Opko Health, Inc. Form 10-Q August 07, 2009

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

(Mark One)

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

For the quarterly period ended June 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 <u>000-27748</u>

**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. x 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.

Large accelerated filer o

Accelerated filer x

Non-accelerated filer o (Do not check if a smaller reporting

Smaller reporting company o

t iii

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

YES o NO x

As of August 4, 2009, the registrant had 252,668,938 shares of common stock outstanding.

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#### 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.

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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.

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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.

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#### PART I. FINANCIAL INFORMATION

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

ASSETS	J	une 30, 2009	Ι	December 31, 2008
Current assets				
Cash and cash equivalents	\$	35,939	\$	6,678
Marketable securities	·	4,997	·	-,
Accounts receivable, net		2,165		1,005
Inventory		5,151		4,063
Prepaid expenses and other current assets		1,675		1,720
Total current assets		49,927		13,466
Property and equipment, net		560		659
Intangible assets, net		5,524		6,336
Goodwill		1,097		1,097
Investment		2,262		
Other assets		335		206
Total assets	\$	59,705	\$	21,764
LIABILITIES AND SHAREHOLDERS EQUITY Current liabilities				
Accounts payable	\$	2,201	\$	2,221
Accrued expenses	·	4,014	·	5,394
Current portion of notes payable and capital lease obligations		86		97
Total current liabilities		6,301		7,712
Long-term liabilities and capital lease obligations		2,595		1,826
Line of credit with related party, net unamortized discount of \$101 and \$133,				
respectively		11,899		11,867
Total liabilities Commitments and contingencies Shareholders equity		20,795		21,405
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 \$2,448 and \$2,384) at June 30, 2009 and December 31, 2008, respectively Series C Preferred Stock \$0.01 par value, 500,000 shares authorized; No shares issued or outstanding		9		10

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Common Stock \$0.01 par value, 500,000,000 shares authorized; 252,594,059		
and 199,020,379 shares issued and outstanding at June 30, 2009 and		
December 31, 2008, respectively	2,526	1,991
Treasury stock - 45,154 and 18,000 shares at June 30, 2009 and December 31,		
2008, respectively	(61)	(24)
Additional paid-in capital	360,341	307,498
Accumulated deficit	(323,905)	(309,116)
Total shareholders equity	38,910	359
Total liabilities and shareholders equity	\$ 59,705	\$ 21,764

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

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# OPKO Health, Inc. 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,			s ended		
		2009		2008		2009		2008
Revenue	\$	2,347	\$	879	\$	4,648	\$	3,703
Cost of goods sold		1,764		1,025		3,325		4,355
Gross margin (deficit)		583		(146)		1,323		(652)
Operating expenses		2 026		2 210		6,183		8,562
Selling, general and administrative Research and development		2,926 2,498		3,218 5,479		8,157		9,835
Write-off of acquired in-process research		2,490		3,479		0,137		9,033
and development				1,398				1,398
Other operating expenses, principally amortization of intangible assets		406		428		812		854
Total operating expenses		5,830		10,523		15,152		20,649
Operating loss		(5,247)		(10,669)		(13,829)		(21,301)
Other (expense) income, net		(494)		(249)		(944)		(518)
Loss before income taxes and investment								
loss		(5,741)		(10,918)		(14,773)		(21,819)
Income tax benefit		(103)		(39)		(138)		(60)
Loss before investment loss in investee		(5,638)		(10,879)		(14,635)		(21,759)
Loss from investment in investee		(38)				(38)		, ,
Net loss		(5,676)		(10,879)		(14,673)		(21,759)
Preferred stock dividend		(58)		(55)		(116)		(110)
Net loss attributable to common	Φ.	(5.50.4)	Φ.	(10.024)	Φ.	(1.4.700)	Φ.	(21.060)
shareholders	\$	(5,734)	\$	(10,934)	\$	(14,789)	\$	(21,869)
Loss per common share,								
basic and diluted	\$	(0.03)	\$	(0.06)	\$	(0.07)	\$	(0.12)
Weighted average number of common								
shares outstanding, basic and diluted		225,648,244	1	83,707,302	2	12,695,483	1	82,139,632
The accompanying Notes to Condensed Co								

# OPKO Health, Inc. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)(in thousands)

	For the six months end June 30,	
	2009	2008
Cash flows from operating activities  Net loss  Adjustments to reconcile net loss to net cash used in operating activities:	\$ (14,673)	\$ (21,759)
Depreciation and amortization	935	906
Write-off of acquired in-process research and development	, , ,	1,398
Accretion of debt discount related to notes payable	32	109
Share based compensation	1,767	4,209
Net recovery of bad debts	(133)	•
Provision for inventory obsolescence	52	
Loss from investment in investee	38	
Changes in:		
Accounts receivable	(1,027)	558
Inventory	(1,140)	(1,015)
Prepaid expenses and other current assets	45	222
Other assets	(129)	(148)
Accounts payable	(20)	(812)
Accrued expenses	(762)	882
Net cash used in operating activities	(15,015)	(15,450)
Cash flows from investing activities		
Acquisition of business, net of cash		48
Investment in investee	(2,300)	
Purchase of short-term marketable securities	(4,997)	
Capital expenditures	(24)	(239)
Net cash used in investing activities	(7,321)	(191)
Cash flows from financing activities:		
Issuance of common stock for cash, to related parties	25,000	
Issuance of common stock for cash	25,990	
Proceeds from bridge loan with related party	3,000	
Repayment of bridge loan with related party	(3,000)	
Insurance financing	217	190
Proceeds from the exercise of stock options and warrants	621	269
Repayments of notes payable and capital lease obligations	(231)	(2,707)
Net cash provided by (used in) financing activities	51,597	(2,248)
Net increase (decrease) in cash and cash equivalents	29,261	(17,889)
Cash and cash equivalents at beginning of period	6,678	23,373
Cash and cash equivalents at end of period	\$ 35,939	\$ 5,484

# SUPPLEMENTAL INFORMATION

Interest paid	\$	50	\$	98
NON-CASH INVESTING AND FINANCING ACTIVITES				
Issuance of capital stock to acquire Vidus in 2008	\$		\$	1,319
The accompanying Notes to Condensed Consolidated Financial Statements are an i	ntegral pari	t of these	e state	ments.

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 focused on the discovery, development, and commercialization of proprietary pharmaceuticals, diagnostic and imaging systems and instrumentation products for the treatment, diagnosis and management of ophthalmic diseases. We are expanding our operations in the ophthalmology business, as well as in other medical areas that can lead to important commercial opportunities. We are a Delaware corporation, headquartered in Miami, Florida.

#### NOTE 2. SUMMARY OF SIGNIFICANT ACCCOUNTING 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 six months ended June 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.

*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 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 June 30, 2009, revenue derived from sales to four significant international customers represented approximately 19%, 16%, 15% and 13% of our revenue, respectively. During the three months ended June 30, 2008, revenue derived from sales to four significant international customers represented approximately 19%, 16%, and 15% of our revenue, respectively. During the six months ended June 30, 2008, revenue derived from sales to four significant international customers represented approximately 19%, 16%, and 15% of our revenue, respectively. During the six months ended June 30, 2008, revenue derived from sales to four significant international customers represented approximately 17%, 15%, 14% and 10% of our revenue, respectively.

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*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 June 30, 2009 and 2008.

	Jur	ne 30,	Jui	ne 30,
(in thousands)	2	009	2	2008
Beginning balance	\$	290	\$	226
Accrual for products sold		67		
Settlements in kind or expired		(62)		
Ending balance	\$	295	\$	226

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

	Jur	ie 30,	Jui	ne 30,
(in thousands)	2	009	2	800
Beginning balance	\$	259	\$	227
Accrual for products sold		128		55
Settlements in kind or expired		(92)		(56)
Ending balance	\$	295	\$	226

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 June 30, 2009 and December 31, 2008, was \$0.2 million and \$0.4 million, respectively. As of June 30, 2009, accounts receivable from four of our international distributors represented approximately 27%, 17%, 14% and 11%, 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 ophthalmic 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.

Equity-Based Compensation. We account for equity-based compensation under Statement of Financial Accounting Standards, or SFAS 123(R), Share-Based Payments. SFAS 123(R) requires that all equity-based compensation be recognized as an expense in the financial statements and that such cost be measured at the fair value of the award. Equity-based compensation arrangements to non-employees are accounted for in accordance with SFAS 123(R) and Emerging Issues Task Force Issue No. 96-18 (EITF 96-18), Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, which requires that these equity instruments are recorded at their fair value on the measurement date. As prescribed under SFAS 123(R), 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 as required by SFAS 123(R). 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. During the three and six months ended June 30, 2009 we recorded \$1.1 million, \$1.8 million, respectively, of equity-based compensation expense. During the three and six months ended June 30, 2008, we recorded \$1.5 million and \$4.2 million, respectively, of equity-based compensation expense. During the six months ended June 30, 2009 and 2008, 1,916,765 and 4,451,585 shares of common stock, respectively, were issued in connection with the exercise of stock options.

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*Fair value*. We adopted the provisions of SFAS 157, *Fair Value Measurements*, or SFAS 157, on January 1, 2008. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. In accordance with the FASB Staff Position No. FAS 157-2,

Effective Date of the FASB Statement No. 157, or FSP 157-2, we adopted the provisions of SFAS 157 pertaining to our nonfinancial assets and nonfinancial liabilities, except those items recognized or disclosed at fair value on an annual or more recurring basis, on January 1, 2009. Neither of the adoptions of SFAS 157 had a material impact on our fair value measurements.

SFAS 157 establishes 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, 2009, we held money market funds and treasury securities, maturing September 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. During the three and six months ended June 30, 2009, we recorded a reversal of expense of \$0.1 million and \$0.1 million, respectively, reflecting our stock price fluctuations. During the three and six months ended June 30, 2008, we recorded \$30 thousand and \$50 thousand of expense, respectively, reflecting our stock price fluctuations during that period. Refer to Note 9.

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 measured at fair value on a recurring basis, subject to the disclosure requirements of SFAS 157 are as follows (in thousands):

	Fair	value me	easureme	nts as of June 30,	2009
	Quoted				
	Prices				
	in				
	Active				
	Markets	Signi	ficant		
	for	Ot	her	Significant	
	Identical	Obse	rvable	Unobservable	
	Assets	Inp	outs	Inputs	
	(Level	•		•	
	1)	(Lev	rel 2)	(Level 3)	Total
Assets:	•	•	ŕ	,	
Money market funds	\$ 30,941	\$		\$	\$ 30,941
Treasury securities	9,995				9,995
OTI put option			187		187
Total	\$40,936	\$	187	\$	\$41,123

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159, which gives companies the option to measure eligible financial assets, financial liabilities, and firm commitments at fair value (i.e., the fair value option), on an instrument-by-instrument basis, that are

otherwise not permitted to be accounted for at fair value under other accounting standards. The election to use the fair value option is available when an entity first recognizes a financial asset or financial liability or upon entering into a firm commitment. Subsequent changes in fair value must be recorded in earnings. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We adopted SFAS 159 in the first quarter of 2008 and the adoption did not have any impact on our financial position or results of operations as we elected not to apply fair value measurement on an instrument by instrument basis.

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Recent accounting pronouncements: In December 2007, the FASB issued SFAS No. 141R, Business Combinations, or SFAS 141R. SFAS 141R applies to business combinations and requires, among other things, the expensing of transaction costs, including deal costs and restructuring costs as incurred, the capitalization of acquired in-process research and development assets, the recording at fair value of, certain contingent assets and liabilities including and earn-out arrangements. Changes in fair value of contingent consideration may be required to be recognized each period into earnings. In addition, material adjustments made to the initial acquisition purchase accounting will be required to be recorded back to the acquisition date. This will cause companies to revise previously reported results when reporting comparative financial information in subsequent filings. SFAS No. 141R is effective for the Company on a prospective basis for transactions occurring beginning on January 1, 2009 and earlier adoption is not permitted. We adopted SFAS No. 141R on January 1, 2009. The adoptions may have a material impact on the Company s consolidated financial position, results of operations and cash flows if we enter into material business combinations after January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*, or SFAS 160. SFAS 160 requires minority interests to be recharacterized as noncontrolling interests and reported as a component of equity. In addition, SFAS160 requires that purchases or sales of equity interests that do not result in a change in control be accounted for as equity transactions and, upon a loss of control, requires the interests sold, as well as any interests retained, to be recorded at fair value with any gain or loss recognized in earnings. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited. We adopted SFAS No. 160 on January 1, 2009. The adoption of SFAS No. 160 did not have a material impact on our condensed consolidated financial statements.

In April 2009, the FASB issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. FSP FAS 107-1 and APB 28-1 enhance consistency in financial reporting by increasing the frequency of fair value disclosures. FSP FAS 107-1 and APB 28-1 relate to fair value disclosures for any financial instruments that are not currently reflected on the balance sheet of companies at fair value. Prior to issuing this FSP, fair values for these assets and liabilities were disclosed only once a year. The FSP now requires these disclosures to be made on a quarterly basis, providing qualitative and quantitative information about fair value estimates for all those financial instruments not measured on the balance sheet at fair value. FSP FAS 107-1 and APB 28-1 are effective for interim and annual periods ending after June 15, 2009. We adopted FSP FAS 107-1 and APB 28-1 in the second quarter of fiscal 2009. The adoption of FSP FAS 107-1 and APB 28-1 did not have a material impact on our condensed consolidated financial statements.

In April 2009, the FASB issued FSP No. 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. This FSP amends the other-than-temporary impairment guidance in U.S. GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of the other-than-temporary impairments on debt and equity securities in the financial statements. The FSP is effective for interim and annual reporting periods ending after June 15, 2009. We adopted FSP No. 115-2 and FAS 124-2 in the second quarter of fiscal 2009. The adoption of FSP No. 115-2 and FAS 124-2 did not have a material impact on our condensed consolidated financial statements.

In April 2009, the FASB issued FASB Staff Position, or FSP, FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*. FSP FAS 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in FASB Statement No. 157, Fair Value Measurements. FSP FAS 157-4 relates to determining fair values when there is no active market or where the price inputs being used represent distressed sales. It reaffirms what FASB Statement No. 157 states is the objective of fair value measurement to reflect how much an asset would be sold for in an orderly transaction (as opposed to a distressed or forced transaction) at the date of the financial statements under current market conditions. Specifically, it reaffirms the need to use judgment to ascertain if a formerly active market has become inactive and in determining fair values when markets have become inactive. FSP FAS 157-4 is effective for interim and annual periods ending after June 15, 2009. We adopted FSP FAS 157-4 in the second quarter of fiscal 2009. The adoption of FSP FAS 157-4 did not have a material impact on our condensed consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*. SFAS No. 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS No.165 requires entities to disclose the date through which they have evaluated subsequent events and whether the date corresponds with the issuance of their financial statements. SFAS No. 165 is effective for interim and annual reporting periods ending after June 15, 2009. We adopted SFAS No. 165 in the second quarter of fiscal 2009. The adoption of SFAS No. 165 did not have a material impact on our condensed consolidated financial statements.

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In June 2009, the FASB issued Statement No. 168, or SFAS No.168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. SFAS No.168 will become the single source of authoritative nongovernmental U.S. generally accepted accounting principles, or GAAP, superseding existing FASB, American Institute of Certified Public Accountants, or AICPA, Emerging Issues Task Force, or EITF, and related accounting literature. SFAS No.168 reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included is relevant Securities and Exchange Commission guidance organized using the same topical structure in separate sections. SFAS No.168 will be effective for financial statements issued for reporting periods that end after September 15, 2009. As a result, SFAS No.168 is effective for us in the third quarter of fiscal 2009. This will have an impact on our disclosures in the condensed consolidated financial statements since all future references to authoritative accounting literature will be references in accordance with SFAS No.168.

# **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 earnings 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 15,692,101 and 29,515,241 potential common shares have been excluded from the calculation of net loss per common share for the three months ended June 30, 2009 and 2008, respectively, because their inclusion would be anti-dilutive. A total of 15,238,119 and 26,856,410 potential common shares have been excluded from the calculation of net loss per common share for the six months ended June 30, 2009 and 2008, respectively, because their inclusion would be anti-dilutive.

NOTE 4. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(in thousands) Accounts receivable, net:	,	ne 30, 2009 2009	31, 2008
Accounts receivable Less allowance for doubtful accounts	\$	2,366 (201)	\$ 1,412 (407)
	\$	2,165	\$ 1,005
Inventories, net: Raw materials (components) Work-in process Finished products Less provision for inventory reserve	\$ \$	2,712 1,520 1,154 (235) 5,151	\$ 2,635 934 749 (255) 4,063
Intangible assets, net: Technology Customer relationships Covenants not to compete Tradename Other	\$	4,597 2,978 317 195 7	\$ 4,597 2,978 317 195 7

Less amortization (2,570) (1,758) \$ 5,524 \$ 6,336

#### NOTE 5. PRIVATE PLACEMENTS OF 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, par value \$.01 at \$1.00 per share representing a range of discounts of approximately 16% to 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.

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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 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 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. INVESTMENT IN BIOTECHNOLOGY COMPANY

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.

#### NOTE 8. RELATED PARTY TRANSACTIONS

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 February 23, 2009, we entered into a Stock Purchase Agreement with the Gamma Trust, of which Phillip Frost, M.D., our Chairman and CEO is the sole trustee. Refer to Note 5.

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.

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 six months ended June 30, 2009, we recorded general and administrative expenses of approximately \$13 thousand and

\$46 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the comparable periods of 2008, we recorded approximately \$44 thousand and \$86 thousand of general and administrative expense.

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among the Investors.

We have a fully utilized \$12.0 million line of credit with the Frost Group, LLC. The Frost Group members include a trust controlled by Dr. Frost, 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. 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.

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 June 10, 2009, we entered into a stock purchase agreement with Sorrento, pursuant to which we invested \$2.3 million in Sorrento and acquired approximately one-third of the outstanding common shares of Sorrento and 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 five percent of its shares. On July 14, 2009, QuikByte Software, Inc., a Colorado corporation (Quikbyte), entered into a Merger Agreement (the Merger Agreement ) by and among QuikByte, Sorrento, and certain other parties named therein. Upon the satisfaction or waiver of the conditions set forth in the Merger Agreement, QuikByte will acquire Sorrento via a merger. At the effective time of the Merger, all of the issued and outstanding shares of Sorrento common stock (the Sorrento Shares ) will be converted into the right to receive shares of QuikByte common stock, par value \$0.0001 per share (the QuikByte Common Stock ). Immediately following the completion of the Merger, the current QuikByte shareholders will own approximately 4.92% of the surviving company, the Investors (as defined below) will own approximately 19.83% of the surviving company, and the former holders of Sorrento Shares will own approximately 75.25% of the surviving company, in each case on a fully-diluted basis. The closing of the Merger is subject to, among other conditions, QuikByte s receipt of an aggregate investment of \$2 million from certain investors (the Investors ) in exchange for shares of QuikByte Common Stock. QuikByte anticipates that affiliates of Dr. Frost will be included

A group of investors led by the Frost Group (the Frost Investors ) previously invested \$5 million in Cocrystal Discovery, Inc., a privately held biopharmaceutical company, and agreed to invest an additional \$5 million payable in two equal tranches. As a result of an amendment to the Frost Investor agreements dated June 9, 2009, OPKO, rather than the Frost Investors, intends to make the first tranche investment (\$2.5 million) on or around September 18, 2009 pursuant to a definitive agreement to be entered by OPKO at the time of the investment on the same terms as those previously agreed by the Frost Investors. Following the second tranche investment of \$2.5 million in Cocrystal by the Frost Investors, OPKO will own approximately 16% of Cocrystal and the Frost Group will own approximately 42% of Cocrystal, each on a fully diluted basis. Dr. Frost, Steve Rubin, and Jane Hsiao currently serve on the Board of Directors of Cocrystal.

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#### 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.

We intend to invest \$2.5 million in Cocrystal on or about September 18, 2009. Refer to Note 8.

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 June 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

Pursuant to FAS 165, we have reviewed all subsequent events and transactions that occurred after our June 30, 2009 unaudited condensed consolidated balance sheet dated as of August 7, 2009, our issue date.

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# Item 2. <u>Management</u> s <u>Discussion and Analysis of Financial Condition and Results of Operations</u> 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 focused on the discovery, development, and commercialization of proprietary pharmaceuticals, imaging and diagnostic systems, and instruments for the treatment, diagnosis, and management of ophthalmic disorders. We are seeking to expand our operations in the ophthalmology business, as well as in other areas of medicine that may lead to important commercial opportunities. 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 June 30, 2009, we had an accumulated deficit of \$323.9 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 JUNE 30, 2009 AND 2008

*Revenue.* Revenue for the three months ended June 30, 2009, was \$2.3 million, compared to \$0.9 million for the comparable 2008 period. The increase in revenue during the three months ended June 30, 2009, is the result of our decision during the 2008 period to only ship a limited number of OCT/SLO units internationally while we addressed a warning letter received from the U.S. Food & Drug Administration (FDA). Results from the three months ended June 30, 2009 primarily reflect sales of our OCT/SLO product to our international customers. We anticipate demand in both the U.S. market and international markets will increase during the remainder of 2009 as we begin to actively promote the OCT/SLO product at tradeshows in the U.S. and internationally.

Gross margin (deficit). Gross margin for the three months ended June 30, 2009, was \$0.6 million compared to a gross deficit of (\$0.1) million for the comparable period of 2008. Gross margin improved for the three months ended June 30, 2009 as compared to the same period in 2008 as a result of the cost reduction initiatives we began implementing in 2008 to reduce our costs associated with our 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 during 2009. During the three months ended June 30, 2008, we incurred approximately \$0.4 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 three months ended June 30, 2009, was \$2.9 million compared to \$3.2 million of expense for the comparable period of 2008. Selling, general and administrative expenses during the three months ended June 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.

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Research and development expense. Research and development expense during the three months ended June 30, 2009, was \$2.5 million compared to \$5.5 million for the comparable period of 2008. The decrease for the three months ended June 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 first half of the second quarter of 2009 and we anticipate that all activities for the Phase III trial will be complete 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 June 30, 2009, includes equity-based compensation expense of \$0.4 million, compared to the 2008 period which includes \$0.6 million of equity-based compensation expense.

Write-off of Acquired In-Process Research and Development. On May 6, 2008, we acquired Vidus Ocular, Inc. (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 three months ended June 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 \$0.5 million for the first three months of 2009 compared to \$0.2 million, net of \$0.1 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 during the three months ended June 30, 2009, interest earned decreased significantly.

*Income taxes.* Income tax benefit for the three months ended June 30, 2009 and 2008, reflects the 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 SIX MONTHS ENDED JUNE 30, 2009 AND 2008

Revenue. Revenue for the six months ended June 30, 2009, was \$4.6 million, compared to \$3.7 million for the comparable 2008 period. The increase in revenue for the six months ended June 30, 2009, as compared to the first six months of 2008 is a result of our decision in the second quarter of 2008 to ship only a limited number of OCT/SLO products internationally while we addressed the FDA warning letter received for our Toronto manufacturing facility. We believe revenue for the six months ended June 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. We anticipate demand in both the U.S. market and international markets will increase during the remainder of 2009 as we begin to actively promote the OCT/SLO product at tradeshows in the U.S. and internationally.

*Gross margin (deficit)*. Gross margin for the six months ended June 30, 2009, was \$1.3 million compared to a gross deficit of (\$0.7) million for the comparable period of 2008. Gross margin for the six months ended June 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 six months of 2009. During the three months ended June 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 six months ended June 30, 2009, was \$6.2 million compared to \$8.6 million of expense for the comparable period of 2008. Selling, general and administrative expenses during the first six months of 2009 and 2008, primarily include personnel expenses, including equity-based compensation expense of \$1.5 million and \$2.9 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 six months of 2009. Partially offsetting these decreases was an increase in professional fees during the six months ended June 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.

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Research and development expense. Research and development expense during the six months ended June 30, 2009, was \$8.2 million compared to \$9.8 million for the comparable period of 2008. The decrease for the six months ended June 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 six months ended June 30, 2009, includes equity-based compensation expense of \$0.2 million, compared to the 2008 period which includes \$1.3 million of equity-based compensation expense. The amount for the 2009 period includes the estimated 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. We anticipate all activities related to this trial will cease in the third quarter of 2009.

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 six months ended June 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 \$0.9 million for the first six months of 2009 compared to \$0.5 million, net of \$0.2 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 six months ended June 30, 2009, decreased significantly.

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

#### LIOUIDITY AND CAPITAL RESOURCES

At June 30, 2009, we had cash, cash equivalents and marketable securities of approximately \$40.9 million. 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 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.

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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.

A group of investors led by the Frost Group (the Frost Investors ) previously invested \$5 million in Cocrystal Discovery, Inc., a privately held biopharmaceutical company, and agreed to invest an additional \$5 million payable in two equal tranches. As a result of an amendment to the Frost Investor agreements dated June 9, 2009, OPKO, rather than the Frost Investors, intends to make the first tranche investment (\$2.5 million) on or around September 18, 2009 pursuant to a definitive agreement to be entered by OPKO at the time of the investment on the same terms as those previously agreed by the Frost Investors. Following the second tranche investment of \$2.5 million in Cocrystal by the Frost Investors, OPKO will own approximately 16% of Cocrystal and the Frost Group will own approximately 42% of Cocrystal, each on a fully diluted basis. Dr. Frost, Steve Rubin, and Jane Hsiao currently serve on the Board of Directors of Cocrystal.

We have a fully-drawn \$12.0 million line of credit with The Frost Group, LLC, or the Frost Group, a related party. The Frost Group members include a trust controlled by Dr. Frost, the Company s Chief Executive Officer and Chairman of the board of directors, Dr. Jane H. Hsiao, Vice Chairman of the board of directors and Chief Technical Officer, Steven D. Rubin, Executive Vice President Administration and a director of the Company, and Rao Uppaluri who is 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.

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 June 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.

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#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

Equity-based compensation. As of June 23, 2006 (the date of inception), we adopted Statement of Financial Accounting Standards, or SFAS 123(R), Share-Based Payments. SFAS123(R) replaces SFAS No. 123, Accounting for Stock-Based Compensation, and supersedes APB No. 25. SFAS 123(R) requires that all stock-based compensation be recognized as an expense in the financial statements and that such cost be measured at the fair value of the award. Equity-based compensation arrangements to non-employees are accounted for in accordance with SFAS 123(R) and Emerging Issues Task Force Issue No. 96-18 (EITF 96-18), Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, which requires that these equity instruments are recorded at their fair value on the measurement date. As prescribed under SFAS 123(R), 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 as required by SFAS 123(R). 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 under the provisions of SFAS No. 141, *Business Combinations* or, SFAS 141. 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 under SFAS 141, 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 June 30, 2009 and December 31, 2008 was \$0.2 million and \$0.4 million, respectively.

Recent accounting pronouncements: In December 2007, the FASB issued SFAS No. 141R, Business Combinations, or SFAS 141R. SFAS 141R applies to business combinations and requires, among other things, the expensing of transaction costs, including deal costs and restructuring costs as incurred, the capitalization of acquired in-process research and development assets, the recording at fair value of, certain contingent assets and liabilities

including and earn-out arrangements. Changes in fair value of contingent consideration may be required to be recognized each period into earnings. In addition, material adjustments made to the initial acquisition purchase accounting will be required to be recorded back to the acquisition date. This will cause companies to revise previously reported results when reporting comparative financial information in subsequent filings. SFAS 141R is effective for the Company on a prospective basis for transactions occurring beginning on January 1, 2009 and earlier adoption is not permitted. We adopted SFAS 141R on January 1, 2009. The adoptions may have a material impact on the Company s consolidated financial position, results of operations and cash flows if we enter into material business combinations after January 1, 2009.

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In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*, or SFAS 160. SFAS 160 requires minority interests to be recharacterized as noncontrolling interests and reported as a component of equity. In addition, SFAS 160 requires that purchases or sales of equity interests that do not result in a change in control be accounted for as equity transactions and, upon a loss of control, requires the interests sold, as well as any interests retained, to be recorded at fair value with any gain or loss recognized in earnings. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited. We adopted SFAS 160 on January 1, 2009. The adoption of SFAS 160 did not have a material impact on our condensed consolidated financial statements.

In April 2009, the FASB issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. FSP FAS 107-1 and APB 28-1 enhance consistency in financial reporting by increasing the frequency of fair value disclosures. FSP FAS 107-1 and APB 28-1 relate to fair value disclosures for any financial instruments that are not currently reflected on the balance sheet of companies at fair value. Prior to issuing this FSP, fair values for these assets and liabilities were disclosed only once a year. The FSP now requires these disclosures to be made on a quarterly basis, providing qualitative and quantitative information about fair value estimates for all those financial instruments not measured on the balance sheet at fair value. FSP FAS 107-1 and APB 28-1 are effective for interim and annual periods ending after June 15, 2009. We adopted FSP FAS 107-1 and APB 28-1 in the second quarter of fiscal 2009. The adoption of FSP FAS 107-1 and APB 28-1 did not have a material impact on our condensed consolidated financial statements.

In April 2009, the FASB issued FSP No. 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. This FSP amends the other-than-temporary impairment guidance in U.S. GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of the other-than-temporary impairments on debt and equity securities in the financial statements. The FSP is effective for interim and annual reporting periods ending after June 15, 2009. We adopted FSP No. 115-2 and FAS 124-2 in the second quarter of fiscal 2009. The adoption of FSP No. 115-2 and FAS 124-2 did not have a material impact on our condensed consolidated financial statements.

In April 2009, the FASB issued FASB Staff Position, or FSP, FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*. FSP FAS 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in FASB Statement No. 157, Fair Value Measurements. FSP FAS 157-4 relates to determining fair values when there is no active market or where the price inputs being used represent distressed sales. It reaffirms what FASB Statement No. 157 states is the objective of fair value measurement to reflect how much an asset would be sold for in an orderly transaction (as opposed to a distressed or forced transaction) at the date of the financial statements under current market conditions. Specifically, it reaffirms the need to use judgment to ascertain if a formerly active market has become inactive and in determining fair values when markets have become inactive. FSP FAS 157-4 is effective for interim and annual periods ending after June 15, 2009. We adopted FSP FAS 157-4 in the second quarter of fiscal 2009. The adoption of FSP FAS 157-4 did not have a material impact on our condensed consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*. SFAS No. 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS No.165 requires entities to disclose the date through which they have evaluated subsequent events and whether the date corresponds with the issuance of their financial statements. SFAS No. 165 is effective for interim and annual reporting periods ending after June 15, 2009. We adopted SFAS No. 165 in the second quarter of fiscal 2009. The adoption of SFAS No. 165 did not have a material impact on our condensed consolidated financial statements.

In June 2009, the FASB issued Statement No. 168, or SFAS No.168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. SFAS No.168 will become the single source of authoritative nongovernmental U.S. generally accepted accounting principles, or GAAP, superseding existing FASB, American Institute of Certified Public Accountants, or AICPA, Emerging Issues Task Force, or EITF, and related accounting literature. SFAS No.168 reorganizes the thousands of GAAP pronouncements into roughly 90 accounting

topics and displays them using a consistent structure. Also included is relevant Securities and Exchange Commission guidance organized using the same topical structure in separate sections. SFAS No.168 will be effective for financial statements issued for reporting periods that end after September 15, 2009. As a result, SFAS No.168 is effective for us in the third quarter of fiscal 2009. This will have an impact on our disclosures in the condensed consolidated financial statements since all future references to authoritative accounting literature will be references in accordance with SFAS No.168.

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#### 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 June 30, 2009, we had cash, cash equivalents and marketable securities of \$40.9 million. The weighted average interest rate related to our cash and cash equivalents for the year ended June 30, 2009 was 0.1%. As of June 30, 2009, the principal value of our credit line was \$12.0 million, which bears a weighted average interest rate of 11.0%.

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, 2009. 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.

There have been no changes to the Company s internal control over financial reporting that occurred during the Company s second 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**

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. 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, the parties agreed to fully and finally resolve the lawsuit and entered into a settlement and release on May 4, 2009. The net impact of the settlement was not material to the Company.

#### **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. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>

Refer to the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 1, 2009.

#### **Item 3. Defaults Upon Senior Securities**

None.

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

The following matter was approved at our annual stockholders meeting, which was held on June 10, 2009. The election to the Board of Directors of the following nominees:

Number of	Number of
Votes Cast For	Votes Withheld
155,037,370	405,281
154,970,972	471,679
154,042,862	1,399,789
155,159,442	283,209
155,159,442	283,209
155,162,142	280,509
155,151,048	291,603
155,157,524	285,127
153,895,161	1,547,490
155,162,142	280,509
	Votes Cast For 155,037,370 154,970,972 154,042,862 155,159,442 155,162,142 155,151,048 155,157,524 153,895,161

# **Item 5. Other Information**

None.

# Item 6. Exhibits.

Exhibit 2.1 <sup>(1)</sup>	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 <sup>(4)+</sup>	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 <sup>(2)</sup>	Amended and Restated Certificate of Incorporation.
Exhibit 3.2 <sup>(3)</sup>	Amended and Restated By-Laws.
Exhibit 4.1 <sup>(1)</sup>	Form of Common Stock Warrant.

- Exhibit 10.1 Form of Stock Purchase Agreement for transactions between the Company and Nora Real Estate SA., Vector Group Ltd., Oracle Partners LP, Oracle Institutional Partners, LP., Chung Chia Company Limited, Gold Sino Assets Limited and Grandtime Associates Limited.
- Exhibit 10.2 Stock Purchase Agreement dated June 10, 2009, among Sorrento Therapeutics, Inc. and the Company.
- 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, 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 June 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 June 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 June 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.
- 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.

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# **SIGNATURES**

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

Date: August 7, 2009 **OPKO Health, Inc.** 

/s/ Adam Logal Adam Logal Executive Director of Finance, Chief Accounting Officer and Treasurer 26

# **Exhibit Index**

Exhibit Number Exhibit 10.1	<b>Description</b> Form of Stock Purchase Agreement for transactions between the Company and Nora Real Estate SA., Vector Group Ltd., Oracle Partners LP, Oracle Institutional Partners, LP., Chung Chia Company Limited, Gold Sino Assets Limited and Grandtime Associates Limited.
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