

Opko Health, Inc.
Form 10-Q
May 08, 2009

Table of Contents

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

(Mark One)

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

For the quarterly period ended March 31, 2009.

OR

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

For the transition period from _____ to _____.

Commission file number 000-27748

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., Suite 1180
Miami, FL 33137

(Address of Principal Executive Offices) (ZIP Code)

(305) 575-4100

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ YES ☐ NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

YES ☐ NO ☐

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

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐	Smaller reporting company ☐
(Do not check if a smaller reporting company)			

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

YES ☐ NO ☒

As of May 5, 2009, the registrant had 220,789,369 shares of common stock outstanding.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Condensed Consolidated Balance Sheets as of March 31, 2009 and December 31, 2008 (unaudited) 6

Condensed Consolidated Statements of Operations for the three months ended March 31, 2009 and March 31, 2008 (unaudited) 7

Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2009 and March 31, 2008 (unaudited) 8

Notes to Financial Statements 9

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 15

Item 3. Quantitative and Qualitative Disclosures About Market Risk 18

Item 4. Controls and Procedures 19

PART II. OTHER INFORMATION

Item 1. Legal Proceedings 19

Item 1A. Risk Factors 19

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 19

Item 3. Defaults Upon Senior Securities 19

Item 4. Submission of Matters to a Vote of Security Holders 19

Item 5. Other Information 20

Item 6. Exhibits 20

Signatures 22

EX-10.1

EX-10.2

EX-31.1 Section 302 Certification of CEO

EX-31.2 Section 302 Certification of CFO

EX-32.1 Section 906 Certification of CEO

EX-32.2 Section 906 Certification of CFO

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements, as that term is defined under the Private Securities Reform Act of 1995, or PSLRA, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in Item 1A-Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2008, and described from time to time in our reports filed with the Securities and Exchange Commission. We do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Risks and uncertainties, the occurrence of which could adversely affect our business, include the following:

We have a history of operating losses and we do not expect to become profitable in the near future.

Our technologies are in an early stage of development and are unproven.

Our drug research and development activities may not result in commercially viable products.

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

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

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

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

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

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

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

Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could

materially impair our ability to generate anticipated revenues.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our products.

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

Table of Contents

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

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

We have no experience manufacturing our pharmaceutical product candidates 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.

Table of Contents

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interests or in the best interests of our stockholders.

Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses.

If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as they apply to us, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned and our common stock price may suffer.

We may be unable to maintain our listing on the NYSE Amex 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.

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

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

	March 31, 2009	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	\$ 2,160	\$ 6,678
Accounts receivable, net	1,487	1,005
Inventory	5,054	4,063
Prepaid expenses and other current assets	2,564	1,720
Total current assets	11,265	13,466
Property and equipment, net	624	659
Intangible assets, net	5,930	6,336
Goodwill	1,097	1,097
Other assets	230	206
Total assets	\$ 19,146	\$ 21,764
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,385	\$ 2,221
Accrued expenses	6,206	5,394
Current portion of notes payable (including \$3,000 with related party at March 31, 2009) and capital lease obligations	3,233	97
Total current liabilities	12,824	7,712
Long-term liabilities and capital lease obligations	2,206	1,826
Line of credit with related party, net unamortized discount of \$117 and \$133, respectively	11,883	11,867
Total liabilities	26,913	21,405
Commitments and contingencies		
Shareholders' equity (deficit)		
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 \$2,390 and \$2,384) at March 31, 2009 and December 31, 2008, respectively	10	10
Series C Preferred Stock \$0.01 par value, 500,000 shares authorized; No shares issued or outstanding		

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Common Stock \$0.01 par value, 500,000,000 shares authorized; 200,379,726 and 199,020,379 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	2,003	1,991
Treasury stock 45,154 and 18,000 shares at March 31, 2009 and December 31, 2008, respectively	(61)	(24)
Additional paid-in capital	308,452	307,498
Accumulated deficit	(318,171)	(309,116)
Total shareholders' equity (deficit)	(7,767)	359
Total liabilities and shareholders' equity	\$ 19,146	\$ 21,764

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

Table of Contents

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

	For the three months ended March 31,	
	2009	2008
Revenue	\$ 2,301	\$ 2,824
Cost of goods sold	1,561	3,330
Gross margin (deficit)	740	(506)
Operating expenses		
Selling, general and administrative	3,257	5,344
Research and development	5,659	4,356
Other operating expenses, principally amortization of intangible assets	406	426
Total operating expenses	9,322	10,126
Operating loss	(8,582)	(10,632)
Other (expense) income, net	(450)	(269)
Loss before income taxes	(9,032)	(10,901)
Income tax benefit	(35)	(21)
Net loss	(8,997)	(10,880)
Preferred stock dividend	(58)	(55)
Net loss attributable to common shareholders	\$ (9,055)	\$ (10,935)
Loss per share, basic and diluted	\$ (0.05)	\$ (0.06)
Weighted average number of shares outstanding, basic and diluted	199,598,277	180,572,915

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

Table of Contents

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

	For the three months ended March 31,	
	2009	2008
Cash flows from operating activities		
Net loss	\$ (8,997)	\$ (10,880)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	466	452
Accretion of debt discount related to notes payable	16	56
Equity-based compensation employees and non-employees	618	2,731
Net recovery of bad debts	(135)	
Provision for inventory obsolescence	46	
Changes in:		
Accounts receivable	(347)	(42)
Inventory	(1,037)	(293)
Prepaid expenses and other current assets	(844)	237
Other assets	(24)	(21)
Accounts payable	1,164	(597)
Accrued expenses	1,097	1,797
Net cash used in operating activities	(7,977)	(6,560)
Cash flows from investing activity		
Capital expenditures	(25)	(32)
Net cash used in investing activity	(25)	(32)
Cash flows from financing activities:		
Proceeds from bridge loan with related party	3,000	
Insurance financing	217	190
Proceeds from the exercise of stock options and warrants	348	168
Repayments of notes payable and capital lease obligations	(81)	(2,495)
Net cash provided by (used in) financing activities	3,484	(2,137)
Net decrease in cash and cash equivalents	(4,518)	(8,729)
Cash and cash equivalents at beginning of period	6,678	23,373
Cash and cash equivalents at end of period	\$ 2,160	\$ 14,644

SUPPLEMENTAL INFORMATION

Interest paid	\$ 1	\$ 95
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The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

Table of Contents

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 continue to seek to expand our current operations by acquiring additional ophthalmic businesses and pharmaceutical and instrumentation technologies, as well as exploring opportunities in other medical markets that have operational characteristics similar to ophthalmology, such as dermatology. We are a Delaware corporation, headquartered in Miami, Florida and with instrumentation operations in Toronto, Ontario.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation. The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three months ended March 31, 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 March 31, 2009, revenue derived from sales to three significant international customers represented approximately 20%, 18%, and 17% of our revenue, respectively. During the three months ended March 31 2008, revenue derived from sales to three significant international customers represented 15%, 15% and 11%.

Table of Contents

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

The following table reflects the amounts recorded for the three months ended March 31, 2009 and 2008:

(in thousands)	March 31, 2009	March 31, 2008
Beginning balance	\$259	\$ 227
Accrual for products sold	61	55
Settlements in kind or expired	(30)	(56)
Ending balance	\$290	\$ 226

Allowance for doubtful accounts. Allowances for estimated sales returns are based upon our history of product returns. The amount of allowance for doubtful accounts at March 31, 2009 and December 31, 2008, was \$0.2 million and \$0.4 million, respectively. As of March 31, 2009, accounts receivable from three of our international distributors represent approximately 33%, 16% and 12%, respectively, of our net accounts receivable balance. As of December 31, 2008, accounts receivable from two of our international distributors represent 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 two operating segments, 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 months ended March 31, 2009 and 2008, we recorded \$0.6 million and \$2.7 million, respectively, of equity-based compensation expense.

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.

Table of Contents

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 March 31, 2009, we held money market funds that qualify as cash equivalents and are required to be measured at fair value on a recurring basis.

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 measurements as of March 31, 2009				
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market funds	\$1,819	\$	\$	\$1,819

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.

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 financial statements from the adoption of this standard.

Table of Contents**NOTE 3 LOSS PER SHARE**

Basic loss per share is computed by dividing our net loss by the weighted average number of shares outstanding during the period. Diluted earnings per share is computed by dividing our net loss by the weighted average number of shares outstanding and the impact of all dilutive potential common shares, primarily stock options. The dilutive impact of stock options and warrants are determined by applying the treasury stock method.

A total of 14,784,137 and 29,515,241 potential common shares have been excluded from the calculation of net loss per share for the three months ended March 31, 2009 and 2008, respectively, because their inclusion would be anti-dilutive.

NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(in thousands)	March 31, 2009	December 31, 2008
Accounts receivable, net:		
Accounts receivable	\$ 1,686	\$ 1,412
Less allowance for doubtful accounts	(199)	(407)
	\$ 1,487	\$ 1,005
Inventories, net:		
Raw materials (components)	\$ 3,430	\$ 2,635
Work-in process	785	934
Finished products	1,140	749
Less provision for inventory reserve	(301)	(255)
	\$ 5,054	\$ 4,063
Intangible assets, net:		
Technology	\$ 4,597	\$ 4,597
Customer relationships	2,978	2,978
Covenants not to compete	317	317
Tradename	195	195
Other	7	7
Less amortization	(2,164)	(1,758)
	\$ 5,930	\$ 6,336

NOTE 5 PRIVATE PLACEMENT OF STOCK

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 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 agreement with the Gamma Trust, dated February 23, 2009 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. The Note and \$48 thousand of interest were paid on April 27, 2009.

Table of Contents

NOTE 7 RELATED PARTY TRANSACTIONS

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. Refer to Note 6.

In March 2009, we paid the \$45,000 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 months ended March 31, 2009 and 2008, we recorded general and administrative expenses of approximately \$38,000 and \$42,000, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

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, capitalized quarterly, on outstanding borrowings under the line of credit at a 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 Dr. Uppaluri has served as a member of Winston's board of directors since September 2008.

We intend to enter 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, we anticipate paying gross rent of approximately \$110,000 per year for a one-year period which commenced February 2009 and 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 the 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. As of March 31, 2009, we have recorded approximately \$20,000 as an accrued liability for this facility.

Table of Contents

NOTE 8 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, effective as of April 30, 2009, the parties agreed to fully and finally resolve the lawsuit. The Company does not believe that the net impact of the settlement was material to the Company.

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

Upon the termination of an employee of Ophthalmics Technologies, Inc., or OTI, we became obligated at the former employee's sole option to acquire up to 10% of the shares issued to the employee in connection with the acquisition of OTI at a price of \$3.55 per share. In February 2009, this employee exercised his put option and we repurchased 27,154 shares of our Common Stock at \$3.55 per share for a total of \$0.1 million. In addition, an existing employee of OTI has the same provision within his employment arrangement with a potential obligation of approximately \$0.3 million. We have recorded approximately \$0.3 million in accrued expenses as of March 31, 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 9 SUBSEQUENT EVENTS

On April 27, 2009, we issued 20,000,000 shares to the Gamma Trust in exchange for \$20.0 million. Refer to Note 5. In connection with the receipt of the \$20.0 million investment from the Gamma Trust, on April 27, 2009, we repaid the \$3.0 million Note along with \$48 thousand of accrued interest to the Gamma Trust. Refer to Notes 5 and 6.

On May 5, 2009, we entered into a settlement agreement with Ophthalmic Imaging Systems. Refer to Note 8.

Table of Contents

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

OVERVIEW

You should read this discussion together with the condensed consolidated financial statements, related Notes, and other financial information included elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 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. Our business presently consists of the development of ophthalmic pharmaceuticals and the development, commercialization, and sale of ophthalmic diagnostic and imaging systems and instrumentation products. Our objective is to establish industry-leading positions in large and rapidly growing segments of ophthalmology by leveraging our preclinical and development expertise and our novel and proprietary technologies. 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 explore strategic opportunities in other medical markets that would allow us to benefit from our business and global distribution expertise, and which have operational characteristics that are similar to ophthalmology, such as dermatology.

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 March 31, 2009, we had an accumulated deficit of \$318.2 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 MARCH 31, 2009 AND 2008

Revenue. Revenue for the three months ended March 31, 2009, was \$2.3 million, compared to \$2.8 million for the comparable 2008 period. The decrease in revenue during the first three months of 2009 is primarily due to a decrease in orders from our international distributors for our OCT/SLO product. During 2008, we participated in a limited number of tradeshow while we focused on enhancing the product and our manufacturing processes. We believe the decrease in participation at these tradeshow resulted in lower sales orders during the first three months of 2009. The decrease was partially offset by new sales in the U.S. We began marketing and selling our OCT/SLO product in the U.S. in the first quarter 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 product at tradeshow in the U.S. and internationally.

Gross margin (deficit). Gross margin for the three months ended March 31, 2009, was \$0.7 million compared to a gross deficit of (\$0.5) million for the comparable period of 2008. Gross margin for the three months ended March 31, 2009, reflect the cost reduction initiatives we began implementing in 2008 to reduce the cost of 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 the first three months of 2009. During the first quarter of 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.

Table of Contents

Selling, general and administrative expense. Selling, general and administrative expense for the three months ended March 31, 2009, was \$3.3 million compared to \$5.3 million of expense for the comparable period of 2008. Selling, general and administrative expenses during the first three months of 2009 and 2008, primarily include personnel expenses, including equity-based compensation expense of \$0.7 million and \$2.1 million, respectively, and professional fees. The decrease in selling, general and administrative expenses primarily reflects decreased personnel costs and the 2008 period included severance and approximately \$1.4 million related to the acceleration of vesting for stock options in connection with the termination of certain employees. In addition, there were decreased sales commissions to our international distributors in the first quarter of 2009. Partially offsetting these decreases was an increase in professional fees. 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 in the U.S. and participation in additional tradeshow in the U.S. and internationally.

Research and development expense. Research and development expense during the three months ended March 31, 2009, was \$5.7 million compared to \$4.4 million for the comparable period of 2008. The increase for the three months ended March 31, 2009, primarily reflects the cost of the Phase III clinical trial for bevasiranib until March 6, 2009 when the trial was shut down. The 2009 period includes the estimated shutdown costs of the trial, including transitioning patients from the trial onto the standard of care therapy. Further, this includes the costs of analyzing the data collected and performing statistical analysis. We anticipate all activities related to this trial will cease in the first half of the third quarter of 2009. We further anticipate that site close out activities will be completed during the first half of the second quarter of 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 three months ended March 31, 2009, includes a reversal of equity-based compensation expense of \$0.1 million, reflecting the reversal of expense recorded in prior periods for certain awards that terminated upon the resignation of several employees, compared to the 2008 period which includes \$0.6 million of equity-based compensation expense.

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

Other income and expenses. Other expense was \$0.5 million for the first three months of 2009 compared to \$0.3 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 our decreased cash balance during the three months ended March 31, 2009, and reduced interest rates, interest earned decreased significantly.

Income tax benefit for the three months ended March 31, 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.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2009, we had cash and cash equivalents of approximately \$2.2 million. Cash used in operations during 2009 primarily reflect expenses 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 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 advance and all accrued interest thereon shall be due and payable on the earlier of May 4, 2009 or such earlier date following the closing of the previously disclosed Stock Purchase Agreement, dated February 23, 2009. The Note bears interest at a rate equal to 11% per annum and may be prepaid in whole or in part without penalty or premium. We repaid the Note in full, plus accrued interest of \$48 thousand on April 27, 2009.

On February 23, 2009, we entered into a stock purchase agreement with the Gamma Trust pursuant to which the Gamma Trust agreed to make a \$20.0 million investment in exchange for 20,000,000 shares of our common stock, par value \$.01 (the "Shares"), at \$1.00 per share, representing an approximately 20% discount to the

Table of Contents

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 20,000,000 shares and received the proceeds of \$20.0 million on April 27, 2009.

We have a fully drawn \$12.0 million line of credit with The Frost Group, LLC, or the Frost Group, a related party. The Frost Group members include a trust controlled by Dr. Frost, who is the Company's Chief Executive Officer and Chairman of the board of directors, Dr. Jane H. Hsiao, who is the Vice Chairman of the board of directors and Chief Technical Officer, Steven D. Rubin who is Executive Vice President Administration and a director of the Company, and Rao Uppaluri who is the Chief Financial Officer of the Company. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit at a 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 and available to us at March 31, 2009, combined with the proceeds received April 27, 2009 from the investment by the Gamma Trust will be sufficient to meet our anticipated cash requirements for operations and debt service for the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements will depend on a number of factors, including possible acquisitions, the continued progress of our research and development of product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims, and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs.

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

Equity-based compensation. As of June 23, 2006 (the date of inception), we adopted Statement of Financial Accounting Standards, or SFAS 123(R), *Share-Based Payments*. SFAS 123(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

Table of Contents

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 March 31, 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.

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 financial statements from the adoption of this standard.

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. The securities in our investment portfolio are not leveraged, and are,

Table of Contents

due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment. At March 31, 2009, we had cash and cash equivalents of \$2.2 million. The weighted average interest rate related to our cash and cash equivalents for the year ended March 31, 2009 was 0.3%. As of March 31, 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 March 31, 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 first 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, effective as of April 30, 2009, the parties agreed to fully and finally resolve the lawsuit. The net impact of the settlement was not material to the Company.

Item 1A. Risk Factors

None.

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

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

Item 3. Defaults Upon Senior Securities

None.

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

Effective as of February 13, 2009, stockholders holding a majority of the voting power of the Company's outstanding capital stock approved the issuance to one or more members of The Frost Group, LLC, a private investment group controlled by Phillip Frost, M.D., our Chairman and CEO, of 20 million shares (the Shares) of

Table of Contents

the Company's common stock, par value \$0.01 per share, in exchange for \$20 million in cash to the Company. Stockholder approval of the investment was in the form of a written consent of stockholders in lieu of a special meeting in accordance with the relevant sections of the Delaware General Corporation Law, and included those of our stockholders holding a majority of the voting power of our issued and outstanding shares of common stock and preferred stock, voting together as a group. Stockholder approval was sought in order to comply with applicable rules of the NYSE Amex Exchange, on which our common stock is listed.

Item 5. Other Information

On May 5, 2009, the Compensation Committee of the Board of Directors (the "Compensation Committee") of the Company held a meeting to review certain compensation matters for the Company's executive officers and non-executive employees. At the meeting, the Compensation Committee granted stock options to certain of the Company's named executive officers to purchase the number of shares of the Company's common stock set forth opposite their name below:

Named Executive Officer	Stock Option to Purchase Shares of Common Stock
Phillip Frost, M.D., Chief Executive Officer and Chairman	350,000
Jane Hsiao, Ph.D., Vice Chairman and Chief Technology Officer	300,000
Steven D. Rubin, Executive Vice President Administration	250,000
Rao Uppaluri, Ph.D., Senior Vice President Chief Financial Officer	225,000

Each stock option was granted effective as of May 5, 2009, with an exercise price per share equal to \$1.16, the closing per share price of the Company's common stock as reported on the NYSE Amex Exchange on May 5, 2009. The Compensation Committee determined not to increase the base salaries paid to its executive officers from the levels set in 2008. The Compensation Committee further determined that no annual cash bonus would be paid for the fiscal year ended December 31, 2008.

Item 6. Exhibits.

Exhibit 2.1 ⁽¹⁾	Merger Agreement and Plan of Reorganization, dated as of March 27, 2007, by and among Acuity Pharmaceuticals, Inc., Fropix Corporation, eXegenics, Inc., e-Acquisition Company I-A, LLC, and e-Acquisition Company II-B, LLC.
Exhibit 2.2 ⁽⁴⁾⁺	Securities Purchase Agreement dated May 6, 2008, among Vidus Ocular, Inc., OPKO Instrumentation, LLC, OPKO Health, Inc., and the individual sellers and noteholders named therein.
Exhibit 3.1 ⁽²⁾	Amended and Restated Certificate of Incorporation.
Exhibit 3.2 ⁽³⁾	Amended and Restated By-Laws.
Exhibit 4.1 ⁽¹⁾	Form of Common Stock Warrant.
Exhibit 10.1	Stock Purchase Agreement by and between the Company and Frost Gamma Investments Trust.
Exhibit 10.2	Promissory Note to Frost Gamma Investments Trust, dated March 4, 2009.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended March 31, 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 March 31, 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 March 31, 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 March 31, 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

Table of Contents

June 11, 2007,
and
incorporated
herein by
reference.

(3) Filed with the
Company's
Annual Report
on Form 10-K
filed with the
Securities and
Exchange
Commission on
March 31, 2008
and
incorporated
herein by
reference.

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

(6) Filed with the
Company's
Quarterly
Report on Form
10-Q filed with
the Securities
and Exchange
Commission on
November 12,
2008 for the

Company's
three-month
period ended
September 30,
2008, and
incorporated
herein by
reference.

Table of Contents

SIGNATURES

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

Date: May 8, 2009

OPKO Health, Inc.

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

22

Table of Contents

Exhibit Index

Exhibit Number	Description
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