2008. Cash used in operations during 2009 primarily reflects payment of liabilities related to the Phase III clinical trial for bevasiranib and related shut down expenses of that trial, as well as selling, general and administrative activities related to our corporate and instrumentation operations. Since our inception, we have not generated significant gross margins to offset our operating and other expenses and our primary source of cash has been from the private placement of stock and through credit facilities available to us.

On October 7, 2009, we closed on the acquisition of Pharma Genexx S.A., 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 for US$16 million in cash.

Effective September 21, 2009, the Company entered into an agreement pursuant to which the Company invested $2.5 million in Cocrystal Discovery, Inc., a privately held biopharmaceutical company (Cocrystal) in exchange for 1,701,723 shares of Cocrystal s Series A Preferred Stock.

On September 18, 2009, we entered into a securities purchase agreement (the Preferred Purchase Agreement) with the private investors named therein (the Preferred Investors), pursuant to which the Preferred Investors agreed to purchase an aggregate of 1,209,677 shares (the Preferred Shares) of the Company s newly-designated 8.0% Series D Cumulative Convertible Preferred Stock, par value $0.01 per share (Series D Preferred Stock), at a purchase price of $24.80 per share, together with warrants (the Warrants) to purchase up to an aggregate of 3,024,196 shares of the Company s common stock, par value $.01 (the Common Stock) at an exercise price of $2.48 per share (the Preferred Investment). Initially, the Series D Preferred Stock is convertible into ten shares of the Company s Common Stock, and the Preferred Shares purchase price was based on the average closing price of the Company s Common Stock as reported on the NYSE Amex for the five days preceding the execution of the Preferred Purchase Agreement. In connection with the Preferred Investment, the Company issued the Preferred Shares on September 28, 2009.

On May 26, 2009, May 29, 2009, and June 1, 2009, we entered into stock purchase agreements with a total of seven accredited investors (Investors) pursuant to which the Investors agreed to make a $31.0 million investment in the Company in exchange for 31,000,000 shares of our Common Stock, par value $.01 (the Shares), at $1.00 per

share.

On March 4, 2009, Frost Gamma Investments Trust (the Gamma Trust), of which Phillip Frost, M.D., our Chairman and CEO, is the sole trustee, advanced $3.0 million to us under a Promissory Note we issued to the Gamma Trust (the Note). The entire amount of this Note and all accrued interest thereon was due and payable on May 4, 2009 or such earlier date following the closing of the transaction contemplated by the Stock Purchase Agreement with the Gamma Trust, dated February 23, 2009. The Note bears interest at a rate equal to 11% per annum and may be prepaid in whole or in part without penalty or premium. We repaid the Note in full, plus accrued interest of $48 thousand on April 27, 2009.

On February 23, 2009, we entered into a stock purchase agreement with the Gamma Trust pursuant to which the Gamma Trust agreed to make a $20.0 million investment in exchange for 20,000,000 shares of our common stock, par value $.01 (the Shares), at $1.00 per share, representing an approximately 20% discount to the average closing price of our common stock on the NYSE Amex exchange for the five trading days immediately preceding the effective date of Audit Committee and stockholder approval of the transaction. We issued the Shares and received the proceeds of $20.0 million on April 27, 2009.

We have a fully-drawn $12.0 million line of credit with the Frost Group, a related party. We are obligated to pay interest upon maturity, compounded 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 and cash equivalents on hand at September 30, 2009, are 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 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 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 such cost is measured at the fair value of the award. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. We estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the Black-Scholes Model and allocate the resulting compensation expense over the corresponding requisite service period associated with each grant. The Black-Scholes Model requires the use of several variables to estimate the grant-date fair value of stock options including expected term, expected volatility, expected dividends and risk-free interest rate. We perform significant analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model. We also perform significant analyses to estimate forfeitures of equity-based awards. We are required to adjust our forfeiture estimates on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates may have a material impact on our Consolidated Financial Statements.

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

Appraisals inherently require significant estimates and assumptions, including but not limited to, determining the timing and estimated costs to complete the in-process R&D projects, projecting regulatory approvals, estimating future cash flows, and developing appropriate discount rates. We believe the estimated fair values assigned to the Vidus 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. The allowance for doubtful accounts recognized in our consolidated balance sheets at September 30, 2009 and December 31, 2008 was $0.4 million and $0.4 million, respectively.

Recent accounting pronouncements: On June 30, 2009, we adopted ASC 855-10-50 Subsequent Events Disclosure (Subsequent Events Standard), which established general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued. The Subsequent Events Standard defines two types of subsequent events. The effects of events or transactions that provide additional evidence about conditions that existed at the balance sheet date, including the estimates inherent in the process of preparing financial statements, are recognized in the financial statements. The effects of events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after that date are not recognized in the financial statements.

In June 2009, the FASB issued Statement No. 167 (SFAS 167), Accounting for Variable Interest Entities. SFAS 167 amends FASB Interpretation No. 46(R) (FIN No. 46(R)), Consolidation of Variable Interest Entities, to require a comprehensive qualitative analysis to be performed to determine whether a holder of variable interests in a variable interest entity also has a controlling financial interest in that entity. In addition, it requires the same such analysis be

applied to entities previously designated as qualified special-purpose entities under SFAS 140. SFAS 167 is effective as of the start of the first annual reporting period beginning after November 15, 2009, for interim

periods within the first annual reporting period, and for all subsequent annual and interim reporting periods. We do not expect the adoption of SFAS 167 to have a material impact on our consolidated financial position, results of operations, or cash flows.

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. 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.

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 September 30, 2009, we had cash, cash equivalents and marketable securities of $63.4 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2009 was 0.1%. As of September 30, 2009, the principal value of our credit line was $12.0 million, which bears a weighted average interest rate of 11.0% as of September 30, 2009.

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 September 30, 2009. Based on that evaluation, the Company s CEO and CFO have concluded that the Company s disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms and is accumulated and communicated to the Company s management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

There have been no changes to the Company s internal control over financial reporting that occurred during the Company s third quarter of 2009 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

None.

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

Refer to the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2009.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

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 3.1[(2)]	Amended and Restated Certificate of Incorporation.
Exhibit 3.2[(3)]	Amended and Restated By-Laws.
Exhibit 3.3[(5)]	Certificate of Designation of Series D Preferred Stock
Exhibit 4.1[(1)]	Form of Common Stock Warrant.
Exhibit 4.2[(5)]	Form of Warrant to Purchase Shares of Common Stock.
Exhibit 10.1[(5)]	Form of Securities Purchase Agreement Series D Preferred Stock.
Exhibit 10.2	Form of Restricted Share Award Agreement (Director).
Exhibit 10.3	Cocrystal Discovery, Inc. Agreements.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2009.
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 September 30, 2009.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2009.

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 September 30, 2009.

+ 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 Current Report on Form 8-K files with the Securities and Exchange Commission on September 24, 2009.

SIGNATURES

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

Date: November 6, 2009

OPKO Health, Inc.

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

Exhibit Index

Exhibit Number	Description
Exhibit 10.2	Form of Restricted Share Award Agreement (Director).
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